SECOND EDITION

AMA EDUCATION CONSORTIUM

HEALTH SYSTEMS SCIENCE

SUSAN E. SKOCHELAK
MAYA M. HAMMOUD
KIMBERLY D. LOMIS
JEFFREY M. BORKAN
JED D. GONZALO
LUAN E. LAWSON
STEPHANIE R. STARR



ELSEVIER

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Editors-in-Chief:

Susan E. Skochelak, MD, MPH

Maya M. Hammoud, MD, MBA

Kimberly D. Lomis, MD

Editors:

Jeffrey M. Borkan, MD, PhD

Jed D. Gonzalo, MD, MSc

Luan E. Lawson, MD, MAEd

Stephanie R. Starr, MD


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Contributors

Neera Agrwal, MD, PhD
Mayo Clinic Arizona
Chapter 5: Value in Health Care

Jose Azar, MD
Indiana University
Chapter 15: Application of Health Systems Science Competencies in Patient Care

Elizabeth Baxley, MD
American Board of Family Medicine
Chapter 12: Structural and Social Determinants of Health

Jeffrey M. Borkan, MD, PhD
Brown University
Chapter 1: What Is Health Systems Science? Building an Integrated Vision
Chapter 17: Looking Ahead: The Dynamic Nature of Health Systems Science, Future Trends, and the Role of Learners as Change Agents

Brian Clyne, MD, MHL
Brown University
Chapter 9: Leadership in Health Care

I. Glenn Cohen, JD
Harvard Law School
Chapter 13: Health Law and Ethics

Elliott J. Crigger, PhD
American Medical Association
Chapter 13/sidebar: The Code of Medical Ethics

Matthew Davis, MD, MAPP
Northwestern University Feinberg School of Medicine
Chapter 14: Health Care Policy and Economics

Ami L. DeWaters, MD, MSc
Penn State College of Medicine
Chapter 4: Health Care Structures and Processes

Jesse M. Ehrenfeld, MD, MPH
Medical College of Wisconsin School of Medicine
Chapter 6: Patient Safety
Chapter 10: Clinical Informatics

Victoria Stagg Elliott, MA
American Medical Association
Chapter 17: Looking Ahead: The Dynamic Nature of Health Systems Science, Future Trends, and the Role of Learners as Change Agents

Tonya Fancher, MD, MPH
University of California, Davis, School of Medicine
Chapter 12: Structural and Social Determinants of Health

Martha E. (Meg) Gaines, JD, LLM
University of Wisconsin Law School
Chapter 1/sidebar: Patients: The Missing Critical Voice in Health Systems Science

Paul George, MD, MHPE
Brown University
Chapter 11: Population Health

Alicia Gonzalez-Flores, MD
University of California, Davis, School of Medicine
Chapter 12: Structural and Social Determinants of Health

Jed D. Gonzalo, MD, MSc
Penn State College of Medicine
Chapter 1: What Is Health Systems Science? Building an Integrated Vision
Chapter 2: Systems Thinking in Health Care: Addressing the Complex Dynamics of Patients and Health Systems

Sara Jo Grethlein, MD
Indiana University
Chapter 9: Leadership in Health Care
Chapter 15: Application of Health Systems Science Competencies in Patient Care

Maya M. Hammoud, MD, MBA
University of Michigan and the American Medical Association
Chapter 2: Systems Thinking in Health Care: Addressing the Complex Dynamics of Patients and Health Systems
Chapter 8: Principles of Teamwork and Team Science

Iman Hassan, MD
Albert Einstein College of Medicine
Chapter 17: Looking Ahead: The Dynamic Nature of Health Systems Science, Future Trends,

and the Role of Learners as Change Agents

Karen E. Hauer, MD, PhD
University of California, San Francisco, School of Medicine
Chapter 16: The Use of Assessment to Support Students' Learning and Improvement in Health Systems Science

William R. Hersh, MD
Oregon Health & Science University
Chapter 10: Clinical Informatics

Jason Higginson, MD, MA
Brody School of Medicine at East Carolina University
Chapter 8: Principles of Teamwork and Team Science

Allison K. Hoffman, JD
University of Pennsylvania Law School
Chapter 13: Health Law and Ethics

Linda Hofler, PhD, RN, NEA-BC
Vidant Health
Chapter 8: Principles of Teamwork and Team Science

Jill Huber, MD
Mayo Clinic
Chapter 11: Population Health

Ian Kim, MD
University of California, Davis, School of Medicine
Chapter 12: Structural and Social Determinants of Health

Russell W.H. Kridel, MD
American Medical Association
Chapter 4/sidebar: Is Private (Solo or Group) Practice for You?

Natalie Landman, PhD
Arizona State University
Chapter 5: Value in Health Care

Luan E. Lawson, MD, MAEd
Brody School of Medicine at East Carolina University
Chapter 6: Patient Safety

Kimberly D. Lomis, MD
American Medical Association
Chapter 12: Structural and Social Determinants of Health

Chapter 16: The Use of Assessment to Support Students' Learning and Improvement in Health Systems Science
Chapter 17: Looking Ahead: The Dynamic Nature of Health Systems Science, Future Trends, and the Role of Learners as Change Agents

Barbara McAneny, MD
American Medical Association
Chapter 4/sidebar: Ask an Expert About Private Practice

Erin McKean, MD, MBA
University of Michigan
Chapter 9: Leadership in Health Care

Ryan Munyon, MD
Penn State Hershey Medical Center
Chapter 4: Health Care Structures and Processes

Chemen Neal, MD
Indiana University
Chapter 15: Application of Health Systems Science Competencies in Patient Care

Robert E. Nesse, MD
Mayo Clinic
Chapter 3: The Health Care Delivery System

Timothy Reeder, MD, MPH
Brody School of Medicine at East Carolina University
Chapter 6: Patient Safety

William M. Sage, MD, JD
University of Texas at Austin
Chapter 13: Health Law and Ethics

Mark D. Schwartz, MD
New York University Langone Health
Chapter 14: Health Care Policy and Economics

Mamta K. Singh, MD, MS
Case Western Reserve University School of Medicine
Chapter 7: Quality Improvement

Susan E. Skochelak, MD, MPH
American Medical Association
Chapter 1: What Is Health Systems Science? Building an Integrated Vision

Stephanie R. Starr, MD

Mayo Clinic
Chapter 2: Systems Thinking in Health Care: Addressing the Complex Dynamics of Patients and Health Systems
Chapter 3: The Health Care Delivery System

Sara Teasdale, MD
University of California, Davis, School of Medicine
Chapter 12: Structural and Social Determinants of Health

Elizabeth Tobin-Tyler, JD, MA
Brown University
Chapter 14: Health Care Policy and Economics

Anne Tomolo, MD, MPH
Emory University
Chapter 7: Quality Improvement

Paul F. Weber, MD, RPh, MBA
Rutgers Robert Wood Johnson Medical School
Chapter 7: Quality Improvement

Natalia Wilson, MD, MPH
Arizona State University
Chapter 11: Population Health

Daniel R. Wolpaw, MD
Penn State College of Medicine
Chapter 1: What Is Health Systems Science? Building an Integrated Vision

Therese Wolpaw, MD, MHPE
Penn State College of Medicine
Chapter 17: Looking Ahead: The Dynamic Nature of Health Systems Science, Future Trends, and the Role of Learners as Change Agents

Steven Yuen, MD
Barrow Neurological Institute
Chapter 5: Value in Health Care

Foreword

James L. Madara, MD, Executive Vice President and CEO, American Medical Association

Technology is changing our world and the practice of medicine at a pace unmatched in human history. Yet for all the societal advancements and technological marvels over the last century, the way we train and educate new doctors has changed little.

Medical school curricula have, of course, expanded over the years to include important new medical breakthroughs and discoveries, but their focus and overall structure remain stubbornly captive to early 20th-century thinking. The result is an ever-widening gap between how physicians in the United States are trained and educated and the realities of the modern health care environment.

Recognizing this gap, the American Medical Association (AMA) in 2013 set out to transform and modernize medical education in this country by creating, and providing funding for, a diverse network of medical schools to innovate, share practices, and push the boundaries of traditional medical education. In short, we inspired them to think big.

This reinvention of the medical school of the future was part of a strategic realignment at the AMA to further our mission to promote the art and science of medicine and the betterment of public health. The other pillars in our renewed strategic focus areas include creating the tools and resources to help physicians thrive in modern health care and developing new and better approaches to combat America's growing health epidemic of chronic disease. Many opportunities for innovation were identified in these efforts; to address these, an AMA innovation ecosystem was created with nodes, including a Chicago-based health care start-up incubator (MATTER) and a Silicon Valley–based innovation company (Health2047). Together, these initiatives are foundational to the AMA's work to lead meaningful innovation and enable a better health care system for patients, physicians, and the nation.

Each of these three core focus areas is shaping health care today and long into the future. However, it is our efforts around medical education, our exciting Accelerating Change in Medical Education initiative, that may ultimately be the most far-reaching and impactful.

Now, more than 5 years into this program, the schools in our Accelerating Change in Medical Education Consortium regularly meet, develop, and share their curricular innovations, which, when aggregated, form a vision of the medical schools of the future: one that measures competency; one that responds to the needs of chronic disease through team-based care approaches, greater continuity, and more outpatient exposure;

and one that adopts new technologies for education and creates new fields of medical science.

These 37 consortium members are schools that will do more than prepare young doctors to care for patients. They will prepare physicians for a lifetime of training and learning. They will prepare them to take leadership roles in their practices, while also exploring the most innovative ways to care for patients, populations, and communities.

The emergence of health systems science will be a key component of the medical schools of the future, bridging the study of basic and clinical sciences and giving new physicians a broad view of the societal influences and administrative challenges that sometimes complicate patient care. Health systems science is that window into the lives of our patients and our communities that makes us more effective, compassionate, and knowledgeable doctors. This offering has been well received, and thus we have produced this—the second edition.

It is important to remember that the history of medicine is the history of innovation and change. For nearly 170 years, physicians have relied on the AMA to keep them informed, engaged, and at the forefront of technological advancements so that they can better meet the ever-changing needs of their patients. With the innovations, tools, and products emerging from the AMA strategic arcs, the AMA is positioning itself as the physician's powerful ally in patient care.

By reinventing medical education and encouraging our doctors of tomorrow to rethink how we deliver care in this new digital age of medicine, the AMA is bringing the future of our profession into sharper focus and improving health care for generations to come.

Preface

Susan E. Skochelak, MD, MPH, Maya M. Hammoud, MD, MBA, Kimberly D. Lomis, MD, Jeffrey M. Borkan, MD, PhD, Jed D. Gonzalo, MD, MSc, Luan E. Lawson, MD, MAEd, Stephanie R. Starr, MD

Since the first edition of this textbook was published in 2017, health systems science has increasingly become integrated into medical education. Competency in this realm ensures that medical school graduates and those graduating from other health professions schools can effectively translate and apply the basic and clinical sciences and meaningfully improve patients' health at the individual, community, and population levels.

The concept of health systems science as a required third pillar of medical education emerged after long debate among members of the American Medical Association (AMA) Accelerating Change in Medical Education Consortium. This consortium was formed by the AMA in 2013 after awarding initial grants to 11 medical schools from across the country. The consortium is a unique, innovative collaboration that allows for the sharing and dissemination of groundbreaking ideas and projects. In 2016, the AMA awarded grants to another 21 schools. In 2019, five more schools were added. The consortium represents one-fifth of allopathic and osteopathic medical schools. These schools are delivering forward-thinking educational experiences to nearly 24,000 medical students—students who will provide care to a potential 41 million patients annually.

More than a century ago, the Flexner report recommended significant changes to increase the scientific rigor and standardization of medical school curricula. The consortium recommends health systems science as the third critical science required of physicians and other health professionals to prepare them for their future roles and to enable them to have the greatest impact on the health of patients and society. Basic science is about understanding the mechanisms and functions of the human body. Clinical science is focused on diagnosis, treatment, and prevention—obtaining histories, examining patients, and choosing interventions that maintain health, ameliorate decline, and maximize the function of the human body. Even if basic and clinical sciences are expertly learned and executed, without health systems science physicians cannot realize their full potential impact on patients' health or on the health of the population. Health systems science includes all the factors in the lives of patients that influence their well-being (e.g., social determinants of health and health disparities); the structures and processes of the health system itself (e.g., patient access, financing,

quality improvement); societal factors (e.g., health policy and advocacy); communication (e.g., verbal, written, team); and information technology (e.g., electronic health records, search engines). Incorporating an understanding of health systems science in medical education will improve the quality and value of care that physicians and other health professionals deliver and that patients and communities experience.

There are other textbooks that explore health systems science from the perspective of managers, administrators, or policymakers, and there are other textbooks that delve more fully into the subjects of each individual chapter of this book. This textbook was the first aiming to define the canon of health systems science and elucidate the health systems science framework for educating health care professionals. We hope it will serve as the base for ever-expanding advancements in the teaching of health systems science and the incorporation of health systems science into practice.

Although this textbook seeks to define health systems science, it is important to note that health systems science is still an emerging discipline. We know health systems science is a dynamic, rapidly changing field. Our intention is that this textbook will serve as a platform on which changes can be made over time. We are just at the beginning of our health systems science journey.

The editors and authors would like to thank the members of the AMA Accelerating Change in Medical Education Consortium for their tireless work to transform medical education by implementing health systems science as well as other significant innovations. This textbook is dedicated to the patients, communities, and populations we serve.

What is health systems science? Building an integrated vision

Jed D. Gonzalo, MD, MSc, Susan E. Skochelak, MD, MPH, Jeffrey M. Borkan, MD, PhD, Daniel R. Wolpaw, MD

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In this chapter

For over 100 years, medical education has relied upon two pillars for training physicians ready to practice medicine: basic science and clinical science. Health systems science—the understanding of how care is delivered, how health care professionals work together to deliver that care, and how the health system can improve patient care and health care delivery—has been part of the hidden curriculum or taught as part of elective courses. There have been many attempts to formalize the role of health systems science in medical school curriculum and make it the third pillar of physician education. Progress toward that goal is steadily advancing.

Health systems science is intimately intertwined with the two pillars of medical education but is also a subject in its own right requiring study by medical students. Additionally, physicians' roles in the health care system are changing significantly, and physicians need to understand health systems science in order to fulfill their evolving roles. Health systems science competencies extend

beyond the historically segregated boundaries of physician training and are applicable to all health professions students.

Learning Objectives

1. Identify the need to align medical education with ongoing changes in health care systems.
2. Differentiate the traditional “two pillar” model from the emerging “three pillar” model of medical education.
3. Describe the conceptual framework of health systems science and compare it to other systems-related concepts in medical education and care delivery.
4. Justify the importance of integrating health systems science with the basic and clinical sciences to achieve the goals of the Triple and Quadruple Aims.
5. Understand the patient perspective on the need for health systems science education.
6. Compare and contrast a traditional view of professional identity formation with the emerging concept of systems citizenship.
7. Identify and discuss barriers for learners to engage in health systems science in clinical learning environments.

This book is devoted to health systems science, which is the fundamental understanding of how care is delivered, how health care professionals work together to deliver that care, and how the health system can improve patient care and health care delivery. An understanding of health systems science provides the building blocks for physicians and other health care professionals to improve all aspects of patient care and health care delivery. Additionally, awareness of health systems science and mindfulness of its role in understanding health care delivery helps to ensure that significant advancements in basic and clinical sciences ultimately translate to improved patient outcomes and improved satisfaction for medical professionals.

> *“We will never transform the prevailing system of management without transforming our prevailing system of education. They are the same system.”*

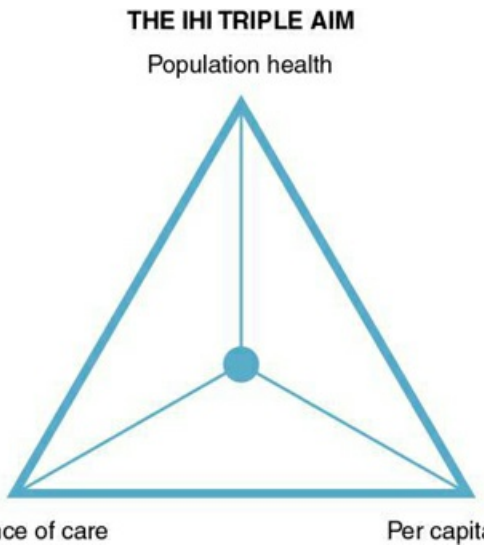
Edwards Deming, an American engineer and quality improvement expert, believed that if people fail in their roles within their jobs, it is because they are socialized in ways of thinking and acting that are embedded in their formative institutional experiences.[1,2] Although this philosophy was proposed for management in business and organizations outside of health care, this philosophy directly applies to the urgent need for health care transformation as well as medical education reform. Rapidly evolving challenges in health care mandate changes in the way health care professionals are educated, and these educational systems will in turn directly impact the health of patients.

I. The need for curricula in health systems science

Health systems are rapidly evolving in the face of substantial challenges. Health systems need to provide care to expanding and diverse patient populations, including the underserved, patients at the extremes of age, and those with chronic, often environmentally enabled, comorbid conditions. The exploding growth of health care-related knowledge and technology promises remarkable benefits but also has the potential for compromising value and even doing harm. At the same time, social, economic, and political forces have become an integral part of the health care transformation. The successful alignment of all of these factors with our goals for the optimal health of people and populations will require that health professions students and medical education programs step up to the plate and engage in an entirely new game. This change requires increased focus on health care delivery and patient-centered care rather than just clinicians' skills in diagnosis and treatment. It is not just that the players, rules, and equipment in the health care game are new—more importantly, they are constantly changing and evolving. Old or static models of education and health care delivery will simply not work. In order to meet Deming's challenge to change the system through educational transformation, health professions students and medical educators must critically prioritize content to ensure adaptive thinking skills and the associated professional identity formation.

II. The rapidly changing health care environment

Health care is currently undergoing and will continue to undergo significant redesigns and changes that will impact the ways in which patients receive care and how physicians and health care professionals "deliver" care. Although several paradigms have been proposed that reflect that ultimate goal of the ideal health care system, the Institute for Healthcare Improvement's (IHI's) Triple Aim (Fig. 1.1) goals of improved patient experience, improved health of populations, and decreased cost embody the key points in all of these models, and reflect the overall goals of the evolving US health care system.[3] Additionally, Porter further defined value as the quality of care relative to the cost required for the care (value = quality/cost).[4] Combined, these two principles form a unifying thread throughout the subsequent chapters in this book.



• **FIG. 1.1** The Triple Aim of Health Care Reform. The IHI Triple Aim framework was developed by the Institute for Healthcare Improvement in Boston, Massachusetts (www.ihi.org).

There are four ongoing developments in US health care that highlight this rapidly changing health care environment: (1) health care policy initiatives, (2) payment reform and value, (3) health care delivery system innovation and transformation, and (4) transformative health information technology, data, and informatics. Identifying these four shifts allows for the elucidation of key implications for physicians and other health care professionals practicing in and leading change within these health systems.

A. Health care policy initiatives

The recognition of the high cost and comparatively moderate quality of US health care has led to years of ongoing debate and policy initiatives to stimulate change and transformation. Signed into law in 2010, the Patient Protection and Affordable Care Act

(better known as the Affordable Care Act) seeks to improve the quality and affordability of health insurance, lower the number of uninsured patients by increasing insurance coverage, and reduce health care costs. The Affordable Care Act (often referred to as "Obamacare" or the ACA), along with other policy initiatives, provides critical drivers for change in US health care at all levels. It has sought to transform health care by improving its value and efficiency, implementing preventive strategies, and refocusing on population health. However, these initiatives are insufficient by themselves to impact the health of patients and populations. In addition, multiple efforts to modify or reverse the ACA (described in later chapters) are currently underway, and future directions for US health care policy are in question at the present time. Nonetheless, whatever direction is taken, the way forward will require professionals who are fluent in a new language and perspective of health care goals and systems.

B. Payment reform and value

For decades, the fee-for-service model of health care has been the predominant method of reimbursement. In this model, health systems and clinicians are provided reimbursement for health care delivery and services independent of the quality of the care delivered or the outcomes obtained. With the recognition of the need for change, there is an evolving push toward reimbursing high-value care rather than quantity of service provided.[5] Several strategies are being used to achieve this transformation. Pay for performance (P4P) and value-based purchasing seek to reimburse based on a reward model for meeting quality measures in care delivery. These strategies depend on utilization of electronic health records and patient registries, while shifting accountability to clinicians and systems to design and implement the best strategies to obtain quality outcomes. In this process, clinicians and systems must reduce inappropriate use of health care resources (e.g., laboratory tests, radiographic testing), understand and employ evidence-based strategies for best outcomes, and initiate health systems change to reach these goals. Bundled payments incorporate expected costs for a typical encounter or episode of care into a single payment. The team of physicians and other health care professionals is held accountable for the communication and coordination along the continuum of care to improve the outcomes of care interventions. For example, a knee replacement surgery for a patient involves numerous physicians and other health care professionals, including the orthopedic surgeon, anesthesiologist, physical therapists, nursing staff, and care coordinators, who collectively seek to provide safe and effective care from the hospital to home or rehabilitation facility, improve function and quality of life, and support seamless transitions of care within a collaborating team of physicians and other health care professionals. This "bundled" approach to organizing and reimbursing care requires an entirely new approach to the process of health care delivery. Lastly, shared savings plans seek to provide financial incentives to health plans and clinicians to improve quality while reducing cost. All of these payment reform initiatives and the predominant shift toward value require physicians and other health care professionals

to understand and engage in the individual and team skills necessary to achieve best outcomes.

C. Health care delivery system innovation and transformation

With the need to implement new health care policies and value, US health systems must redesign and transform the structures and processes of health care to achieve the Triple Aim.[3] The current system is often fragmented, with inadequate processes for communication and collaboration. The result is one of high cost and inefficiency, unacceptable levels of patient safety events and medical errors, and a compromise in the kinds of authentic patient-clinician partnerships required for shared decision making and patient-centered care. Additionally, current health system design and delivery processes are not well aligned with the needs of the most vulnerable patient populations, specifically those with behavioral and mental health challenges, those from racial or ethnic minority groups, and those from rural and socioeconomically disadvantaged backgrounds.[6,7] The current shift in health care transformation seeks to drive the health system to operate more like an ideal system—one that aligns with person- and population-centered care goals, allowing for appropriate distribution of resources where they are most needed.

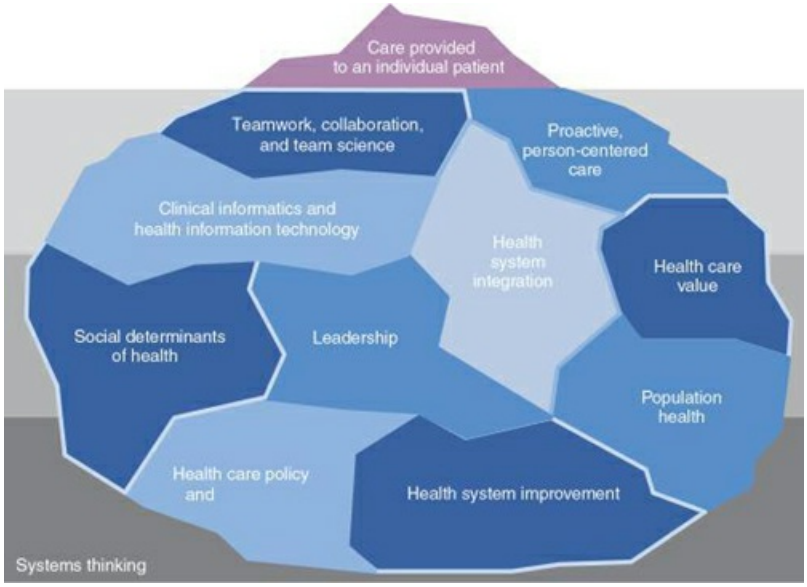
To this end, health systems will increasingly seek to develop team-based models of care that optimize interprofessional collaboration and communities of care. This will require a frameshift not only in how physicians and other health care professionals view all members of the health care team but also in how teams coordinate care in the larger context of the health system, and how patients, families, and social networks are engaged as well. There is growing appreciation for the multiple social and ecological determinants of health that require health systems and clinician teams to factor homes, neighborhoods, and communities into plans for health promotion and disease prevention. Health systems are transforming to add a focus on populations or groups of patients, expanding the traditional lens of one patient at any given time. This transition to population-based care requires a skill set not previously addressed in the education of most physicians and other health care professionals.

D. Transformative health information technology, data, and informatics

The success of health care delivery innovation and transformation relies upon working expertise in health information technology and "big data." There has been an explosion of readily available clinical data and discovery, all of which requires critical appraisal and thoughtful application in health systems and at the point of care. Electronic health records are currently a mixed blessing, offering up equal measures of timely information exchange and frustrating barriers.[8] Large databases are offering previously unavailable windows into health care at the practice level as well as the larger health system levels but also carry their own set of pitfalls. These unprecedented opportunities

and challenges require clinicians and health systems to understand, engage, and redesign system and point-of-care information technology resources to improve health for patients and populations.

The "iceberg" of health care transformation (Fig. 1.2) highlights the numerous concepts and factors that are intricately connected and interrelated to care provided to any one patient in any one episode of care. Traditionally, the focus of health care delivery has remained "above the water," on the clinician-patient encounter within a clinic, hospital, or other health care setting. Patient care must continue to be a necessary focus of health care as well as medical education. Clinicians must be able to communicate with patients, pursue and make accurate diagnoses about medical issues, and determine best treatment modalities, all while using shared decision-making processes. They must utilize the continuously updated knowledge cloud and contribute where appropriate to discovery. These are evolving perspectives on traditional physician-centric roles—almost all above the water. Medical education leaders, medical students, and those studying in other health care fields can no longer ignore the complex network of processes, systems, and insights that lie beneath the surface of the individual patient encounter. The rest of the iceberg is fast becoming foundational preparation for contributing to optimal patient care in the evolving health care environment of the 21st century. This, in a nutshell, is the focus of this textbook.



• **FIG. 1.2** The "Iceberg" of Health Care Concepts Impacting Health. Numerous factors and concepts are often underappreciated in the clinician-patient interaction within a clinic room. Traditionally, these concepts have not been included in the scope of medical education.

III. Clinician readiness to practice in the evolving health care system

This expanded view of this mandate for the medical education system translates directly into role expectations for physicians and other health care professionals in evolving health systems and, in turn, highlights unmet needs in our current approach to training. Physicians and other health care professionals will be expected to move beyond traditional narrowly defined roles to participate in collaborative teams as both leaders and supporting players and, perhaps most importantly, to contribute to a system's view of meaningful patient outcomes beyond disease-specific diagnosis and treatment. The following reports highlight the "new" and emerging needs for learners who will soon be entering the health care workforce and need to learn health systems science[9]:

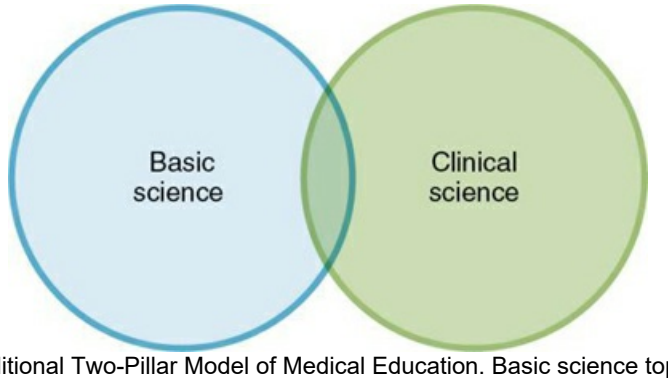
- Chang and colleagues identified essential skills needed for medical student graduates to be better prepared to practice in 21st-century health care, including leadership skills, understanding of organization norms and values, navigating health care finances, quality improvement skills, information technology, and patient engagement.[10,11]
- Crosson and coauthors identified health systems leaders' perceptions regarding the areas in which graduates were not adequately prepared to practice in health systems, including office-based practice competencies, care coordination, continuity of care, familiarity with clinical information technology, leadership and management skills, systems thinking perspectives, and procedural skills.[12]
- Thibault highlighted the need for interprofessional collaboration skills to improve the transition from undergraduate medical education to residency training.[13]
- Skochelak reviewed recommendations for change in medical education and identified common themes of better aligning physicians' skills with the changes in the health care delivery system, emphasis on social accountability, and importance of leadership.[14]
- Lucey identified the need for future clinicians to embrace the knowledge and skills of clinical quality, patient safety, data-driven improvement, and innovation in order to improve systems of care.[15]
- Combes and Arespacochaga, in a report from leaders in the American Hospital Association, identified a range of "deficits" encountered in graduates from US training programs, including cost-conscious care, care coordination, and interprofessional communication.[16]

IV. The third medical science: Health systems science

A. The current two-pillar model of medical education

In 1910, Abraham Flexner published the first comprehensive review of American and Canadian medical education, effectively revolutionizing medical education in the United States and Canada. The report established that medical education for physicians should include a rigorous grounding in biologic sciences and scientific theory as the underpinning of medical practice.[17] The report called for training physicians to practice in a scientific manner and to engage in research. It also must be noted that an unintended consequence of Flexner's report was the closure of a number of medical schools that had been servicing those underrepresented in medicine, such as physicians of color and women physicians, thereby reducing the number of those trained for decades.[18]

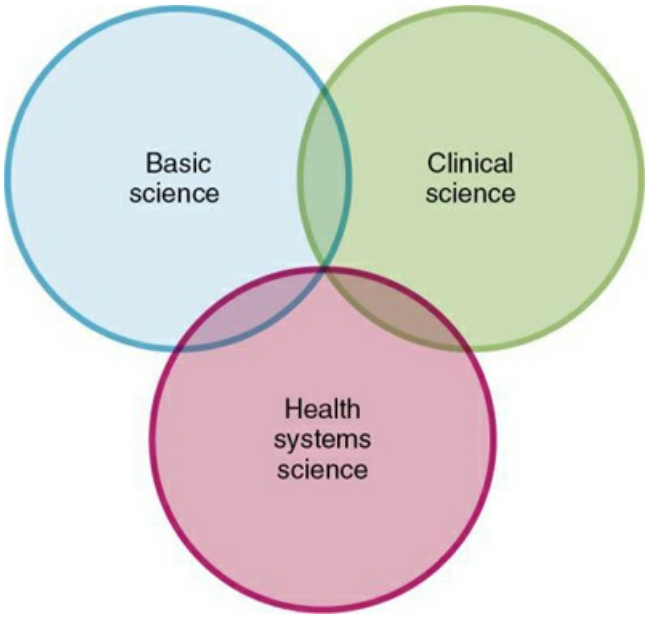
Nevertheless, Flexner's recommendations have had a profound impact on medical education, with many of the core tenets of the report still in place over 100 years later, including a requirement for a certain number of years dedicated to medical education and a firm grounding in scientific theory. A specific result of Flexner's report was the 2+2 model of education, featuring 2 years of pre-clerkship learning in the basic and clinical sciences followed by 2 years of immersive clinical education and apprenticeships, something not standard at many medical schools of that era. While the time devoted to the pre-clerkship period has been truncated in recent curriculum revisions, the basic format of an initial bolus of basic science is still the norm in most US medical schools,[17] and until very recently this science content has been based primarily on a two-pillar model (Fig. 1.3).



• **FIG. 1.3** Traditional Two-Pillar Model of Medical Education. Basic science topic areas have included subjects such as biochemistry, anatomy, physiology, and pathology. Clinical science topic areas have included subjects such as physician examination skills, communication, and clinical diagnosis.

B. Conceptualizing health systems science—the "third pillar" of medical education

Abraham Flexner's report in the early 20th century helped fulfill a critical need of the time: standardizing and elevating the rigor of science in medical training.[13] Even though most medical educators in US medical schools since Flexner have recognized the limitations of focusing entirely on the basic and clinical sciences, the core curricular structure has remained the same.[12,14,16,19,20] In the meantime, the landscape of health care has changed dramatically: foundational science along with diagnostic and therapeutic options have exploded in range and complexity, the understanding of the biopsychosocial-environmental model of health and disease has progressed dramatically, and societal-economic-political pressures have emerged as major influencers, all supported by unprecedented data and information systems. Aligned with a growing appreciation of the expanded health care "iceberg" depicted in Fig. 1.2, educators have proposed a "third pillar" of medical education, termed *health systems science* (Fig. 1.4).[9,21]



• **FIG. 1.4** Three-Pillar Model of Medical Education. Health systems science—the "third science"—complements and synergizes with basic and clinical sciences and addresses subject areas including value-based care, teamwork, and health system improvement.

The shifts in systems of care are having a direct impact on the profession of medicine and are changing how doctors work and contribute to the health of society. The contemporary practice of medicine requires a fundamental adjustment for doctors trained in Flexner's model of rigorous education in the basic sciences followed by clinical application and research under the supervision of experienced professors.[13,20] This professional development pathway revolved around the idea of sovereign physicians utilizing enlightened biomedical science to lead the way in curing disease.

Although scientific discovery continues to enhance health care capabilities and opportunities, the world of medical practice and physician roles have changed and continue to evolve, and it is clear that basic and clinical science alone are insufficient to reach our goals in health care. Optimal health care in the 21st century requires the expertise and integration of multiple domains of health systems science. It is no longer enough to know why and how biologic systems work or to prescribe and implement the latest medical or surgical therapy; health professionals must be able to factor in the multiple complexities of social, environmental, economic, and technical systems and translate this expertise to the care of individual patients and populations. The challenge for medical education is to introduce this systems complexity into the traditional bimodal sequence of biomedical and clinical science in a substantive, meaningful fashion. To achieve this goal, a range of attitudes, skills, and knowledge domains that had been previously marginalized or assumed—such as learning to function in interprofessional teams, communicating effectively across multiple mediums from cultural divides to electronic databases, linking the ability to make a diagnosis and treatment plan with action and advocacy in an expanded view of professionalism, improving patient and population experience while reducing costs, and navigating fragmented social, economic, and policy gaps—will need to be incorporated into the foundations of educational curriculum. Whether pursuing the Triple Aim, pursuing the Quadruple Aim (which also includes health care worker wellness), or preparing students to succeed in the 21st century, medical educators need to completely rethink how classroom and experiential learning are structured, while students must consider the prioritization of these topics in their learning. This will require not only significant reengineering of classrooms and practice experiences but also attention to how our learners view themselves as the professionals who will embrace and lead meaningful change that improves care.

Filling in these gaps requires a new knowledge base and skill set for future physicians to both participate in and contribute to the transformation of the health care delivery system in order to achieve the Triple Aim and the Quadruple Aim. The third pillar of science in medical education—health systems science, described in this chapter—provides much of what is needed, particularly when it is seamlessly integrated with the basic and clinical sciences. The development of new types of physicians and health care professionals who are competent in all three medical sciences is required for both the patients for whom they will care and the health of society as a whole.

C. What is health systems science?

Health systems science is defined as the study of how health care is delivered, how health care professionals work together to deliver that care, and how the health system can improve patient care and health care delivery. Health systems science provides a comprehensive and holistic vision of topics, subjects, and competencies for individuals training and providing care within health care systems.[11,12,21,22] This third medical science should ideally synergize, complement, and be integrated with the core content and concepts of the traditional basic and clinical sciences. Using a person-centered

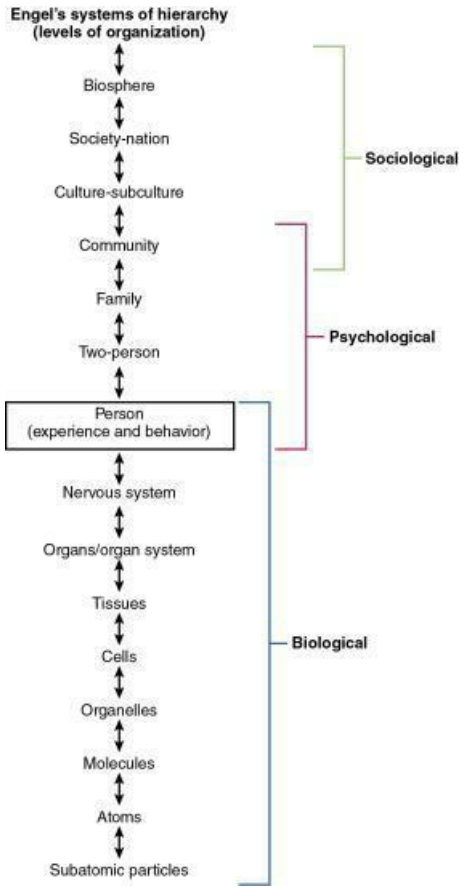
perspective that also reflects the Triple Aim, the basic and clinical sciences cannot meaningfully be applied to patient care in the absence of health systems science—this integration provides the context necessary for the care of individual patients and achieving desired outcomes.

D. Engel's biopsychosocial model

In the 1970s, George Engel described the goals of the patient-physician relationship as including (1) the promotion of healing, (2) relief of suffering, and (3) encouragement and education regarding behaviors to improve health.[23] He explained the need for physicians to understand their patients in several dimensions, both diagnostically and personally, to achieve the goals of this relationship. He emphasized the perspective of illness manifesting at numerous levels of patient- and systems-related factors in addition to disease pathophysiology. His biopsychosocial model of medicine proposes that effective physicians in the 21st century cannot isolate and focus on only one component (i.e., pathophysiology) of the organized whole, as doing so will neglect or compromise the object of study (the patient). Physicians must have holistic approaches that integrate the biologic, psychological, social, and systems components in order to help patients make the most informed and effective medical decisions, resulting in the greatest impact on the process and outcomes of care. The biopsychosocial perspective requires one to consider a human being to be both a biologic organism and a person who lives in the context of family and community. Engel believed:

> Patients' journeys through health and illness are often not predictable. Clinicians who have the skills and willingness to accompany their patients on these complex journeys will be more effective as healers and more satisfied with their work.

The foundation of Engel's model is based upon general systems theory, as described by Bertalanffy[24] and later by Senge (Fig. 1.5).[1] Systems theory proposes that every level of organization—including molecular, cellular, organic, personal, interpersonal, familial, societal, and biospheric—affects every other level. Systems theory provides a conceptual framework whereby both the organized whole and the component parts can be studied and therefore supplies the basis for health systems science. The health systems science curricular framework and definition are an expanded view of the "sociological" domain to include sciences related to health care delivery and improvement sciences, among others.



• **FIG. 1.5** Engel's Biopsychosocial Conceptual Model for Medicine. This model is used in the identification of a health systems science curriculum. The three tiers—biological, psychological, and sociological—are designated on the right side of the figure.

E. How health systems science is more than the individual components

The awareness and inclusion of health systems science topics in medical education programs at the undergraduate medical education (UME), graduate medical education (GME), and practice levels have been patchy at best, though the field has been rapidly evolving and advancing in recent years. Numerous publications and presentations have addressed selected content areas within health systems science domains, including novel curricular innovations and assessments of such curricula.[14,15,25,26] Multiple works have described ideal physician outcomes, curricula, or both, addressing content beyond the traditional basic and clinical sciences such as quality improvement, interprofessional teamwork, health care policy, transitions of care, and related areas of physician development.[16,27-29] Since 2000, several textbooks have been published exploring areas of education and care delivery related to specific health systems science domains. For example, *Understanding Patient Safety*,[30] *Understanding Value-Based Healthcare*,[31] and *The Health Care Handbook*[32] eloquently describe some of the core concepts in health systems

science.

Collectively, these contributions are critical for advancing learners' knowledge, attitudes, behaviors, and skills in these areas. However, there remains an important need to fully define the scope of the principles and application of health systems science, identify a full range of core health systems science topics, make explicit the relationships across and between topics that could be included in health systems science domains, and provide an integrated, comprehensive model of health systems science. Overall, despite a range of innovative and effective focused curricular enhancements, efforts to engage learners in a systematically designed health systems science curriculum have been limited.

F. How health systems science is connected to the triple and quadruple aims

There is broad agreement that the US health care system is not operating in a manner that is effective or satisfying for many patients or their clinicians. In addition, US per capita health care costs greatly exceed those of any other country in the world while health outcomes lag as measured by almost any indicator.[33] Multiple initiatives on local, regional, national, and international levels have attempted to address this state of affairs, though most of these efforts have been limited and narrowly focused. Donald Berwick, the former head of both the IHI and the Centers for Medicare & Medicaid Services, proposed the Triple Aim as a strategic organizing framework that is relatively comprehensive, addressing many of the major deficiencies in the current US health care system.[3]

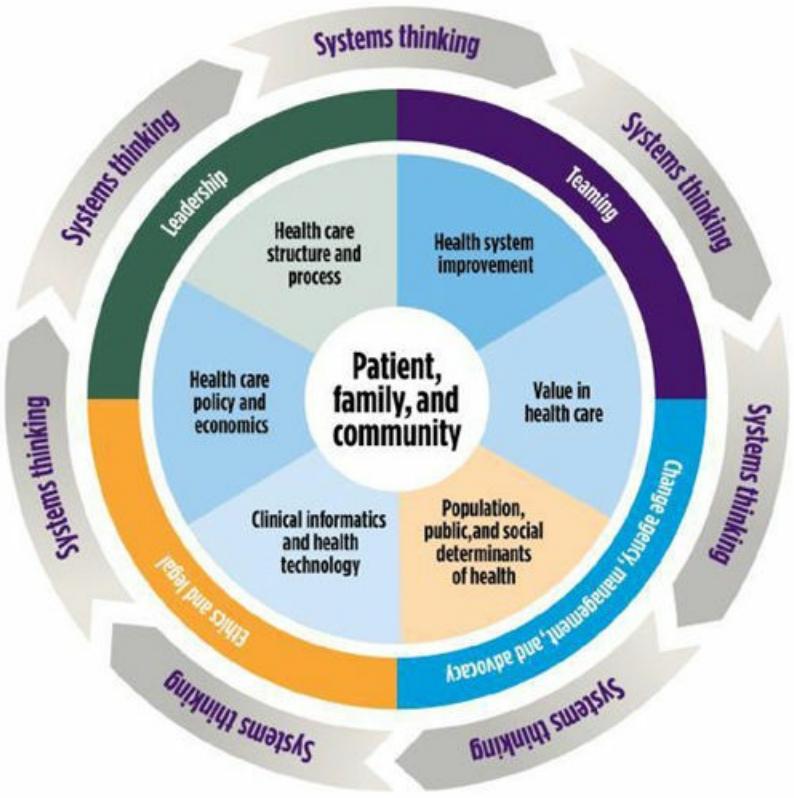
It is believed that pursuing these linked goals of improving the experience of care, improving the health of populations, and reducing per capita costs of health care will help the United States achieve high-value health care. A 2015 follow-up study of the impact of the Triple Aim 7 years after its publication found that the framework is now widely recognized and utilized because many organizations collaborated with the IHI and the Triple Aim was adopted as part of the national strategy for US health care in the ACA.[34]

One critique of the Triple Aim is that it does not account for the workforce burnout that is threatening its effectiveness as a framework for improving health outcomes. The increasing awareness of the statistics on burnout symptoms are sobering (nearly half of physicians are reporting burnout), and impaired physicians are at risk for not delivering high-quality care.[35] Bodenheimer and Sinsky have incorporated this idea into a friendly amendment to the Triple Aim, proposing "adding the goal of improving the work life of health care providers, including clinicians and staff" to create the Quadruple Aim.[36] Causes of burnout are complex, ranging from long, often unpredictable workloads to loss of control over the workplace environment and time-consuming electronic health record documentation that can distract from the process of caring. Many physician and health care organizations are now investing significant resources in identifying and ameliorating the systematic causes of burnout while seeking means to increase physician resilience.

The Triple Aim and the Quadruple Aim are widely recognized as the touchstones of health care transformation. It is abundantly clear that the traditional biomedical sciences cannot achieve improved health care outcomes alone. To a large extent the United States has tried, at great expense, and the results are hugely disappointing. Health systems science provides not only the missing pieces of this complex undertaking but the robust framework needed to support and advance the remarkable achievements and promise of our scientific understandings and therapies. It supplies the knowledge, attitudes, and skills required to identify challenges through broader person and population lenses, integrate and optimize interventions across the full spectrum of our capabilities, and track the results. It is also interesting to consider that the Quadruple Aim is a direct result of sophisticated systems thinking, and systems thinking is a critical element of the practice and educational agenda of health systems science.

V. Health systems science curricular domains

Three categories of curricular topics or domains are included in the health systems science curricular framework: (1) core functional domains, (2) foundational domains, and (3) linking domains. Fig. 1.6 illustrates the relationship between all three types of domains. Here, all domains are described with a working definition for curricular content; these domains also coincide with subsequent chapters. As with any emerging science, conceptual domains of content will evolve in an iterative manner as new concepts are identified, subcategories of content expand into individual domains, and relationships across domains are better understood across professional disciplines and in multiple educational settings. For example, a less well-developed concept map was published in the first edition of this textbook[37] (see Fig. 2.2 there). The revised version (Fig. 1.6) in this edition represents an evolution in expert thinking on the domains of health systems science.



• **FIG. 1.6** Core Functional, Foundational, and Linking Domains for a Health Systems Science Curriculum. The inner circle includes the core functional domains. The middle circle includes the foundational domains. Systems thinking is the domain that links all these concepts together. *Source:* (Used with permission of the American Medical Association. ©Copyright American Medical Association 2020. All rights reserved.)

A. Core functional domains

1. Patient, family, and community

The patient, family, and community domain includes all issues focused on the patient's experience of care, the values each patient has in his or her own health, and the patient's behaviors and motivations for engaging in health care and his or her own health, as well as the contextual influence of patients' families and communities.

2. Health care structure and process

The health care structure and process domain includes all of the health care elements of how health care is provided, such as the organization of individuals, institutions, resources, and processes for delivery of health care to meet the needs of patients or populations of patients, including the processes of collaboration and coordination. Several specific examples of curricular content in this domain include (1) knowledge of clinical settings (i.e., clinics, hospital units, etc.) and processes occurring within outpatient and inpatient settings; (2) fragmentation and insufficiencies encountered by patients in the health care continuum; and (3) the ability to identify the importance of teamwork within clinical "teams" and "communities" that span diverse settings.

3. Health care policy and economics

The health care policy and economics domain encompasses all issues related to the decisions, plans, and actions undertaken to achieve specific health care goals and the issues related to efficiency, effectiveness, value, and behavior in the production and consumption of health care. These sciences are used to promote health through the study of all components of the health care system and managed care. Specific examples of curricular content in this domain include (1) history and core principles of health care policy, (2) the basics of how health care is financed and the impact of health care policy on insurance and reimbursement, and (3) incentives for clinicians and hospitals within different US payment models.

4. Clinical informatics and health technology

The clinical informatics and health technology domain includes all issues related to the application of informatics and information technology to deliver health care services, including clinical decision support, documentation, technology, and tools (e.g., electronic health records), and the utilization of data to improve health. Specific curricular examples in this domain include (1) core principles of informatics sciences, including biomedical informatics, patient security, and rights protection in regard to data; (2) awareness of real-time data viewing and decision support to manage data registries and analyze clinical reports; and (3) awareness of current functionality and challenges in current health information exchange.

5. Population, public, and social determinants of health

The population, public, and social determinants of health domain includes all issues

related to traditional public health and preventive medicine, including the full range of social determinants of health affecting the entire population rather than only sick individuals, and the improvement strategies at the population health level to address gaps in care. The content in this domain also includes the organized assessment, monitoring, or measurement to prevent disease and injury, promote health, prolong life, or improve any other health outcome for a group of individuals (e.g., geographic populations such as nations, communities, ethnic groups, or any other defined group), including the access to and distribution of such outcomes within the group, and the dynamic interrelationships among various personal, socioeconomic, and environmental factors that relate to health outcomes or prevention. Specific curricular examples for this domain include (1) the ability to build a community asset map to identify local resources that can help address a leading health indicator, (2) definition of patient risk behaviors within the context of health determinants in uninsured populations, and (3) development of cultural skills to work with individuals from diverse cultural backgrounds.

6. Value in health care

The value in health care domain broadly includes content related to the performance of a health system in terms of quality of care delivery, cost, and waste. From the quality perspective, the content in this domain maps to one of the six Institute of Medicine dimensions of quality: patient safety, timeliness, effectiveness, efficiency, equitability, and patient-centeredness.[7,31] (Note: The Institute of Medicine was renamed the National Academy of Medicine in 2015.) The content also includes all issues related to the cost of health care, waste components, and service requirements. Finally, the content includes understanding the epidemiology of, as well as seeing and classifying, gaps in care and care delivery. Specific curricular examples for this domain include (1) definition and stakeholder perspectives of value in health care; (2) components of high-value health care systems; (3) key correlations of quality and safety principles with patient outcomes; (4) the importance of identifying, reporting, and analyzing safety events; and (5) the relationship between quality and cost and efforts by health care professionals and teams to address costs of care.

7. Health system improvement

The health system improvement domain includes all content related to processes of identifying, analyzing, or implementing changes in policy, health care delivery, or any other function of the health care system to improve the performance of any component of the health care system. Issues herein include quantifying and closing gaps (action), variation/measurement (specifically related to quantifying and closing gaps, not to health care measures in general), analysis of data, interventions, and innovation and scholarship. Specific curricular examples in this domain include (1) selecting a quality indicator and developing an improvement plan, (2) drafting a Plan-Do-Study-Act worksheet that outlines a test of change, and (3) developing the ability to adapt to different improvement challenges with different evidence-based methodologies.

Additionally, the scholarship approach to improving health systems is addressed by

this domain, which includes all content relevant to the conduct and scholarly dissemination of health systems science content, health services research that investigates any health systems science domain, or both. Scholarship is defined as (1) discovery, which is consistent with traditional research; (2) integration, which makes connections across disciplines and places specialties in a larger context; (3) application, which demonstrates the vital interaction between research and practice; and (4) teaching (educational scholarship), which emphasizes the creation of new knowledge about teaching and learning in the presence of learners.[38] Specific curricular examples in this domain include (1) development, completion, and presentation of scholarly quality and patient safety projects; (2) opportunities for population-based research projects; and (3) expertise through advanced application of knowledge and skills in interprofessional team-based care, quality improvement, leadership, and change management, as demonstrated through scholarly projects.

B. Foundational domains

Topics (knowledge and skills) identified as transcending multiple core curricular domains are clustered into foundational domains. These domains, especially leadership and teaming, relate to direct patient care competencies and serve to connect and highlight the relationship (and sometimes tensions) between direct patient care priorities and a systems-focused view. Therefore many UME curricula traditionally address this content, but these domains must be emphasized within the health systems science context.

1. Change agency, management, and advocacy

The change agency, management, and advocacy domain includes all content, knowledge, and skills focused on the recognition by all health care professionals that they ought to be agents of change to improve health systems for patients. Each health care professional should feel empowered to advocate for his or her individual patients to receive the best-quality care and to suggest and implement changes in the health care system. In order to advocate and make changes, knowledge and skills in change management processes are critical to ensure ideal outcomes. Specific examples of curricular content in this domain include (1) knowledge and awareness of how health care professionals at all levels can impact and change the system; (2) the skills required to advocate for patients at the individual, group, and population levels; and (3) the ability to identify and address barriers to implementing necessary change.

2. Ethics and legal

The ethics and legal domain includes all content focused on the ethical and legal issues and factors involved in health care delivery and the health systems science areas. Specific examples of curricular content in this domain include (1) understanding the relationship between law and ethics in the design and operation of US health care and (2) the ability to describe the ways in which the transition from a one patient and one doctor dynamic to a systems approach based on teams, organizations, and populations

presents challenges for health law and ethics.

3. Leadership

Leadership includes all content related to inspiring motivation in others to create goals toward a desirable vision. In the context of UME, leadership pertains to team-based care, quality improvement projects, and the like. Specific curricular examples for this domain include (1) types of leadership in health care (and key competencies required for each type) and key skills physicians must develop to become true leaders and (2) reflection on personal values and synchrony with life goals as well as understanding how successful leaders create alignment between personal and institutional values.

4. Teaming

The teaming domain includes all issues related to collaboration and team science, specifically through the process of individuals working together on specified tasks to achieved shared goals. This domain fully encompasses interprofessional education. Specific curricular examples for this domain include (1) knowledge and awareness of interprofessional providers' roles and skills, (2) communication required to function in teams in an integrated/coordinated system, and (3) skills to function in a team and apply reflective practice in the context of quality improvement and patient safety.

C. Linking domain: Systems thinking

Systems thinking as a linking domain refers to the content that unifies or "links" the core curricular domains or subcategories to other core curricular domains, or links core curricular domains or subcategories to contents of the broader medical school curriculum.[1,39] The knowledge and skills of systems thinking allow students to be cognizant of and apply a comprehensive, holistic approach to medical care and health care issues. It includes all issues related to the attention to a complex web of interdependencies, an awareness of the "whole" and not just the parts, and the ability to recognize multidirectional cause-and-effect relationships with all causes emerging as the effect of another system dynamic. For example, systems thinking allows learners to understand the influence of the ACA on the determinants of health within a community and, as a result, the ability for their patients to access health care and adhere to care plans.

As with any emerging science and its inclusion in professional education, the richness and greatest impact of systems thinking lies at the intersection of conceptual content domains, and there is considerable overlap in the conceptual areas described previously. These domains are not discrete and separate categories but overlap and interrelate as they comprise the integrated whole of health systems science. For example, discussion of health care processes and microsystems directly relates to specific and detailed discussions regarding teamwork, provider incentives discussed in health policy and economics directly influence value-based care and improvement, and professionalism implications must be included in conversations related to patient data protection concepts in clinical informatics and health information technology.

VI. Case studies: Renal disease and treatment—where basic, clinical, and health systems science merge

These cases offer evolutionary developmental steps whereby health systems science concepts are introduced at each stage but with increasing complexity to match the level of the learner.

Case study 1: First year of medical school dilemma

A first-year student learns about kidney biochemistry and physiology and notes that on the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation for estimating glomerular filtration rates (GFR) found on the National Institutes of Health website,[40] the formulas are divided between "blacks" and "whites." She asks her renal faculty member who has lectured for decades during the Renal Block about this, and he replies that these are the established formulas and no one has ever questioned them before. When probing deeper, he suggests that the reason may be due to greater muscle mass among blacks. The student asks further questions:

1. What is the scientific basis for the racial "profiling" of renal function or muscle mass?
2. Is there evidence that blacks have different kidneys than whites?
3. What might be the interwoven social, medical, and economic factors that play into this—from occupational differences to poverty to differential access to care and treatments?
4. Who is considered "black" and who is considered "white" in America? She herself has a dark brown complexion with parents from Argentina and Brazil, while her anatomy partner is dark skinned but his parents are from southern India.

Case study 2: Third year of medical school dilemma

A group of third-year medical students, halfway through their clinical rotations, meet up in the hospital cafeteria and compare notes about their experiences so far. Although they are excited by the opportunity to apply their newly acquired medical knowledge and skills to patients, they are shocked by the state of the electronic health record (EHR) systems they are encountering—and the deleterious effects they see on patients and physicians. For example:

- *On their family medicine rotation, patients showed up at their primary care physician after discharge from the hospital with no records—paper or electronic—of what happened. There is no way for their EHR to access these records, even if this information is critical to patients' health and to prevent readmission for the same problems that got them admitted in the first place. The patients do not remember what medications were*

changed or what they were supposed to do after discharge, and hoped their primary care doctors might know.

- *On their inpatient internal medicine rotation, they watched as their supervising residents and attendings spent triple the time on EHR documentation as compared to direct contact with patients and heard them gripe, "Did we sign up to be typists or doctors?" and "I have to put in 2 hours every night finishing my charts after I go home —when I should be spending time with my kids or catching up on journals."*
- *On their outpatient pediatric rotation during well-child visits, their attendings paid more attention to checking the boxes in the EHR than they did to their patients, and later the students overheard some parents saying that "the doctor hardly even looked at my child."*
- *On their surgery rotation, the students were invited to learn to prescribe medication and found that it took them 3 minutes and 27 clicks to order acetaminophen with codeine, and, even then, they were not sure if they had prescribed the right dosage or formulation.*

The students develop questions to help resolve these problems:

1. What are the system issues present in these examples, and how might they be corrected?
2. What are the financial implications?
3. What harm may there be to the patient, and how could it be corrected?
4. How might a care team approach help with documentation?
5. What technological or organizational innovations might you like to see in EHRs during your professional lifetime?

Case study 3: Intern dilemma

A family medicine intern prepares to discharge from the hospital to home a 71-year-old male patient following a long hospitalization for new-onset congestive heart failure complicated by acute renal failure. The discharge instructions include six new medications, a low-salt diet, support hose, exercise, and follow-up with a primary care physician in 5 days. She orders a visiting home nurse to go to the house and provide guidance, help administer and monitor medication adherence, check home safety, and measure blood pressure and weight. Unfortunately, the medications are administered on different schedules (once a day in the morning, twice a day, three times a day, once in the evening, etc.), and two of the medications are "off-formulary" and are unaffordable for the patient. In addition, there are no primary care physicians in his area that accept his insurance. The patient lives in a community that is a "food desert" and is unable to get low-salt food. There are no sidewalks, and the visiting home nurses consider his neighborhood too dangerous to service. The patient quickly deteriorates, and after 4 days he decompensates sufficiently that his family calls 911. An ambulance takes him back to the hospital's emergency department, and he is admitted to the intensive care unit for a week.

1. How might the discharge be handled, given the barriers to care?
2. How can rehospitalization be avoided?

3. How might the hospital, residents, staff, and attendings help reduce the health disparities in the community?
4. How can the health system assume responsibility for "episodes of care," including follow-up?
5. How might community-wide interventions reduce rates of disease prevalence and incidence?

Case study 4: Renal fellow dilemma

A renal fellow quickly masters the treatments for renal failure, including the physiology and chemistry of renal dialysis. When involved in renal consults in a major teaching hospital, he notices that many of the patients scheduled to start renal dialysis have other serious comorbidities ranging from advanced Alzheimer's disease to end-stage metastatic cancer. He is pretty certain that neither quality of life nor life expectancy is influenced by the dialysis, but his attending chides him, "Look, who are you to be a one-man death panel?" and "Anyway, there is a special federal law that pays for all of it that was pushed by kidney patients in the 1980s."

1. What are the indications and counterindications for dialysis for patients at the end of life?
2. How might renal dialysis or other expensive medical interventions be judiciously applied to individual patients and populations—and is rationing reasonable?
3. What evidence is required to support the broad utilization of a medical intervention?
4. What health policy and legislative initiatives are reasonable for special interest groups?

VII. Professional identity formation

Physicians have traditionally been trained to care for one patient at a time in the office or hospital, making autonomous decisions and utilizing supporting personnel. Additionally, other health care professionals have been trained to focus on their area of expertise and contribute to a physician's ultimate decision in the hope of improving patient care. Political and business perspectives have increasingly affected how medicine is delivered and altered expectations of the clinicians within the system, resulting in many clinicians who are ill-equipped to venture outside of this model, migrating more and more to an "employee" approach to medical practice. The lack of training in systems and the complex determinants of care has become a self-fulfilling prophecy. As a result, change in health care is often led by managers, accountants, and policymakers who are skilled in understanding the financial implications of potential change but may not be well versed in understanding the needs of person-centered care.[11] It is clearly time for physicians to engage in this process. One of the key foundational principles of this textbook is that the goals of education in the health professions need to be broadened and rebalanced. Knowledge acquisition in the basic and clinical sciences is not enough. Practicing within an increasingly limited box of diagnosis and treatment is not enough. Physicians and health care professionals need to be collaborators and leaders in a system transformation that is already well on its way, and medical education must do its part to develop and support students for these new professional roles.

An interesting way to conceptualize this need for a different "type" of provider is through the constructive-developmental theory as set forth by Kegan.[41,42] In studying adult learning, he described "orders of mind," each with a qualitative shift in complexity. Most adults and clinicians live in a "socialized" or a self-authoring mindset. In the socialized mindset, physicians and health care professionals have the ability to subordinate their desires to the desires of others (this very nicely describes the "employee" mentality alluded to earlier). They are guided by others or institutions and are focused on "getting along" rather than changing or confronting a problematic situation. Individuals exhibiting a "self-authoring" mind are inclined to "own" their work, exhibiting agency, self-motivation, and vision (though this may be fairly rigid and uncompromising). These "self-authoring" qualities are often viewed as essential characteristics of leadership. They can also be viewed as characterizing the old model of a physician as an independent agent or "cowboy," acting alone in calling the shots and pointing the way. However, the self-authoring mind may lack the capacity for meaningful teamwork and collaboration and is at risk of falling short in the context of the kind of complex adaptive challenges that are so common in health care. Kegan's model of development describes one additional step—the "self-transforming" mind. A self-transforming mind is characterized by the ability to mediate conflicts, thoughtfully review and appropriately integrate input from multiple sources and perspectives, see the larger context and backstories, and flexibly lead in an environment of uncertainty and change. This aptly describes the environment in health care today, and the goal of

our educational systems should be to support the development of self-transforming minds in our learners. Health professions students must begin to view this as a process and outcome of their own personal growth in medicine.

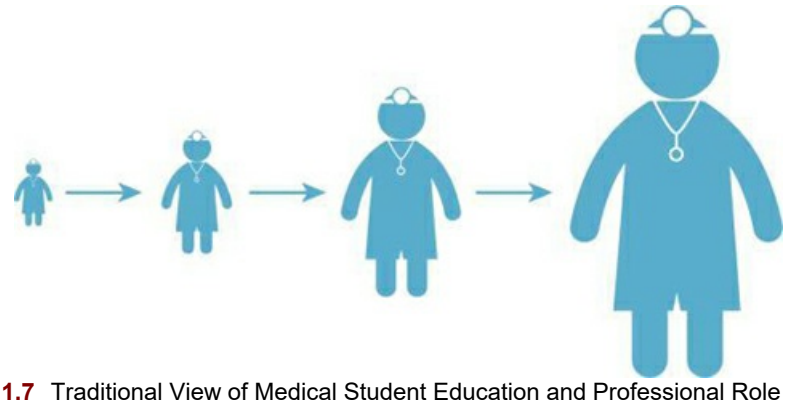
The process of becoming a self-transforming leader is complex, but there is a clear relationship between this mindset and the health systems science skills and knowledge required to be a leader and a change agent in evolving health systems and in associated educational pathways.[41] Systems thinking in particular, with its emphasis on complexity, depth of insight, and metacognition, is emerging as a critical component of a new professionalism. In order to become effective contributors to a health care environment that is more collaborative than "self-authoring," future physicians will need to aspire to a new professional identity. They will require a native "fluency" in the language of teams, a vision that takes into account the entire "iceberg," and an ability to apply the domains of health systems science to the care of patients and populations.[1]

The rapidly evolving health care landscape creates an immediate need to reevaluate medical education curriculum and meaningfully incorporate health systems science. The key here is "meaningful"—the two-pillar model is deeply embedded in our educational DNA and career pathways, and this will require no less than a transformative rebalancing of priorities and incentives. At the core of this transformation is a need to develop and educate a new generation of clinicians with a different view of their roles and responsibilities.

Health systems science consists of knowledge and concepts that are patient-centric rather than physician-centric. The goal is not limited to the treatment of disease—it is guided by the health and outcomes of patients and populations, taking into account multiple complex factors. Health systems science fluency requires the clinician to understand the challenges and successes encountered by patients as they traverse the health "system" to obtain care and achieve or sustain health. This understanding is independent of any one profession or health care role. This new professional identity is required by all health professionals not only to provide patient-centered care but also to appropriately function in the rapidly evolving and increasingly collaborative care models needed to achieve the Triple Aim.

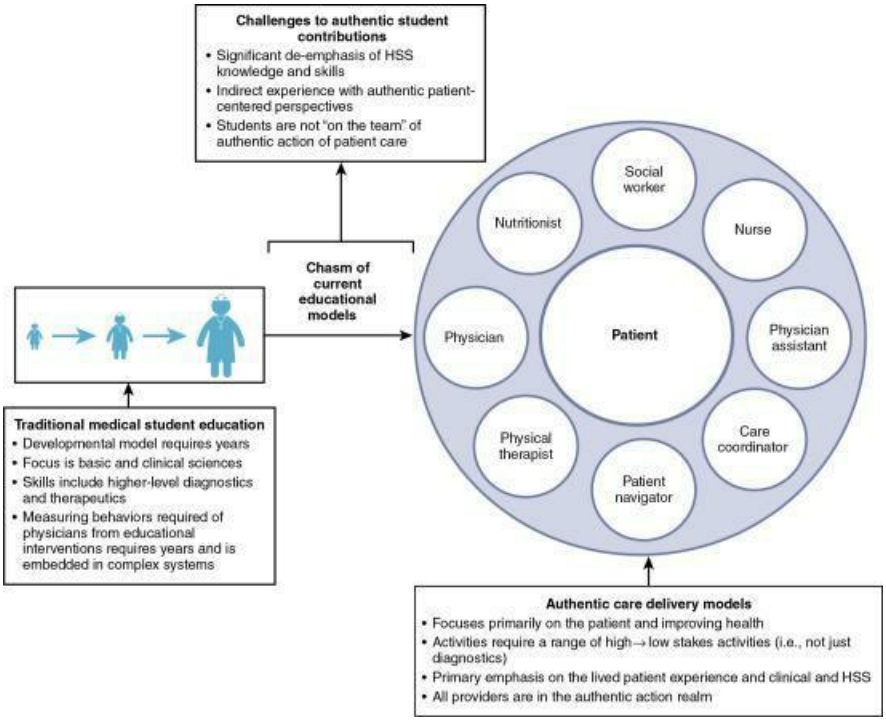
A. Physician-centric role identity

In traditional models of medical education, students entered medical school and assumed the role of the "apprentice." In a method adopted and advanced by Flexner in the early 1900s, students' learning occurred primarily from working with and observing more senior physicians. Physicians were viewed as an actively practicing repository of knowledge, information, and decision-making processes for nearly all aspects of a patient's care. In this model, students observed or "shadowed" in the clinical environment before developing more autonomy over time toward a path of independent practice. Fig. 1.7 depicts this traditional view of medical student education and professional role identity formation.



• **FIG. 1.7** Traditional View of Medical Student Education and Professional Role Identity Formation. Student growth during medical school has traditionally focused on "physician-centric" education, which is, by and large, separated and divorced from authentic perspectives into health care processes and interprofessional collaboration.

While this basic model has remained in place over the last 100 years, the experience of this pathway has changed dramatically. Increasing regulatory and supervisory requirements have effectively limited the ability of learners to authentically experience and contribute to patient care. As a result, students are often viewed as extraneous and even a burden on the functions and process of patient care, making them feel devalued (Fig. 1.8).



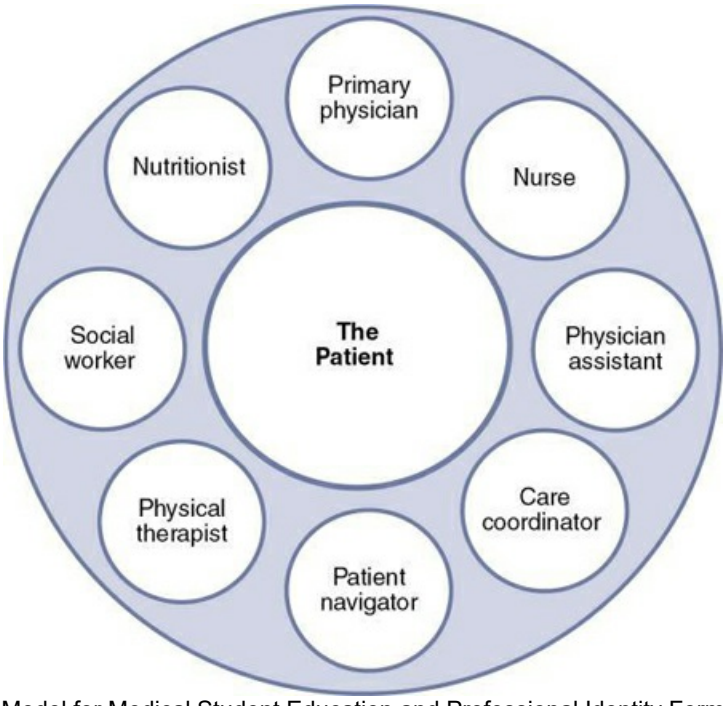
• **FIG. 1.8** Conceptual schematic of the current chasm between traditional physician-centric medical education and making authentic patient-centered contributions in care delivery.

A key analogy that captures the essence of the new professional role identity needed in evolving health care systems is one of the digital native versus the digital immigrant.

A digital immigrant is an individual who was born into a culture without all of the current-day technological advances. While these individuals adapt as best they can, they often find it difficult to fully integrate new and emerging technology into the fabric of their lives. In contrast, digital natives are those who were born into the technology environment, and therefore it becomes part of their "DNA." Extending this analogy to the challenge of educating for emerging systems of care, health professions schools and training programs need to find ways to promote and support the knowledge, skills, and professional identity of "health systems science natives."

B. Patient-centered, systems role identity

For clinicians in training to develop an early professional role identity that aligns with the needs of the 21st-century health care system, students must be provided with early immersive experiences to learn about and engage in health systems science. Akin to the need to perform clinical preceptorships to learn clinical skills such as cardiac and lung auscultation, communication, and history taking, students must authentically engage with health systems science through clinical work. This involves students being embedded into interprofessional care teams and becoming true contributors to health care teams (Fig. 1.9). In this model, students engage in health systems science by participating in roles that are not traditionally physician-centric roles. When students serve in these collaborative team environments and provide value through engagement in concepts outside of the physician-patient interface (the tip of the iceberg in Fig. 1.2), they can begin to understand the roles of other health professionals and have the opportunity to develop a new patient-centered systems role identity.



• **FIG. 1.9** Model for Medical Student Education and Professional Identity Formation in the

Context of a Health Systems Science Curriculum. Within health systems science, medical students can begin to view health care systems in new ways and potentially undertake authentic systems roles (e.g., patient navigator). Through these roles, students fully engage with the health system and see firsthand the roles of other team members and health care processes. This proposed model provides students with opportunities to see their professional role as one within the health system and among other team members.

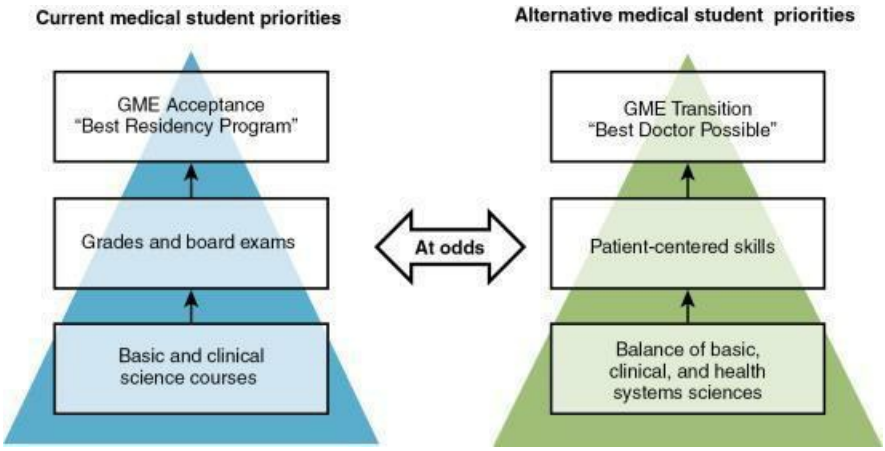
On a larger level, the shift toward health systems science is emerging as a new professional identity in health care, the "systems citizen."[43,45,46,61] As new health care delivery models become more prevalent, there is an extension of the physician's professional identity that moves beyond individual behaviors or traits (e.g., altruism, showing respect to others, trustworthiness) and the ability to make accurate diagnoses and prescribe correct therapeutics. The new professional identity is a patient-centered systems identity—a systems citizen—that promotes a more proactive and symbiotic relationship for a physician with the health care system.[47-49,61] The health systems science competencies embodied by systems citizen physicians will allow for the transformation of the health care delivery system and improve patient health.

VIII. Challenges for learners to engage health systems science

A number of important factors remain to be addressed to best implement health systems science in medical education. Progress is being made, but the following factors are important to address.

A. Address the hidden curriculum

The hidden curriculum is the influence of institutional structure and culture on the learning environment.[50] Policies, the formal curriculum, examinations, and the professional development of faculty reflect institutional goals and values, which in turn affect the learning environment.[31,51,52] Additionally, the hidden curriculum often reinforces the notions of physician autonomy and authority, influencing trainees' perceptions of patient worth and team member roles as they model faculty behaviors.[53-55] Although trainees have identified gaps in their health systems science education, this content is assigned a lower priority because it is not included in licensing and board examinations and residency placement criteria (Fig. 1.10).[29,56-61] The environments in which physicians are training may have a lasting effect on their behaviors.



• **FIG. 1.10** Medical Student Competing Agendas as the Primary Pedagogical Challenge for a Health Systems Science Curriculum in Undergraduate Medical Education. The left side of the figure reflects student perspectives of current priority areas for their education. The basic and clinical sciences are viewed as essential components of learning for grades and board examinations, both of which primarily test biomedical concepts. These evaluative measures are perceived as the primary influence on acceptance into the best residency program of their choice. The right side of the figure demonstrates student perspectives on their awareness of the importance to focus on alternative areas. Students identify the importance of balancing basic, clinical, and health systems sciences, which will allow them to develop a skill set for patient-centered care. Students identify these skills as critical for transitioning into graduate medical education (GME) training to be able to better care for patients.

Emerging evidence suggests that students who train in clinical environments with lower resource utilization are more likely to practice similar methods in the future, suggesting that role modeling during training years is a critical element in learner development.[62,63] If role models do not demonstrate health systems science-informed clinical practice, learners will be less likely to incorporate these behaviors into their own practice.[64,65] Creating initiatives to introduce health systems science curricula will require a change in institutional values and culture. Therefore implementation and evaluation of specific curricular changes will model the expected value changes for the rest of the medical education community at each institution.[50] Since perceptions of learning environments vary between institutions, efforts to evaluate the effects of the hidden curriculum must be directed toward each specific locale.[66] Understanding each community's readiness for educational change will assist the institution's leadership in understanding the barriers and tensions of implementing the formal curriculum and allow them to devise incentive structures for faculty (via resources and promotion) and students (via examinations) accordingly. Increasing students' recognition of the importance of health systems science to their careers could be addressed by exposing students to integrated, longitudinal, and meaningful patient-centered experiences. Aligning their health systems science education with positive experiences in health systems improvement efforts may reduce gaps in the curriculum and create a "fluid" learning environment. Evolving discourse on health systems science education at the national level should include conversations about student, medical school, and physician accountability in espousing health systems science tenets in their practice and teaching of medicine.

B. Demonstrate the potential for adding value to the practice

Traditionally, clinical training experiences in UME link students directly with residents and attending physicians during clinical care duties.[20] This apprenticeship model requires time to mentor and educate students, which often decreases efficiency and negatively impacts physician productivity and profitability of the health system.[67-71] The increasing need for physicians and care delivery models to optimize efficiency and quality while minimizing cost, and the added work in mentoring medical students in today's models, need to be reexamined. Faculty and schools have traditionally presumed that students cannot add value to patient care today. Recommendations have been made for increased education and research into further integrating medical schools with academic health centers and community health programs.[72,73] Recently, educators have recommended an increased focus on identifying and providing value-added roles for medical students to "share the care" of health care delivery.[74,75] The application of health systems science competencies in experiential roles within the health care system can oftentimes be "lower stakes" (e.g., health coaching) compared with traditional biomedical decisions (e.g., ordering medications). This key difference opens several opportunities for medical students to engage with the health system by

performing authentic systems-based tasks that can add value and improve care processes and patient outcomes, while also promoting learning of health systems science content.[21,25,75] Students can add value by serving as patient navigators and health coaches, facilitating effective care transitions, and assisting with medication reconciliation and education. These meaningful roles align with the clinical care needs of the health system, specifically focusing on important quality and efficiency metrics such as reducing readmissions, improving care transitions, and improving patient satisfaction. These new student roles have the potential to lessen the "burden" on the system and mentors, enhance student education in health systems science, and potentially improve health outcomes.

C. Improve the undergraduate-to-graduate medical education transition

In the current education model, students progress from medical school into residency programs, often in different health systems. This transition between UME and GME creates unique challenges for education programs seeking to enhance learning and assessment in health systems science–related competencies.[12,13,16,77] The GME milestones as part of the Accreditation Council for Graduate Medical Education's Next Accreditation System and the UME Entrustable Professional Activities outcome goals for graduating medical students developed by the Association of American Medical Colleges are not similar in language or content, limiting the assessment in this transition.[78-80] Although Entrustable Professional Activities and milestones can be used in a complementary manner, ideal educational "handoffs" are hindered by a lack of consistency in how they are defined and developed.[81] Additionally, variation across GME programs' expectations of graduating medical student competence in health systems science, and assessment and prioritization of these areas in the residency selection process, further reinforce gaps in the UME-to-GME transition. Medical education initiatives are seeking to achieve a common language to guide learning and assessment, specifically for health systems science, to reliably ensure that physicians are prepared to meaningfully participate in complex, evolving, team-based care models. In the coming years, a common "transition" competency and assessment language and system will allow for a more meaningful and seamless transition from UME to GME.

IX. Chapter summary

Despite these and other challenges, progress is occurring. David Sklar, then editor of *Academic Medicine,* in an article titled, "What Would Excellence in Health Professions Education Mean If It Addressed Our Most Pressing Health Problems?" recognized the importance of health systems science by saying, "The success of the medical school and its rating for excellence would partly depend on the effectiveness of its education and care in health systems sciences, which would include population management."[82] The United States Medical Licensing Examination now includes health systems science questions in each of the three step examinations, and the National Board of Medical Examiners has developed a subject examination on health systems science. Students at schools that emphasize health systems science are reporting that residency program directors are interested in their experiences and health systems science projects in residency application interviews. In aggregate, these and other examples indicate that health systems science as the third pillar of medical education has been well established and is strengthening through dissemination across the education and training continuum.

X. Overview of book chapters

The subsequent 16 chapters of this book address the key components of health systems science. This book has been specifically designed for all health professions students, including students in medicine, physician assistant, nursing, and public health schools. However, these core concepts are applicable to all clinicians with an interest in these areas and to medical education faculty responsible for educating the next generation of health providers about health systems science and the evolving frontier of health care education.

In Chapter 2, the authors explore systems thinking, the domain that links all health systems science domains. In Chapters 3 through 15, each chapter takes on a critical component of health systems science, with a discussion of the key concepts that are applicable to current-day practice and factor in the evolving landscape of health care delivery. Chapter 16 provides students with insights into assessment strategies and how they might utilize feedback from a variety of sources to help them understand how they are performing within health care systems in which they are learning and assisting in the provision of patient-centered care. Finally, Chapter 17 explores the future of health systems science, including a science fiction story about how health professionals and health professions students may one day address an emerging health threat.

XI. Chapter template

The goal of this textbook is to enhance education for health professions students, faculty, and other individuals interested in advancing their knowledge and skills in health systems science, with the aim of ultimately improving the health of patients. To this end, each chapter of this book is intended to provide useful information and stimulating concepts for the reader to consider on a broad scale. Each chapter highlights salient aspects of medicine that are deemed appropriate for the soon-to-be or currently practicing clinician within the health care system. Each chapter additionally seeks to incorporate tables, case studies, and exercises to stimulate further engagement with each of the concepts.

CHAPTER TEMPLATE

Learning Objectives
Chapter Outline
Core Chapter Content
Chapter Summary
Questions for Further Thought
Annotated Bibliography and References

The authors fully anticipate, given the rapid transformation of health care redesign, that specific content that could be included in a textbook such as this could quickly become out of date. Each chapter has been purposefully designed to build a framework for subsequent knowledge and conceptual learning, so the anticipated changes could still be directly applied to this structure and therefore be applicable across time. Readers are encouraged to supplement this reading and content with other resources that have the potential to build upon these concepts in a synergistic manner.

Questions for further thought

1. What is health systems science, and why is it important to 21st-century health care delivery?
2 How will success in achieving the elements of the Triple and the Quadruple Aims address some of the most serious problems confronting health care in the United States?
3. What are three payment (reform) strategies that are designed to replace the current fee-for-service model and enhance the value of health care delivery?
4. How can development of the knowledge and skills necessary to function and lead change in our health care systems lead to enhanced patient-centered care?
5. What meaningful roles can students assume during immersive experiences in our health care systems that allow them to participate authentically as members of a health care team? How are these roles different than those previously available through an apprenticeship model of medical education?

PATIENTS: THE MISSING CRITICAL VOICE IN HEALTH SYSTEMS SCIENCE

Martha E. (Meg) Gaines, JD, LLM

> *"The energy of patients and members of the public worldwide who care about improving health is a huge, but still largely unrecognized and untapped, resource. The aim of patient engagement is to shift the clinical paradigm from determining "what is the matter?" to discovering "what matters to you?"*[1]

> *"If the 20th-century was about thinking the world apart, then the 21st-century must be about thinking it back together again."*[2]

During the last century, scientists—physicians chief among them—achieved remarkable advancements in medicine leading to significant increases in life expectancy for many. This focus on scientific achievement was driven by a search for knowledge, however, and not primarily by any systematic inquiry regarding the needs of patients, families, and communities ("patients"). "Patients" is used for brevity here and refers in all instances to patients, families, and communities.

The 21st-century challenge to apply these advances to patients in health care settings must fold our voices back into the process. Without us, successful application will be sporadic at best, depending on clinicians to guess what patients will and won't "comply with" or "adhere" to; the existing examples of these pernicious obstacles are too many.

Clinicians and students seeking to develop competency in health systems science would do well to stretch their thinking about the role patients can and must play at all levels of system change: the clinic and hospital (microsystem), the organization and community (mesosystem), and national policy decision forums (macrosystem). Simply

put, the failure to engage patients fully as partners in health systems change amounts to doing the same thing over and over again while expecting a different result—insanity.

There science, though our failure to emphasize its importance makes funding for research and publication in this area more difficult. Still, patient-centered outcomes research funding in the United States has spurred new projects that allow us to join other countries that have been exploring this field for almost a decade.[3]

So how can educators prepare 21st-century physicians to fully engage patients as partners in their own care, in how care is "delivered," and in reforming how health care is valued, reimbursed, measured, and administered (i.e., the fundamentals of health care infrastructure)?

We can begin by attending to our language to ensure that we really say what we mean and mean what we say.[4] Training physicians to "deliver" health care *to* patients is very different from training them to co-create health care *with* patients. Do we want patients to "receive" deliveries or co-create with clinicians? If we mean the latter, we need to embed that intention in the words we use with students and patients. A number of recent evidence-based techniques have been developed to more effectively and systematically learn from patient experience and incorporate that feedback into quality improvement initiatives at the practice and health system levels.[5,6]

Likewise, we must be careful in our approach to "interprofessional collaboration" and "team-based care." Patients are not commonly included in those constructs. In the team-based care model proposed in this chapter, we must beware of patients continuing to be isolated in the middle, remaining "out of the loop" of their own care even as we seek to engage students more meaningfully in the schema. Perhaps if we draw arrows between and among all the members of the team and the patient in the model—all of which connect through the patient in the center—we will ensure that health care is answering the important question "what matters to you?" and not merely "what is the matter with you?"

Twenty-first century clinicians must learn the skills necessary for co-creation, the ability to:

- Listen without preconceptions.
- Learn from every patient.
- Respect patients' hard-earned skills and knowledge.
- Help patients believe in their innate ability to make decisions even in health care matters.
- Partner fully to co-create health care that matters to patients.
- Teach what patients want and need to learn and when.
- Encourage patients to ask questions, research information, and own their own health.
- Create and protect the space and time necessary to form real relationships.
- Understand the essential complexity and fallibility of all humans.
- Blame neither themselves nor their patients for common human frailties.

This will require educators and patients to travel an as-yet unpaved road to co-create a curriculum together. In the end, our students will remember what we do and not what we say; we must show them the kind of radical transformative process we want them to replicate in their health systems science work.

Martha E. (Meg) Gaines, JD, LLM, is the director of the Center for Patient Partnerships and a Distinguished Clinical Professor of Law at the University of Wisconsin–Madison. The Center conducts research about issues relevant to patient care and health care delivery from the patient's perspective.

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Systems thinking in health care: Addressing the complex dynamics of patients and health systems

Jed D. Gonzalo, MD, MSc, Maya M. Hammoud, MD, MBA, Stephanie R. Starr, MD

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In this chapter

Systems thinking is a philosophy, mindset, and set of tools that facilitate an individual’s thought process to see the interrelatedness of the parts of a system and the cohesion across those parts. The benefit of systems thinking is higher-leverage thinking and action. Systems thinking principles have been increasingly promoted as critical for innovation, problem solving, and collaboration in multiple fields, including the health professions. As health care becomes more complex, with raised awareness that patient and health system issues are complex, adaptive challenges, medical educators are seeking to develop higher-order competencies for current and future health care professionals to address these challenges. This chapter explores the concept of systems thinking, applies systems thinking habits and tools to health care situations, and demonstrates the importance of systems thinking to health and health care.

Learning Objectives

1. Define systems thinking.
2. Explain the characteristics of a complex system.
3. Identify why health systems fit the definition of complex systems.
4. List and summarize the habits and tools of a systems thinking health care professional.
5. Explain the importance of systems thinking to patient care.

I. Burning platform for change in health care delivery and the need for systems thinking

Physicians have traditionally been trained to care for one patient at a time in the office or hospital, making diagnostic and therapeutic decisions and working with supporting personnel when necessary. As politics, business, and health systems have increasingly encroached on prerogatives over the last few decades, many physicians are ill-equipped to venture outside of this traditional physician-based model. The belief that physicians are either unable to participate in or uninterested in systems and in understanding the multiple and complex factors and determinants of health that impact care has become a self-fulfilling prophecy. This means change in health care is often led by managers, accountants, and policymakers who are skilled in understanding the financial implications of potential change but may not be well versed in understanding person-centered care, the biopsychosocial model of care that occurs with individual patients, or the system in which this care is delivered.[1] It is imperative for systems and physicians to engage in a more holistic view of health care delivery and the change process. Practicing in an increasingly limited box of diagnosis and treatment is not enough. Physicians need to be collaborators and leaders in a system transformation that is already well underway.[2] They need new learning capabilities to optimize the health of patients and to thrive in an increasingly complex, interdependent, and changing world. Systems thinking is the critical ingredient in this transformational process.

II. Systems thinking in health care

Systems thinking is a holistic approach to understanding a system's component parts, and the interrelatedness of these parts, to better understand how a system works and evolves over time.[3,4] This competency and mindset has been recommended by educators and systems leaders alike to be increasingly developed in both current-day and future physicians. As a result, the past several years have witnessed an increase in graduate medical education with the systems-based practice competency domain and in undergraduate medical education with the focus on health systems science competencies (the component parts of patient care and health systems), and the ability to integrate these component parts in the decision-making and thinking process.[5-10]

A. Linear and systems thinking

In general, there are two different types of thinking: linear thinking and systems thinking. Linear thinking approaches problems in a logical, sequential manner. If there is a challenge, one must identify the issue and implement a solution to obtain an end result. Systems thinking, however, takes a more holistic and cohesive approach to challenges and visualizes the seen and unseen drivers, connections, and consequences of interactions at play in any given situation.[10,11] One must examine the system as a whole while simultaneously understanding the component parts in order to understand and influence a system. To provide patient-centered care, physicians and other health care professionals must take into account all the systems around the patient and how they interact with each other. For example, a patient's health is not only determined by the treatment prescribed. It is also determined by the support and resources available in the home, community, and workplace.[12] Therefore a physician or other health care professional must consider the patient's system and address the social determinants of health to understand the environments in which people are born, live, learn, and work that can affect a wide range of health, functioning, and quality-of-life outcomes and risks. Furthermore, a patient's interaction with a physician or other health care professional is only a fraction of his or her interaction with the larger health care system; therefore a provider must consider and evaluate those interactions and be ready to call for change if the system is not optimized for ideal patient care.

This approach may be counterintuitive to human beings, especially as physicians and other health care professionals were trained in a paradigm that seeks to break issues down into component parts so that they can be fixed or at least understood. In this reductionist approach, physicians and other health care professionals may come to believe that understanding each part allows an understanding of the larger system. However, this approach may fail to allow physicians and other health care professionals to see the behavior of the system as a whole for two main reasons. First, in the process of deconstructing the system into component parts, the cohesion and functional aspects of that system are lost—the connectedness disappears in the process of analysis. Second, the system itself may manifest behaviors or characteristics that do not reflect behaviors

of any one individual component. This therefore prevents the study of a system by only examining the constituent parts.[13] Balanced with more traditional linear and analytic thinking, systems thinking provides the necessary insights during an individual's or team's approach to patient or systems issues to achieve better outcomes.

III. Health care delivery as complex adaptive challenges

The US health care delivery system involves numerous structures and processes that seek to align and achieve high-quality patient outcomes. Health systems, though, are complicated, nuanced, and complex. They rarely lend themselves to analysis, assessment, or improvement through simple means. Health care involves a complex web of interdependent and interrelated parts that influence each other on a constant basis, creating a larger system that is continually in flux and dynamic, rather than static. Managed care required physicians to think more broadly about a patient's care, the environment, and the neighborhood in which the patient lived. Fast-forward to today, and the gaps in current medical education programs are increasingly clearer.

For authentic and sustained change in health care, patients and systems alike need physicians and other health care professionals with the knowledge, skills, and systems thinking mindset to initiate, contribute to, and facilitate change—at both the patient and the system levels. Complex adaptive challenges by their nature require systems thinking skills and mindset to approach and make change. Systems thinking is a key skill and foundational educational process that is critical to agency and making a difference; to make a difference requires a more complete, nonlinear, and nonreductive perspective. Systems thinking provides a set of tools and skills, in addition to a mindset and perspective, that allows one to think about, operate in, and improve the system.

IV. The habits of a systems thinker

The Waters Foundation identified and developed a library of "Habits of a Systems Thinker" (Fig. 2.1) and tools (see Figs. 2.2 and 2.4) that are used in multiple international settings, especially education. The habits and tools allow individuals and teams to examine systems and thinking processes. The following sections summarize each "habit" and provide a clinical example of its application to health care.



• **FIG. 2.1** The Habits of a Systems Thinker. *Source:* (Reprinted with permission from the Waters Center for Systems Thinking, Pittsburgh, PA.)

A. Habit 1: Seeks to understand the big picture

HABIT 1

Seeks to Understand the Big Picture



The core of systems thinking is the desire and ability to see situations using a holistic lens. Human nature (and often health professions training) tends to encourage a focus on the details of the immediate situation at hand. Systems thinkers fundamentally seek to understand the big picture as they address the situation's specifics. To do this, systems thinkers consider previous events or factors that may have influenced or contributed to the present situation as well as possible results (i.e., downstream effects) of present actions. Systems thinkers also pause to consider factors somewhat removed from the situation that may have bearing on what is occurring in the present. They maintain balance between the big picture and important details. Physicians and other health care professionals work in fast-paced environments and are trained to use their expertise to apply the ideal interventions (tests, procedures, treatments) to diagnose disease, cure illness, and minimize suffering for the patient immediately in front of them. An inability to see the big picture may lead to unintended negative consequences for the patients in their care.

Example

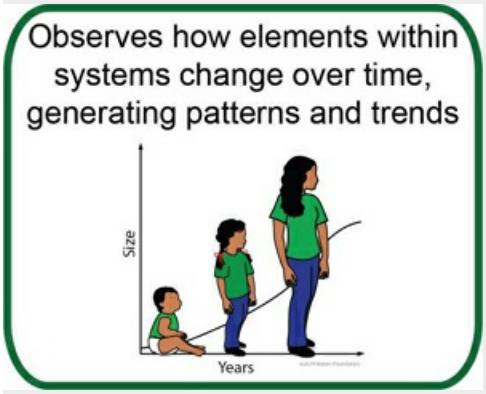
Consider the case of a 44-year-old male patient seen by his physician for uncontrolled chronic asthma. The physician has been well trained, adeptly classifies the man's asthma, and prescribes the appropriate daily control medication. She reviews his use of medications and ways to prevent exposure to his asthma triggers. She does this with compassion and caring, bringing the best asthma care to his situation. In her busy clinic day, she does not think to ask whether he has concerns regarding his ability to pay for his medications and does not anticipate that the treatment she has prescribed may not be started because he cannot afford the medication's cost. Upon discharge from the clinic, the patient goes to the pharmacy to learn that the prescribed medication is too costly for him to purchase. Without his medications, several weeks later he has an asthma exacerbation and is admitted to the hospital for acute care. The physician's inability to see the big picture may also result in missed opportunities to improve the care for future similar patients. Even after the visit is completed, a systems thinker may take a moment to recognize that adding a routine question soliciting patient concerns for medication costs may help identify opportunities for her to prescribe a reasonable lower-cost alternative.

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B. Habit 2: Observes how elements within systems change over time, generating patterns and trends

HABIT 2

Observes How Elements Within Systems Change Over Time, Generating Patterns and Trends



Systems thinkers observe how components of a system change over time and are able to see patterns and trends as they emerge. Systems thinkers consider the important elements that change in the system and how they have changed over time. They observe how quickly or slowly the important elements increase or decrease, and they derive the patterns or trends that emerge over time. Systems thinkers use this habit to move beyond the here and now and see the system as dynamic and changing over time. Health systems and the sequence of events in caring for patients are constantly changing, and while changes are ideally made to improve the quality of care, their cumulative impact can have negative effects on patients and on the health care team. Without this habit, health care professionals miss opportunities to improve patient care and the wellness of their colleagues.

Example

Consider a busy pediatric clinic in a community-based setting. Over several years, patient complaints regarding wait times have increased, and the nurse practitioners and pediatricians comment to each other about increasing burnout given upset families who complain about the length of time they spend in the clinic. The health care professionals want to provide optimal care in a timely manner, and the families' frustrations add to their long work days. The clinic director feels the care team has not changed their approach in working as hard as they can to provide best care in a timely way and is unable to consider how the system may have changed over time to contribute to increased patient wait times. If he reflected on how the steps of checking patients in have changed in the preceding 18 months, he would further uncover the new questions that are being asked as a requirement at the reception desk, additional questionnaires that are required for patients to complete before they are roomed, and three new screening questions that are now asked by a nursing assistant once the patient is roomed. These data would create a better appreciation for how the changing

system has resulted in unintended negative consequences (patient and health care professional dissatisfaction). He would also be more likely to see concrete opportunities for changing the system, such as allowing patients to complete questionnaires prior to arriving for appointments, to improve care.

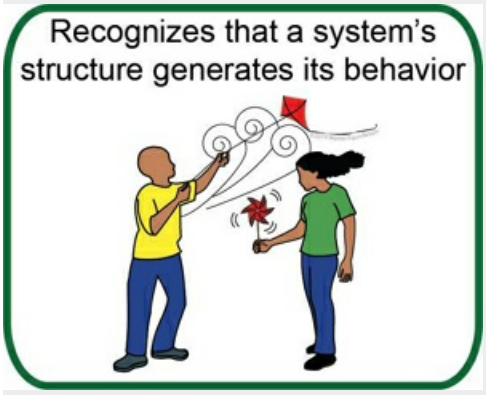
Systems thinkers identify important trends to which they need to pay attention to help them achieve their goals and desired outcomes. In this example, the clinic director needs to notice the trend in increasing paperwork and information collection from patients, which is contributing to the lengthy visits and patients' frustration. Recognizing those changes over time would allow him to address the concerns and be proactive about anticipating future changes.

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C. Habit 3: Recognizes that a system's structure generates its behavior

HABIT 3

Recognizes That a System's Structure Generates Its Behavior



A systems thinker focuses on system structure and avoids blaming individuals when things go wrong. As Paul Batalden has stated, "Every process (system) is designed to perfectly achieve the results it gets."[15] Systems thinkers observe how the parts of the system affect one another and how the organization and the interaction of the parts influence the outputs or outcomes of the system. When things go wrong, systems thinkers reflect on how the existing system, the interaction of its parts, or both have contributed to the poor outcome. They focus on internal causes rather than dwelling on external blame. In years past, medical errors have often been attributed to the mistakes of individual health care professionals. Health care systems are complex systems, and without systems thinking, health care professionals and leaders cannot see how a system's structure can be the reason for errors or put patients at risk for safety events.

Example

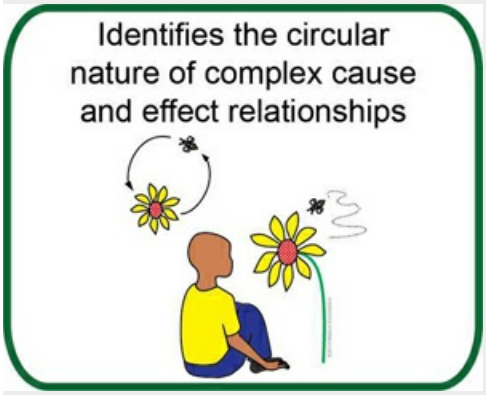
Electronic health records (EHR) have been widely adopted in medical practice. They are made up of the electronic patient chart, including laboratory and imaging results, and typically include computerized provider order entry and many safety and best practice alerts. While in theory such an electronic and comprehensive system should create user-friendly comprehensive access to patients' information and increase patient safety, the system has also created unanticipated negative consequences that can potentially increase the risks to patients. The EHR has led to a decrease in medication errors and improved guideline adherence; however, due to some design issues, it sometimes creates a mismatch between user and clinical workflow, leading to work disruption and provider dissatisfaction and burnout.[16] In addition, the excessive number of alerts lead to "alert fatigue," and physicians and other health care professionals may begin to ignore the alerts and compromise patient care.[17] The EHR is an example of a system in which structure influences the behaviors of the person using it. As systems thinkers, physicians and other health care professionals should reflect on how the system is influencing their behavior and challenge themselves to contribute to creating better systems for optimal patient care. They can envision the desired system behavior and help create the structures that will produce the desired outcomes.

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D. Habit 4: Identifies the circular nature of complex cause and effect relationships

HABIT 4

Identifies the Circular Nature of Complex Cause and Effect Relationships



A systems thinker sees the interdependencies in a system and uncovers circular causal connections or feedback loops. Complex cause and effect relationships are often circular, and the effect comes back around and impacts the cause. Systems thinkers observe how the parts affect one another and determine where the feedback loops emerge. They study the feedback loops to determine if one loop is more influential over time than another. Systems thinkers use causal loops as a visual tool to represent

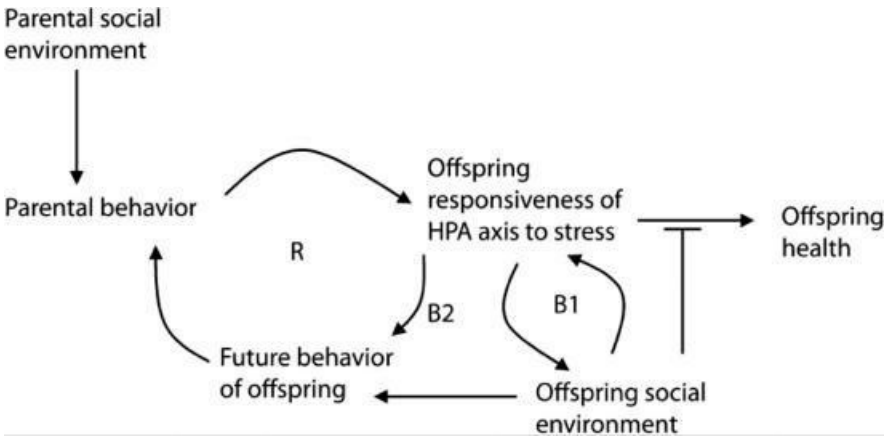
complex cause and effect relationships. Causal loop diagrams can be utilized in health care to understand cause and effect and improve patient and population outcomes. The diagram consists of the variables, the causal loops, and the identification of the loop as either reinforcing or balancing. By representing a problem or issue from a causal perspective, the structural forces that produce the behavior can be more easily explored. The diagrams can be used for a variety of purposes, including designing and building an intervention, interpreting research findings that are conflicting, or building new theories.

Example

Individuals respond to stress differently, and these differences may interact with stress-generating social exposures over time to affect many health outcomes, such as diabetes and hypertension. The impact later in life of early-life exposure and stress responsiveness demonstrates that parental behavior can modify the long-term responsiveness of offspring through mechanisms involving epigenetic modifications of the glucocorticoid receptor gene.[18,19] Greater stress responsiveness could also promote the selection into environments that tend to reduce stress, creating a balancing feedback loop. Additionally, stress responsiveness and parental behavior affect the behavior of the offspring toward their own offspring as well as their stress responsiveness. A causal loop diagram showing the long-term effects and transgenerational transmission of early life experiences (Fig. 2.2) can help better capture the dynamic processes that shape these effects over time by illustrating the interconnections between all the variables.[20]

The health of individuals and populations is a manifestation of a system, which depends on biology, individuals' interactions with each other, and individuals' interactions with their environment over time. A systems approach and identifying the processes that operate at the level of the individuals and populations and their interconnections can help develop theories in population health, including the problem in health disparities.[20]

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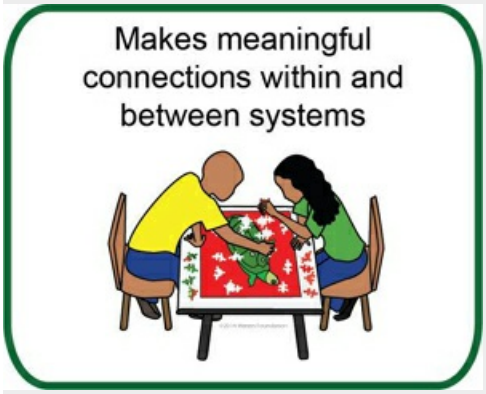


• **FIG. 2.2** Causal loop diagram showing the long-term effects and transgenerational transmission of early life experience. *B,* Balancing; *HPA,* hypothalamic-pituitary-adrenal; *R,* reinforcing. *Source:* (Used with permission from Diez Roux AV. Complex systems thinking and current impasses in health disparities research. *Am J Public Health.* 2011;101[9]:1627-1634.)

E. Habit 5: Makes meaningful connections within and between systems

HABIT 5

Makes Meaningful Connections Within and Between Systems



A systems thinker sees how concepts, facts, and ideas link together, which can lead to new learning, discoveries, and innovations. Systems thinkers study the relationships among pieces of the system and how they affect understanding of the whole. They consider how the different perspectives of a system work together to benefit the system, and they appreciate how the understanding of one system transfers to the understanding of another system.

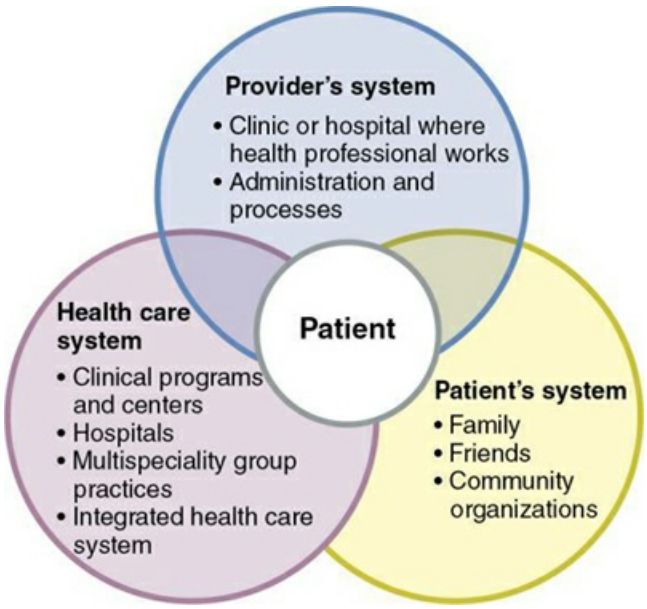
Example

Dr. G. runs a medicine inpatient service in a large hospital system. He is often pressured to discharge patients as soon as safely possible because of a shortage of beds and patients experiencing long waits in the emergency department. Dr. G. is frustrated

because he typically rounds on the patients to be discharged first thing in the morning and writes their discharge orders. He does not understand why some of those patients do not physically leave the floor until the evening. To address this issue, Dr. G. needs to consider all the pieces of his system and the interactions with the other systems that are affecting the outcome (Fig. 2.3). Currently, he is only focused on his piece of seeing the patient and writing the discharge order. First, he needs to consider the rest of his system, such as the clerk processing the discharge order and the nurse's timing of the discharge instructions, and how it is affecting the discharge time. He also needs to consider the interaction of the patient with the larger health care system, such as securing the medications from the pharmacy prior to discharge or arranging for a home visiting nurse. Dr. G. also needs to think about how the patient's own system is affecting the time of the discharge. For example, is a family member available to pick up the patient when he or she is ready to leave? Dr. G. needs to consider all these variables and how they are linked to the patient being able to physically leave the floor to develop a more efficient discharge process. He might also want to consider reviewing the operations of another unit that has proven to be efficient with discharges. It may be possible to transfer that unit's practices to his own unit.

Increasing efficiency and quality improvement in complex hospital systems require the ability to make connections and transfer information to enhance understanding of the system and the ability of physicians and other health care professionals to work and learn within that system.

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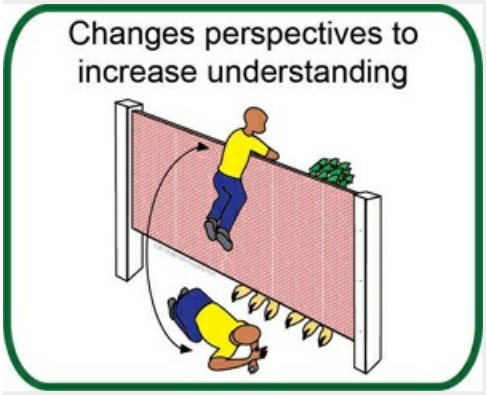


• **FIG. 2.3** Intersection of the Different Systems in Health Care.

F. Habit 6: Changes perspectives to increase understanding

HABIT 6

Changes Perspectives to Increase Understanding



A systems thinker increases understanding by changing the ways he or she looks at the system. Individuals see the world from their own perspective reflecting their personal point of view shaped by their personal experiences and values. While an individual's perception is his or her reality, the more perspectives that are considered, the closer physicians and other health care professionals get to a shared or actual reality. In order to increase understanding by changing perspective, one must be willing to seek, take, and coordinate the perspectives of others. The medical profession operates at a very fast pace, and physicians and other health care professionals see the system through their own lens. If they do not step back and take in the perspectives of others, suboptimal care results.

Example

Consider the case of a patient who has just had major surgery and is ready to be discharged home because he has met all the criteria to be discharged from the physician's perspective. However, this patient is recently divorced and his grown children do not live in town, so he has no assistance at home. Medically, it may be safe to discharge him, but he needs assistance for postoperative care, meal preparation, transportation, and other activities of daily living. In this case, in order to provide optimal care the physician needs to be willing to:

- Seek the patient's perspective
- Take the patient's perspective into consideration
- Coordinate the patient's perspective into the care plan

Physicians work in large teams. The patient is a part of the team, and it is very important take all perspectives into consideration in order to better understand the system and be willing to change practice based on those perspectives.

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G. Habit 7: Surfaces and tests assumptions

HABIT 7

Surfaces and Tests Assumptions



A systems thinker tests theories and surfaces assumptions, perhaps with others, in order to improve performance. Physicians and other health care professionals make assumptions every day. These assumptions are based on experiences, and they can be very helpful in assisting physicians and other health care professionals to understand the world around them. Occasionally, these assumptions can hinder the understanding of reality, so it becomes very important to surface and test these assumptions in order to improve performance. This becomes especially important in the current complex health care system so physicians and other health care professionals do not jump to the wrong conclusions. Clinicians are under a lot of pressure to act now, rather than spend time reasoning things out with others on the team and thinking about the facts. Clinicians need to make sure actions and decisions are founded on reality. Likewise, when physicians and other health care professionals accept or reject other people's conclusions, they need be confident that their reasoning is based on facts. This can be achieved by understanding the Ladder of Inference theory (Fig 2.4E). People perceive reality and facts based on their beliefs, which lead them to make assumptions and take actions based on those assumptions.

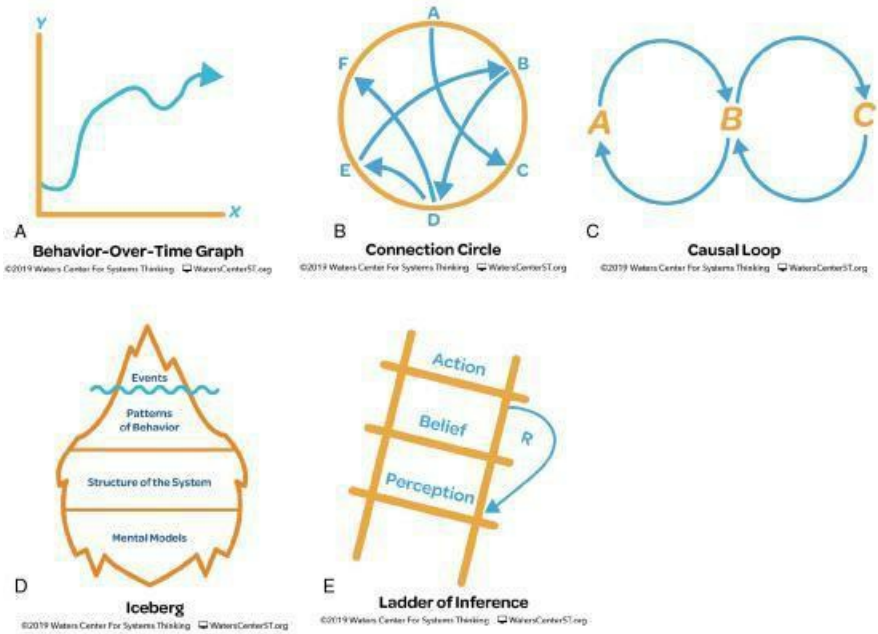
Example

Consider the case of a clinic where patients often show up late to appointments. The physician who recently came from a different health care system became very frustrated with those patients and set a 20-minute late show rule. If patients were more than 20 minutes late, he would not see them. In his previous private practice, this rule decreased the no-show rate significantly. In this new practice, this rule did not seem to help as much. The physician then learned from his team that between the hours of 1 and 3 pm every day, it can take over an hour for his patients to find a parking spot in the congested hospital lot, so he asked his clerical staff to inform patients of the

problem with the parking at that time. This helped his patients plan better, and his clinic ran more efficiently and on time.

This is a simple example of how previous beliefs and assumptions make individuals take actions that can compound the problem instead of solving it. It was important for the physician in this case to consider whether his assumptions about his patients and his new system were similar to what he experienced previously before applying the same solution to the same problem in a different environment. A systems thinker will rigorously examine assumptions in order to gain insight into a system. Insight put into action can lead to improved performance. The Ladder of Inference is a visual tool that helps people consider how and why assumptions are made, how one's experiences develop one's beliefs, and how actions are taken based on perceived data. This will help them examine carefully how their theory or model matches the current system under study and ask questions.

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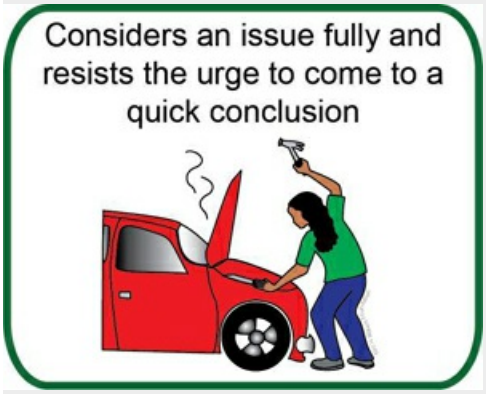


• **FIG. 2.4** Tools of Systems Thinking. (A) Tool 1—Behavior-Over-Time Graph. (B) Tool 2—Connection Circle. (C) Tool 3—Causal Loop. (D) Tool 4—Iceberg. (E) Tool 5—Ladder of Inference. *R,* Reinforcing. *Source:* (Reprinted with permission from the Waters Center for Systems Thinking, Pittsburgh, PA.)

H. Habit 8: Considers an issue fully and resists the urge to come to a quick conclusion

HABIT 8

Considers an Issue Fully and Resists the Urge to Come to a Quick Conclusion



A systems thinker takes the necessary time to understand the dynamics of a system before taking action. In the fast modern world, people can often be under pressure to devise quick fixes to the problems encountered. Quick fixes in a complex system might work in the short term, but they can have unintended and undesired consequences in the long term. Taking a systems view helps one see the impact of an action on all the parts, short and long term, as well as helping one recognize the impact of feedback and time delays in implementing a solution. Visual representation of the components of the system and their relationship to one another can help one understand cause and effect of different actions on the entire system. More importantly, building these diagrams can help the team come together and reach important insights, which can contribute to reaching robust solutions.

Example

Consider the case of a hospital that has been experiencing significant operating room delays. While cases are scheduled from 7 am to 5 pm every day, the majority of the operating rooms have been running until 8 pm. This has been costly to the system because it requires a lot of staff overtime and causes patient dissatisfaction with the delays. In trying to solve this problem, one can quickly jump to conclusions and assume the surgeons are scheduling less time than they actually need and request that all surgeons schedule more time for their procedures. While this might look like an attractive short-term solution, one has to consider all the unintended consequences of this decision. Importantly, it is critical to consider the issue fully and address all the components that can be contributing to this problem. Operating room delays can be due to many issues in the system, including surgeon delay, operating room turnover, and postanesthesia care unit (PACU) overflow. These all in turn can be due to lack of available hospital beds. Each of these causes will require a different solution. It is crucial to look at the entire system before making assumptions, reaching quick conclusions, and implementing solutions that will not fix the problem. If the problem of significant operating room delays was due to PACU overflow resulting from a lack of hospital beds that in turn was resulting from delayed discharges, extending the surgeons' procedure time will not fix the problem, and it will lead to fewer procedures per day, increased costs to the system, and longer wait times for patients. The solution

should be focused on more timely discharges.

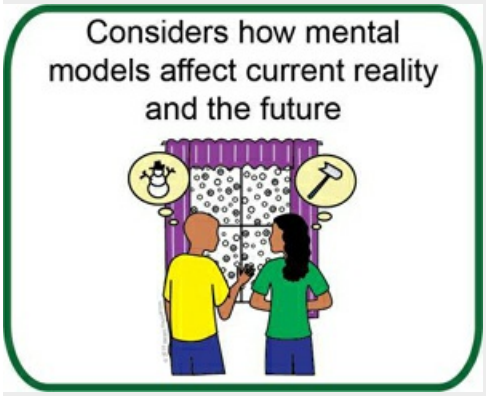
A systems thinker is patient and will take time to understand the system's structure, connections, and behaviors before recommending and implementing a solution. A systems thinker also understands that a quick solution can create more problems in the long term and is able to balance the tension created when a solution is not immediately implemented with the importance of a deeper understanding of the system so the right long-term solution can be developed.

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I. Habit 9: Considers how mental models affect current reality and the future

HABIT 9

Considers How Mental Models Affect Current Reality and the Future



A systems thinker is aware of how beliefs and attitudes influence perspectives and actions. In any given situation, an individual perceives and interprets what is happening, thus creating a picture, or mental model, of some aspect of the world. A systems thinker is aware of how these mental models influence perspectives and, ultimately, actions taken. In today's rapidly changing and complex health care environment, where interprofessional collaborations are more important than ever, shared mental models are a critical component of effective teamwork. Team members must be able to have a shared understanding of their tasks and roles and must be able to communicate and understand each other's and patients' perspectives through shared mental models.

Example

Consider the case of TJ, a 32-year-old woman with metastatic cervical cancer. Her care team involves the gynecologic oncologist, an oncology nurse practitioner, and a social worker. TJ expresses to the team that she does not desire to know much information about her diagnosis or prognosis. She also does not want her mother to know about her prognosis because her mother has heart problems and TJ does not want her mother to

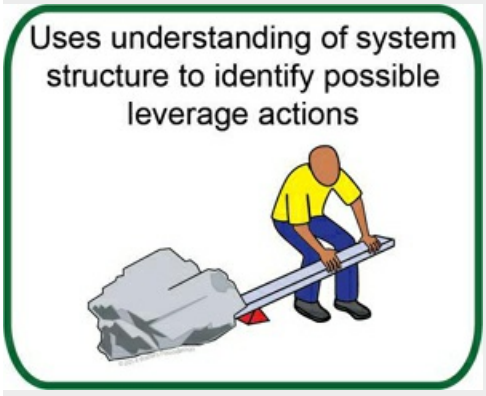
worry. This information is communicated among the team and marked in a note in the EHR. The entire team has a shared mental model about the patient's desires. As TJ's disease progresses, she is admitted to the hospital for kidney failure. The attending on the service is not aware of TJ's desires and shares the prognosis with her in the presence of her mother while recommending hospice care. The attending assumes this is the right place and time to share this information because the patient has support present. In this case, the attending is making assumptions based on her own beliefs. She does not share the same mental model as the rest of the team, and the communication occurs in an undesired manner. A systems thinker would have had a shared understanding of her role and would have communicated with the primary health care team to make sure everyone was on the same page. A systems thinker would be aware that changing a mental model about an issue would change current actions and future results. The Iceberg (see Fig. 2.4D) illustrates how mental models influence the creation of structures (e.g., policies, laws, and physical structures). The mental models are at the base, as an underpinning to the structures that individuals create. These structures then generate patterns of change over time as well as the discrete events that occur.

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J. Habit 10: Uses understanding of system structure to identify possible leverage actions

HABIT 10

Uses Understanding of System Structure to Identify Possible Leverage Actions



A systems thinker uses system understanding to determine what small actions will most likely produce desirable results. Based on an understanding of the structure, interdependencies, and feedback within a system, a systems thinker implements the leverage action that seems most likely to produce desirable outcomes.

Example

Consider Dr. H., a primary care physician who is very interested in improving blood sugar control in his patient population. He had set up ways for his patients to send their blood sugar results regularly either by phone, fax, or secure e-mail to his nurse. His nurse then enters those numbers in the EHR and notifies Dr. H. with a note so he can review the patients' results and decide whether any changes are needed to their insulin regimens. If a change is needed, he sends his nurse a note with the new recommendation. The nurse then contacts the patient to notify him or her of the change. Dr. H. notes one day that the EHR is becoming much more sophisticated. He then approaches his health technology staff and inquires if it is possible to create a form that will be accessible to patients through the patient portal so they can enter their blood sugars directly themselves. Then he would receive notification and would be able to review directly and send the patient back a note with any new recommendations. Dr. H. is told this is possible. It takes 3 months to implement this change, and all physicians and other health care professionals who take care of diabetic patients are notified of this system capability. Many start to use it.

In this case, Dr. H., who is a systems thinker, thought of the available system (the EHR) and how he could leverage this system to provide better and more efficient patient care. In a health care system that is so complex with many interdependent components, it is important to identify the actions that can be leveraged to produce long-term desirable results. This is only possible when one understands the system well and uses one's knowledge to identify those actions.

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K. Habit 11: Considers short-term, long-term, and unintended consequences of actions

HABIT 11

Considers Short-Term, Long-Term, and Unintended Consequences of Actions



Systems thinkers look ahead and anticipate not only the immediate results of actions

but also the effects down the road. They think about and evaluate the short- and long-term unintended consequences of their actions that could lead to new actions and then consider the tradeoffs. They take the necessary time to reflect on the consequences of their actions and think about who will be impacted and what possible results, both desirable and undesirable, they will see from the decision. They carefully weigh the price of the short-term pain with the value of the long-term gain.

Example

Dr. M. is a medical oncologist whose practice is part of a large, very busy, multidisciplinary team in the breast care center. He hired a new nurse practitioner, Sarah B., 3 months ago to help with the patient load. Sarah B. is a great team player and has excellent communication skills. Since she joined the practice, she has received multiple accolades from patients and other team members. However, while working with Sarah B., some knowledge deficits have been identified, and she does not follow up on laboratory results in a timely fashion despite multiple reminders from Dr. M. At this point, Dr. M. does not see a future for Sarah B. in the practice because these deficits are compromising patient care and she does not seem to be willing to learn or change. Dr. M. is contemplating letting go of Sarah B. before her 6-month probationary period is up. He also has the opportunity to hire a nurse practitioner who used to work for him at a previous practice. Taking immediate action will relieve him of having to worry about Sarah B.'s performance and allow him to hire a more competent nurse practitioner. As a systems thinker, Dr. M. needs to weigh the consequences of firing Sarah B. versus giving her more time to possibly improve. While the benefits are clear to his practice, he needs to think of the tradeoffs. How is this going to impact the other team members and the patients? Sarah B. is very well liked, and others do not know of the knowledge deficits and follow-up care issues. Are others going to think that he terminated Sarah B.'s employment so he can hire his "friend," the nurse practitioner he knew previously? How is this going to affect others' morale? What if the new nurse practitioner does not get along with the team as well as Sarah B. did? Is the team going to give the new employee the chance to succeed? In order to be prepared for the unintended consequences of his action, Dr. M. needs to consider multiple factors when making that decision. He needs to think about all those who will be impacted by his decision and how the unintended consequences can create new problems that might affect patient care that would then need fixing. He needs to carefully consider if there is a solution, such as developing Sarah B.'s knowledge in areas in which she is deficient, that might take more time to implement but would potentially minimize the risks of unintended consequences.

Health care is complex, and there are many interconnections. When considering taking action to fix a problem, it is important for the physician or other health care professional to consider the bigger picture and broaden the boundaries of what he or she pays attention to so he or she can carefully evaluate the short-term and long-term consequences.

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L. Habit 12: Pays attention to accumulations and their rates of change

HABIT 12

Pays Attention to Accumulations and Their Rates of Change



Systems thinkers pay attention to the elements in the systems that change. They see the quantity of material or information that has built up or diminished over time. They identify what they can measure and assess and how quickly or slowly accumulations increase or decrease. They also evaluate how these accumulations impact other elements in the system and what might happen if an accumulation reaches a tipping point.

Example

Dr. R. recently joined an obstetrics practice that is working toward growth in response to the recent building of a new women's hospital that can accommodate more deliveries. Dr. R. is well liked by her patients and her reputation in the community grows as an excellent physician. She does not put a limit on the number of new obstetrics patients she takes, and her practice grows very quickly. Several months later, her patients begin to complain that they cannot schedule appointments because there are no openings in her schedule. Dr. R. quickly realizes that, when she was accepting a large number of new patients, she did not account for the increasing frequency at which she needs to see her obstetric patients later in their pregnancies. She did not pay attention to the rate of the growth of her practice and how that will affect patient care. In addition, she recently learned that the increasing number of patients in her practice as well as in the practices of the two other obstetricians who were hired at the same time will exceed the number of deliveries the new hospital will be able to accommodate. In this case, neither Dr. R. nor the two other doctors had considered the effect of their growing practices on the number of additional deliveries the new hospital could handle. Systems thinkers pay attention to the rate of growth of their practice while paying attention to how this accumulation will impact other elements of the system—in this case, the ability of the new hospital to handle all the deliveries.

Tracking patterns and trends in health care delivery can help monitor a system and

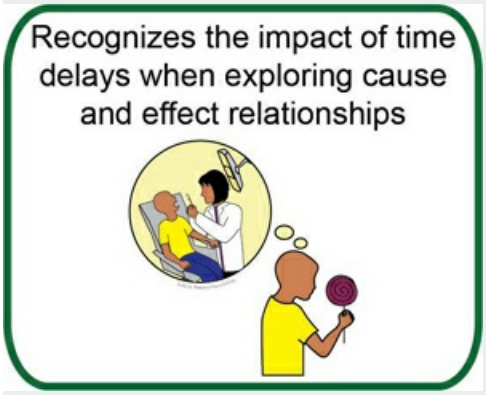
its rate of change. Graphing the actual accumulation over time makes the changes visual and can be helpful in determining the effects of the inflow and outflow on the accumulation. This can be applied to concrete measures such as number of patients served or more abstract measures such as patients' perceptions of the quality of care they receive. This can inform the physician or other health care professional of adjustments needed to provide optimal patient care.

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M. Habit 13: Recognizes the impact of time delays when exploring cause and effect relationships

HABIT 13

Recognizes the Impact of Time Delays When Exploring Cause and Effect Relationships



Systems thinkers understand that cause and effect are frequently not closely related in time. They consider whether the change they are making will show immediate results or will require patience to see the impact. If they need to wait, they consider how long it will take to see desired results once the change is made to the system. They recognize the need to monitor the results, consider the impact of time delays, and make minor adjustments before discarding a potentially valuable idea.

Example

Dr. L. is an orthopedic surgeon whose clinic consistently runs behind despite being staffed by an excellent physician assistant and nurse team. While his patients like him a lot, they frequently complain of the wait times. Long waits are affecting his patients' satisfaction scores. Dr. L. reviews his schedule and recognizes an opportunity to improve patient flow if he changes the schedule template to stagger new and return visits. Even though the new template is stricter on the schedulers, he believes it will better utilize the physician assistant team member's skills. Dr. L. estimates that his patients' satisfaction scores will increase by at least 10% because most of the

dissatisfaction seems to be connected to wait times. Dr. L. implements the change and carefully considers the role of time delays in the effects he expects to see. He takes into account that his schedule is usually full almost 3 months in advance, so the new template will not be fully implemented for several months. He also recognizes that he receives patients' satisfaction scores about 3 months after the patients complete them. Therefore, he will not expect to see the full results of the change he makes to his schedule for at least 6 to 9 months. If Dr. L. did not take into account the time delay in seeing the effect on his scores, after only 1 or 2 months he would assume that his changes did not make a difference and might not continue to adopt them.

Many of the quality improvement projects in health care can have a significant delay before achieving fully desirable effects. This is true whether the change affects the efficiency of the system itself or patient outcomes, especially when considering the effects of particular interventions on chronic disease. It is important to always recognize the impact of time delays when exploring cause and effect relationships.

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N. Habit 14: checks results and changes actions if needed: "successive approximation"

HABIT 14

Checks Results and Changes Actions If Needed: "Successive Approximation"



Systems thinkers establish benchmarks to help assess gradual improvement. They consider the indicators they expect to see as they are looking for progress, and they schedule time to pause and assess the effects of the current plan in order to take necessary actions and adjustments. They embrace change as a process and constantly strive for improvement. They learn from experience and use that experience to improve their actions through a successive approximation process such as a Plan-Do-Study-Act (PDSA) cycle (see Chapter 7).[21]

Example

Dr. A. is an internist who takes care of many obese patients with chronic diseases such as hypertension and diabetes. She consistently counsels her patients on lifestyle modifications without much success. She notices that patients often set ambitious goals. The gap between their current fitness levels and their fitness goals is so wide that if any of their fitness indicators plateau (weight, lower blood pressure, good glycemic control, etc.), they easily get discouraged and do not sustain their efforts. She hires a wellness coach to assist her patients in reaching their goals. Every 3 months, she reviews the fitness indicators for the patients who are receiving coaching, assesses the effectiveness of individual patients' plans, and makes adjustments as necessary in order to achieve desired goals. Dr. A. recognizes the importance of checking results through successive approximation and changing actions as needed.

The PDSA cycle is part of the Institute for Healthcare Improvement (IHI) Model for Improvement. It is a common tool used for quality improvement projects. It helps individuals and teams test a change, see how it works, and make changes as necessary for continuous improvement.

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V. Application of systems thinking to health care

While the examples in the previous section review each of the systems thinking habits in isolation for simplicity, it is important to recognize that a systems thinker will apply multiple habits in most health care scenarios. In this section, we review cases that incorporate several habits and integrate systems thinking tools. These cases allow consideration of how the habits of a systems thinker can help clinicians optimize patient care while considering the systems that could influence the patient's outcomes. In any one case, some habits may be required, used, and used well, or perhaps neglected and not used at all.

Case study 1

Mrs. Wilson is 28 weeks pregnant. She has missed the majority of her prenatal care appointments and has not had any of the recommended laboratory testing. As her physician, you seek to understand the reasons behind her missing visits and testing as you emphasize the importance of prenatal care.

Chapter 1 explains the importance of using concepts and skills from basic, clinical, and health systems science to improve the health of all individual patients and groups of patients. Many clinicians (including trainees) may more readily consider a systems thinking approach when working on quality improvement projects (discussed in Chapter 7) and other initiatives to improve the system or the health of a group of patients. Systems thinking is just as important and relevant when caring for individual patients.

Many well-meaning clinicians might first experience frustration and jump to conclusions regarding potential reasons for Mrs. Wilson's missed appointments. A common first step is to begin by explaining the importance of prenatal visits. However, she may already know these visits are important but may have barriers to following through with scheduled visits and testing despite her best attempts. A systems thinking mindset provides one framework for compassionate clinicians as they work to ensure Mrs. Wilson delivers a healthy term infant and receives care that respects her unique circumstances and challenges. As a systems thinker, you might begin by *surfacing and testing assumptions* (Habit 7). Are you assuming Mrs. Wilson does not know that the visits and labs are important? Simply stating this fact at the beginning of the visit, while factual and appropriate, may close Mrs. Wilson off to sharing specific challenges she faces that you might help her address so she can make her appointments. A clinician in this situation could use the *Ladder of Inference* tool (see Fig. 2.4E), which helps identify how beliefs lead to actions and what individuals choose to notice in the future. This is closely related to the concept of unconscious bias, where minds have evolved to translate past experiences into "fast thinking" that can result in jumping to inaccurate conclusions.

You begin by listening to Mrs. Wilson's story to get to know her and understand how her pregnancy has been progressing thus far from her perspective. This demonstrates *changing your perspective to increase understanding* (Habit 6), and your ability to *consider*

the issues fully and resist the urge to come to a quick conclusion (Habit 8). In doing so, you learn that she has multiple barriers to keeping her appointments (transportation challenges, change in insurance, and inability to miss work).

As a systems thinker, as you continue to gather her history and perform her examination, you explicitly *consider how mental models affect current reality and the future* (Habit 9). In this case, considering both your own mental models and those of Mrs. Wilson might help you more quickly arrive at a plan that integrates your goals for her, her own goals, and her life situation. This habit is especially germane when there are potential cultural differences between the clinician and the patient. Using this habit might help the clinician identify Mrs. Wilson's culturally specific beliefs about pregnancy and the role of the medical system in the health of her baby.

Case study 2

You notice it takes several hours for patients who are admitted to the hospital to be moved from the emergency department (ED) to their hospital-based units. This is causing significant delays and contributing to wait time for other patients who cannot be evaluated because there are not enough open ED beds. You and your team wish to evaluate the cause of the delays.

There are many types of projects teams can design and complete to improve health care; Chapters 6 and 7 explore these topics in detail. Physicians and other health care professionals who use their systems thinking mindset to see and successfully close system gaps in care not only impact the individual patients they directly care for, but also improve the care of future patients and multiply their impact. Many habits of a systems thinker are routinely employed in health care improvement efforts.

In this example, each role on the ED clinical microsystem team (physicians, nurses, desk staff, etc.) sees the patients' movement through the ED from a different perspective. The collective perspective of all roles is needed on the quality improvement team as each member *seeks to understand the big picture* (Habit 1). The team members fully consider each step a patient experiences in his or her journey from the first step (checking in at the ED front desk) to the final step (being discharged from the ED or being successfully transferred to a hospital-based unit). Because the team *makes meaningful connections within and between systems* (Habit 5), it recognizes that there are likely factors affecting the ability of hospital-based units to be ready to receive patients when the ED is ready to send them. This, then, requires the involvement of both microsystems (the ED and the inpatient medicine team) at the mesosystem level in order to step back and consider all of the potential points at which delays can occur and why they occur.

Successful quality improvement teams identify a specific goal (in this case, perhaps the number of minutes waiting from when ED staff members are ready to send a patient to a hospital unit to the time the patient actually moves to the unit) to be sure the interventions they try actually result in the desired change. In this case, the team measures the average wait time for each shift over 1 week at the beginning of the project. Stated another way, the team members *pay attention to accumulations* (here, wait time) *and their rates of change* (Habit 12) as they implement the changes they design.

How will they know what changes to make to ensure they see a decrease in the wait

time when transferring patients? The team members must *use their understanding of system structure to identify possible leverage actions* (Habit 10). This means they use their map or outline of the patient steps (from ED check-in to arrival at the hospital unit) to consider where the wait time is greatest. They *observe how elements within systems change over time, generating patterns and trends* (Habit 2). They *change perspectives to increase understanding* (Habit 6) by talking with members of the ED and hospital unit teams to learn which factors likely play the largest role in wait times (such as short staffing on the hospital units overnight, patient transfers occurring at the same time as a nursing change of shift, or slow hospital unit patient discharges to home, limiting available hospital unit beds). Once they develop and implement their changes (perhaps streamlining the steps needed to transfer patients, changing staffing, and anticipating ways to minimize transfers at times of change of shift), this effective quality improvement team *checks results and changes actions if needed: "successive approximation"* (Habit 14). The team members will remeasure the average daily transfer wait times over a week and learn whether they achieved their desired improvements.

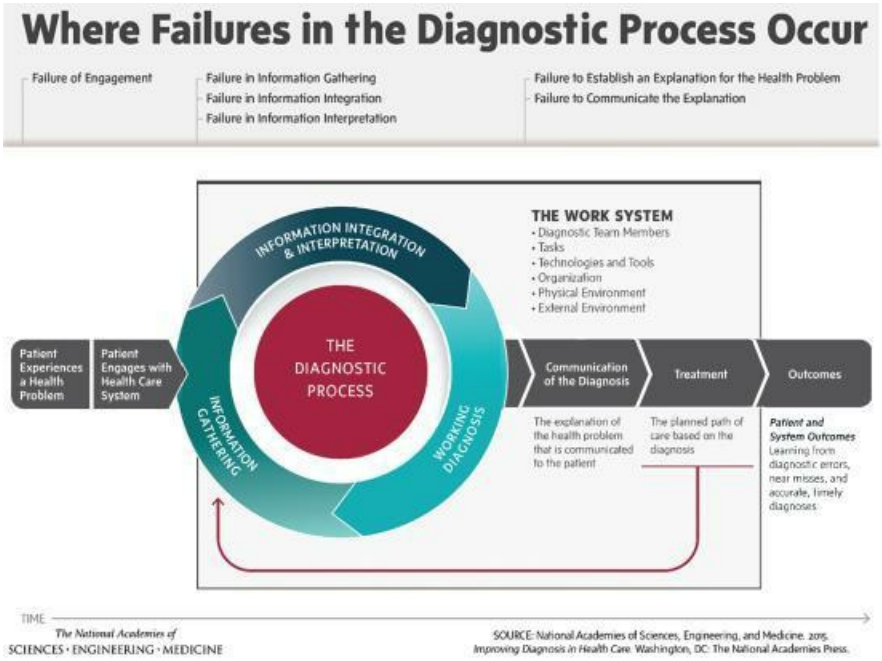
The importance of a systems thinking mindset for all quality improvement team members cannot be understated. While many physicians and other health care professionals have early ideas for what will be most effective in improving the care of patients (in this case, decreasing time to transfer from the ED to a hospital unit), well-meaning professionals will experience frustration and not succeed unless they have the necessary roles on their team, a rigorous approach to understanding the current system, specific measurement to know if desired change has occurred, and multiple iterations of improvement until desired change is seen.

Run charts (discussed in Chapter 7) are one type of Behavior-Over-Time graph (see Fig. 2.4A) critical to measuring success or failure. This quality improvement team would plot dates or other time points along the x-axis and average transfer wait time on the y-axis as a data display to help the team see progress over time.

Case study 3

As an intern, you are involved in the care of a 35-year-old woman seen in the ED for fatigue and indigestion. After a complete history and physical examination, laboratory results show a normal complete blood count and chemistry panel. She is diagnosed with gastroesophageal reflux and insufficient sleep and discharged to home. The patient returns 8 hours later for worsening symptoms. This time another attending physician recognizes the possibility of heart attack and correctly makes this diagnosis. He mentions two other female patients with recent missed heart attacks and suggests your involvement in a planned review of the cases to identify and suggest potential systems issues that can be leveraged to prevent future missed diagnoses. The team convenes to analyze these three cases using a systems lens.

Diagnostic errors (missed diagnoses because of either delay in diagnosis or making an incorrect diagnosis) can occur when clinicians fail to elicit a key part of the history or physical examination required to make an accurate diagnosis, or when they have underdeveloped diagnostic and critical thinking skills. However, there are increasing efforts to conceptualize diagnostic errors more broadly as systems errors (Fig. 2.5).[14] A missed or wrong diagnosis can be caused by one or more systems issues.



• **FIG. 2.5** National Academy of Medicine Representation of Diagnostic Error Process. *Source:* (Reprinted with permission from Balogh E, Miller BT, Ball J, eds; Institute of Medicine; Board on Health Care Services; Committee on Diagnostic Error in Health Care. *Improving Diagnosis in Health Care*. Washington, DC: The National Academies Press; 2015.)

There is a necessary balance when considering diagnostic errors that needs to be identified between the system driving diagnostic errors and the human operators making decisions within the system. Certainly, individual decision making and one's reflection in and on action skills must be considered in all situations involving a diagnostic error. Similarly, one must never assume or punitively attribute the sole contributor to a diagnostic error as the individual involved. The work system and context are at the core of many unsafe events or errors, and if the human operator was performing the same task in a different system, the result may have been different.

As part of their analysis, the team looks at visit notes for each of the three cases, with the goal of determining whether they can identify obvious omissions in the history gathering, the reported physical examinations, the studies (labs, radiographic studies, specialty consultations), or a combination of these, used to make the initial diagnoses during prior presentations. Before their work begins, the team members decide to approach the case review using a systems thinking lens. First, they agree to *surface and test their own assumptions* (Habit 7), specifically that they do not make assumptions about the physician's decisions in a case without understanding the context. Because they are retrospectively looking at a known error, the team proceeds using an important systems thinking habit: they *consider the error fully and resist the urge to come to a quick conclusion* (Habit 8). After carefully considering the individual patient-physician interaction details, they do not find an obvious reason for the missed diagnosis other than perhaps failure to consider myocardial infarction as a possible diagnosis. They decide to use a *Ladder of Inference* (see Fig. 2.4E) tool to further analyze the physicians' thinking and look for any relevant assumptions. They use another systems thinking

habit: *considering how mental models affect current reality and the future* (Habit 9). They recognize that all three cases of missed myocardial infarction involved female patients. After discussing the cases further with the original physicians who evaluated each patient, they recognize that the patients' gender (in some cases, age and gender) triggered implicit assumptions by each clinician that myocardial infarction was not a potential diagnosis to be considered.

The team then steps back to analyze the three cases using a microsystem lens. Using the systems model of diagnostic errors of the National Academy of Medicine, it lists the steps leading up to and following the physician-patient encounter that could have impacted diagnostic accuracy. The team members use another systems thinking habit as they *recognize that a system's structure generates its behavior* (Habit 3). They remember that the ED does have a protocol in place at the admissions desk that triggers evaluation for myocardial infarction based on presenting age and symptoms but recognize that all three patients did not meet criteria for the protocol, which includes only male patients if age is less than 65 years. They also recognize that in two cases the patients were being evaluated during change of shift, and the patients experienced a transition from one physician to another early in their evaluation. The team *considers again how mental models affect current reality and the future* (Habit 9) when it recognizes that the physician receiving the handover may have accepted an abbreviated list of diagnostic possibilities from her or his colleague without probing more deeply or taking an independent history.

Following these and other steps in the analysis of these three cases, the team *uses its understanding of system structure to identify possible leverage actions* (Habit 10) to prevent similar diagnostic errors. The team members create an intervention team with stakeholders from the microsystem (ED nurses, electrocardiogram technicians, physicians) to revise the protocol to include a broader patient age range and list of presenting complaints based on the cases and their review of the literature. They *consider the short-term, long-term, and unintended consequences of their actions* (Habit 11), such as delays in care for other ED patients from an anticipated increase in patients requiring additional evaluation. They track the patients in their health system diagnosed with heart attack to look for other cases of missed diagnosis of heart attack in the ED. They work with the practice to track patient wait times with other measures to ensure there are no unintended negative consequences from the new protocol.

In short, this example highlights the need to use both analytic and systems thinking when providing care and seeking to improve the care delivery process after less-than-ideal outcomes occur.

VI. Chapter summary

Medical education is well along its journey of embracing the three pillars of medical education: basic science, clinical science, and health systems science. Certainly, the skills and knowledge in health systems science must move beyond the classroom and formal education and become part of the fabric of current health care systems and care delivery. Systems thinking is an essential component of a health care professional's mindset and skill set. In a world of health care that is by definition complex, involving people and associated relationships and interconnections, important and meaningful change is not possible without this kind of mindset and approach to thinking.

Questions for further thought

1. What is systems thinking?
2. What is the importance of being a systems thinker?
3. How do I use systems thinking tools?
4. How do I know whether I am a systems thinker?

Annotated bibliography

Gonzalo JD, Ahluwalia A, Hamilton M, Wolf H, Wolpaw DR, Thompson BM. *Aligning education with health care transformation* identifying a shared mental model of "new" faculty competencies for academic faculty Acad Med 2, 2018;93: 256-264.

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Senge PM. The Fifth Discipline The Art and Practice of the Learning Organization Rev. and updated ed 2006; Doubleday/Currency New York.

This pivotal book by Peter Senge provides a road map for organizations to become learning organizations. In the book, five disciplines necessary for learning organizations are described, including systems thinking, personal mastery, mental models, shared vision, and team learning. The description of systems thinking informs understanding of this philosophy, skills for health care, and the context of this health systems science book.

Sweeney LB, Meadows D. The Systems Thinking Playbook Exercises to Stretch and Build Learning and Systems Thinking Capabilities 2010; Chelsea Green Publishing White River Junction, VT.

The Systems Thinking Playbook *provides a myriad of short gaming exercises that can be used by educators within classroom settings or workshops to demonstrate the core principles of systems thinking. These are classified by the areas of learning including systems thinking, mental models, team learning, shared vision, and personal mastery. The book has a companion DVD, which provides authentic examples of the authors introducing and facilitating the games.*

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The health care delivery system

Stephanie R. Starr, MD, Robert E. Nesse, MD

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In this chapter

The US health care system is not currently designed to center on outcomes from patients' perspectives nor align incentives to achieve the Institute for Healthcare Improvement's Triple Aim. All health care professionals must have a basic understanding of this dynamic and complex delivery system, including the desired outcomes for health care delivery, the forces for system change (specifically, accountable care and value-based payment reform), and the

challenges posed by these anticipated changes. They must also understand the structures and processes, deliverables (outcomes), and limitations of current US health care delivery. The Affordable Care Act increased access to care, and the Medicare Access and CHIP Reconciliation Act (MACRA) legislated new performance metrics and payment models for care. Payment for value based on outcomes and total cost (versus a fee-for-service model) are demanding and accelerating change in the system.
Patient-centered medical homes and other new models for outpatient care are relatively new structures for US health care delivery. Those who seek to be collaborative members of high-functioning teams must adopt a patient-centered view of the system and embrace the expanded roles of all team members, regardless of discipline and commensurate with their training and licensure. Current delivery systems must become congruent with accountable care and population health mandates. Health care professionals must understand how planned payment reforms will realign the system and how care teams must leverage health care improvement strategies, data analytics, and population management to close current deficiencies in care delivery and ensure that patients receive care, education, and support to maximize their health.

Learning Objectives

1. Describe the desired outcomes of health care delivery and the catalysts for system change.
2. Predict the implications of recent changes such as accountable care and payment for value on health care delivery systems.
3. Review the congruence of current delivery systems with accountable care performance requirements and new population health care models.
4. Summarize the use of improvement strategies, population management, and data analytics to close gaps in health care delivery.

I. Desired outcomes of health care delivery

The complex US health care system is not the product of a deliberate, thoughtful, coordinated, and evidence-based approach to maximizing the health of society. Individual health care professionals and frontline multidisciplinary teams may be exemplary in their training and practice, but optimal health outcomes do not occur when these professionals and teams are ineffectively integrated to coordinate a patient's episodic or longitudinal care. The ingredients for success (regardless of practice model) include effective teams focused on patient outcomes and experiences, with aligned systems of care delivery that share information. Over time there have been competing priorities, legislation, and historical accommodations to address changing societal health priorities. The early 20th-century focus on infectious diseases is shifting to an emphasis on safe, high-quality care and the burden of chronic disease in an aging population. These changes have not included an explicit focus on a patient-centered system. In 2016, direct provision of health care was estimated to contribute only 16% to health outcomes, with health determinants and health behaviors contributing 47% and 34%, respectively.[1] The diverse US population (spread across a wide geographic footprint) and influence of multiple stakeholders with disparate perspectives contribute to the complexity we see today.

Political acrimony and unresolved gaps in health care quality, access to care, and cost have accelerated demands for change in recent years, with no clear solution to meet these demands. Many groups (including pharmaceutical manufacturers, providers, insurers, and others) have been "blamed" for high costs and health care underperformance.[2,3] Two reports by the Institute of Medicine[a] (IOM)—*To Err is Human*[4] and *Crossing the Quality Chasm*[5]—ignited national conversations about the gaps in health care delivery and health outcomes and, most concerning, how the system itself has harmed the patients who entrust their care to physicians and other health care professionals. There is no single answer to what is wrong and what must be corrected to "fix" the US health care system, and its complexity will require transformative changes, recognizing we will always be working to improve an imperfect system.

Health care professionals and trainees often have personal experiences as patients and family members that highlight the system's flaws. Even as insiders, health care professionals frequently feel powerless to address the gaps they see. This sense of powerlessness stems in part from the lack of understanding of current health care systems, the factors contributing to gaps in these systems, and the tools to close the gaps. This lack of understanding is not specific to level of training or profession; few participants in the system have even a limited understanding of the network of interactions, competing priorities, resources, and economic pressures in the existing system or for the future needed to truly heal the sick, ameliorate suffering, and, ideally, achieve health for all.

It was not until 2008 that the health professions began to share a common mantra for societal health system goals that also considered both the gains and the costs in the ledger: the Triple Aim.[6] Published by the Institute for Healthcare Improvement (IHI),

the Triple Aim seeks to ensure (1) health for all individuals (population health), (2) an ideal experience for all patients as they interface with the system (including quality and satisfaction), and (3) achieving both at the lowest possible cost (reducing the per capita cost of health care). Physicians and other health care professionals have an opportunity and moral obligation to transform and align the US system to achieve the Triple Aim by closing gaps in all aspects of health care quality. Because physicians are more likely to be successful in this endeavor while experiencing satisfaction in their work with aligned incentives and system support,[7] health care professional wellness is the fourth component of the "Quadruple Aim."[8] The IOM defines health care quality as including six dimensions: care that is safe, timely, effective, efficient, equitable, and patient-centered[5] (often abbreviated as STEEEP; see Chapter 7). The system must focus on the needs of the population (society) and the needs of individual patients.

So, what constitutes an ideal experience for patients? The immediate goals of patients are relief of symptoms and suffering and preservation of health. All patients deserve interactions with the health care system that acknowledge and, when possible, incorporate their preferences, values, and capacity. Patients need timely access to and respect from the physicians and other professionals in the system, and shared decision making with those professionals in order to understand the choices they make regarding their care. Patients deserve equity; Chapter 12 discusses structural and social determinants of health that place some patients at increased risk for disparities in care delivery. Patients need to accomplish these goals of care without having to choose food over medications or worry about financial ruin because of a chronic or life-threatening health condition.

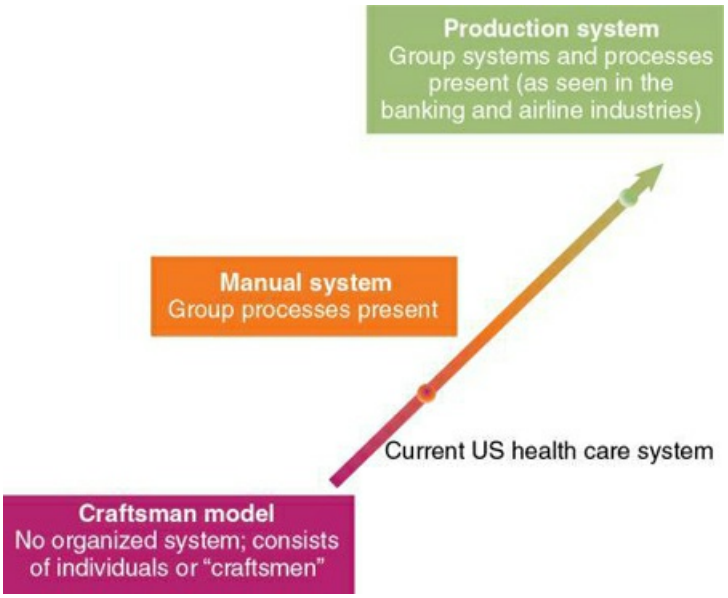
Health care organizations, payers, and society need a system that achieves the Triple Aim, rewards high-value care (as defined later), and ensures the recruitment, development, and retention of caring and competent health care professionals.[9]

II. Catalysts for change in US health care delivery

A. Poor integration, payment misalignment, and unnecessary variation in care

The US health care system comprises a plethora of health care organizations, including academic, public, private, not-for-profit multispecialty, community-based, and government institutions (such as the Department of Defense, the Indian Health Service, and the Department of Veterans Affairs [VA]). Hospitals, and by extension, outpatient centers, clinics, and acute care facilities, are the central focus of health care delivery. Patients encounter many facilities as they move through a continuum from self-care to primary care within patient-centered medical homes (PCMHs), episodic specialty care, and inpatient care. From patients' perspectives, this system exists in name only, in that the care is often not coordinated and the players in these settings do not reliably communicate or share resources in an effective way. Reimbursement mechanisms have selectively favored procedures, tests, and other interventions at the relative exclusion of health maintenance and coordination of care that does not require in-person encounters. For example, if a primary care practice utilizes a patient portal to provide health advice that precludes the need for an office visit, this interaction is frequently not reimbursed. Traditional fee-for-service models that reimburse for care delivery and services regardless of the efficacy or value of that service have provided a distinct disincentive to addressing the quality and cost of care, or the patient's experience of care. In addition to calls to transform the system to meet patient and societal needs, there is increasing acknowledgment of unprecedented misallocation of resources and waste.[10]

One way of benchmarking the health care system and its historical evolution is to compare it with the airline industry. Both the health care and airline industries had similar origins as "craftsman" systems, in which successful outcomes were determined largely by the capability (intelligence, memory, and other skills) of individual professionals (health care providers and pilots, respectively).[11] It is helpful to reflect on how the two systems have diverged significantly. Pilots are trained and work in a "production" model, whereby they perform "standard work" with frequent data provided to them in real time to allow and support needed changes in the protocol. In contrast, traditional health care professional education and care delivery has been based on an "apprentice" model with a focus on individual, not system, learning and performance. In the apprentice model, there is infrequent recognition of standard work (Fig. 3.1). Patient outcomes are too dependent on the individual physician involved, as well as the strengths or weakness of the systems and processes that inform and support the delivery of care.[11]



• **FIG. 3.1** Health Care System Evolution, From Craftsman to Production System. *Source:* (Modified with permission from Burton DA. Anatomy of healthcare delivery model: how a systemic approach can transform care delivery. Health Catalyst; 2014. Available at: https://www.healthcatalyst.com/anatomy-healthcare-delivery-model-transform-care. Accessed October 18, 2019.)

The Dartmouth Institute has documented variations in quality and use of resources in the current system that include overuse and underuse of care (with poorer outcomes associated with higher use of resources).[12] While some variation in care is appropriate based on comorbid conditions and patient preferences and values, there is compelling evidence care delivery can be improved by applying "standard care protocols" or "care pathways" for common conditions for which there is strong evidence for best care.

Care pathways (e.g., diagnostic steps via laboratory and imaging studies) are now frequently embedded in electronic health records (EHRs) to provide specific information, support provider decision making, and promote best practice using the experience of colleagues and experts who developed the protocols. Best practice is always a balance between the delivery of efficient and effective care with an optimal use of resources and the recognition that patient care requires personal attention so that subtle problems are not missed and the patients' interests are served.

To illustrate the concept of care pathways, consider a patient evaluated for anemia. This evaluation includes blood tests (applied in the proper sequence) to identify the cause of the anemia. Rather than order all the tests at the outset, when the clinician consults the anemia pathway he or she would be directed to first check the size of the red blood cells, and if the cells are small (microcytic) to then order a ferritin level, which is a first-line test for iron deficiency anemia. If that test is abnormal and there is no evidence of blood loss, iron replacement is the likely best treatment. However, if the test is normal, thalassemia is possible and further evaluation is needed. Practice guidelines alone are not a panacea, and optimal practice occurs when health care professionals use clinical judgment that synthesizes the evidence, the patient's context, and the patient's preferences and values.[13]

Comparing both industries provides two insights: (1) health care can be improved by applying a production model where appropriate, and (2) we must recognize the important differences between health care and the airline industry, especially as it relates to patient safety.[14] Pilots operate complex machines doing duplicative work. Physicians and other health care professionals function in a less predictable environment. Health care delivery is complex, requiring systems and critical thinking with incorporation of patients' preferences and values (i.e., care that reflects needs of individual patients). Health care professionals often lack systems that inform and support them to ensure high-quality care (STEEEP) for all patients. Physicians and other health care professionals often want to do "everything" for the patient before them, so aligning resources in order to not only support the individual patient but also sustain the system can lead to cognitive dissonance between personal ideals and the reality of health care delivery. Rather than aspire to do everything for everybody, the system must leverage expertise and a better understanding of value to provide the right care for the right patient at the right time (see Chapter 5).

The efficient practice of medicine combines the effective use of production systems (standard work for the majority of patients for a given condition or in a given setting) with the precepts of professionalism to create capacity for the artful diagnosis and compassionate treatment of patients as individuals based on trusting relationships. Both the production model and appropriate individualization are needed to achieve the Triple Aim.

B. Legislative action

Recent legislation has introduced new structures for the delivery of health care and new payment models. While it is not necessary to know all the acronyms, it is helpful to understand the basics of the new legislation and its influence on the milieu of value-based care, a foundational element of payment reform. All value-based care models include an element that makes health care professionals accountable for their performance and contains financial penalties and rewards based on measures of quality, service, and cost.

Two seminal pieces of legislation codified this change in the United States. The Affordable Care Act of 2010 (ACA) increased access to affordable care for many individuals by expanding eligibility for Medicaid and introducing a federal program for individual and small-group insurance known informally as "The Exchange."[15] Chapter 14 describes the development of the ACA in detail. The Medicare Access and CHIP Reconciliation Act of 2015 (MACRA) legislated new provider performance metrics and payment models for care. The Merit-based Incentive Payment System, (MIPS) a Medicare program outlined in MACRA, provides additional remuneration based on "shared savings" for providers who meet performance targets for quality, safety, use of EHRs, and cost. MACRA also introduced a variety of Advanced Alternative Payment Models (AAPMs), which seek to change reimbursement from payment for individual services to payments for care provided for a condition over time. In these models, physicians share financial risk in the care process. An example AAPM, the Medicare

Pathways to Success program, sets targets for performance and cost, then shares risk by rewarding provider groups that meet those targets and penalizing those who do not after 3 years. Other AAPMs include the Bundled Payments for Care Improvement Advanced (BPCIa), which sets a target price for condition management over time, and Comprehensive Primary Care Plus (CPC+), which supports comprehensive primary care patient management over time for a defined population of patients.

The implementation of value-based payment models mandated by the ACA and MACRA are underway, but it is too early to measure their success or failure. While it is not necessary for physicians and other health care professionals to know the details of all value-based care models, it is helpful to understand their basic components and their impact on care delivery. This chapter focuses more generally on the components of value-based payment reform, including the growth of accountable care organizations (ACOs), the specific payment models mandated by MACRA, and the effects that they are having on the US health care system.

C. Accountable care organizations

MACRA-related financial incentives and legislative mandates are increasing the number of new US care models and organizational structures for care delivery, such as ACOs.[15] Recognizing that fragmentation of care has contributed significantly to errors and other gaps in quality while also increasing costs (such as those attributed to redundant care),[16] ACOs are provider-led organizations charged to manage the entire continuum of care, overall costs, and quality of care for a defined population.[17] ACOs seek to improve coordination of care by establishing a "medical home" to manage patient care.

ACOs can take a variety of forms and functions, including outpatient practice settings such as primary care clinics, large integrated group practices, and hospital practice groups, as well as government systems such as the Department of Defense and the VA. A provider-driven care model that accepts accountability for measuring performance and outcomes and assumes risk (or shares gains) for that performance can be established in a variety of settings. These ACOs are structured based on criteria defined by the Centers for Medicare & Medicaid Services (CMS), and regulatory structures are intended to support patient choice and the organized delivery of care. ACOs are provider driven by statute, with specific rules that mandate provider and patient presence on associated boards of directors. Most ACOs provide governance and systems to support implementation of AAPMs (described earlier) and coordinate the care of multiple providers engaged in an episode of care. ACOs that include a strong presence of primary care physicians (commonly called a "medical home") can support an ongoing relationship over time for continuing care.

D. Value-based payment

Value in health care can be expressed as the quality of care (the sum of outcomes, safety, and service) divided by the cost of care over time.[18,19] Many stakeholders are

now using an expanded definition that reflects the STEEEP IOM dimensions of quality mentioned earlier. The value equation relates directly to the Triple Aim as it encompasses the overarching goal of best experience of care and best health (outcomes) for the population at the lowest cost, but its components allow stakeholders in the system to more easily measure quality and value gaps to improve care. Chapters 5 and 7 provide more detail on the concepts of value, quality, and measurement.

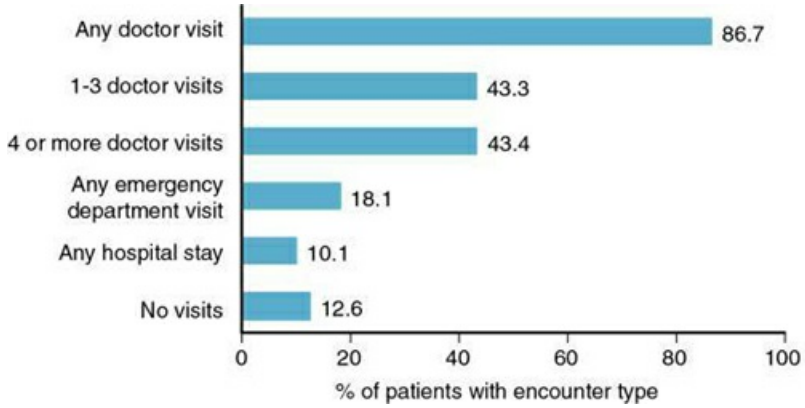
The ACA focuses on increasing health insurance coverage. It provides financial incentives and supports demonstration projects to develop new care and payment models for a more integrated, less fragmented system focused on high value (highest quality at the lowest cost). In April 2015, MACRA repealed the sustainable growth rate formula for Medicare payments and empowered the Secretary of Health and Human Services to replace that system with the MIPS, which supports value-based incentive payments, along with alternative payment models (APMs). In 2019 and beyond, medical groups with a high percentage of Medicare patients in APM contracts are eligible for a lump-sum annual bonus based on their Medicare expenditures. It is the intent of the CMS to move beyond pay-for-performance models such as the MIPS program to broader implementation of APMs in the coming years. Differential payment updates and bonuses will be awarded to providers who implement APMs for a significant percentage of their patients (compared to providers who continue traditional fee-for-service Medicare payments or "upside only" pay-for-performance models).

The shift from a fee-for-service model to a value-based model is complex and faces many challenges. Value-based models are dependent on reporting of quality, safety, and patient experience measures. In a value-based model, providers need sophisticated analytics to enable ongoing monitoring of financial and quality performance for each population of patients. The ACA includes a number of provisions designed to positively affect the Triple Aim, including expanded use of PCMHs, bundled payments, value-based purchasing, and payment reform. All of these initiatives depend on sharing of clinical information and improved feedback regarding performance that is actionable and available in a timely manner. Given current limitations of information sharing and measurement of value in the context of the preferences, values, and circumstances of individual patients, health care professionals are challenged to ensure that patients remain the center of the focus in value-based models. Payment systems will continue to change, and there will likely continue to be a blend of both fee-for-service and value-based models in the near term.

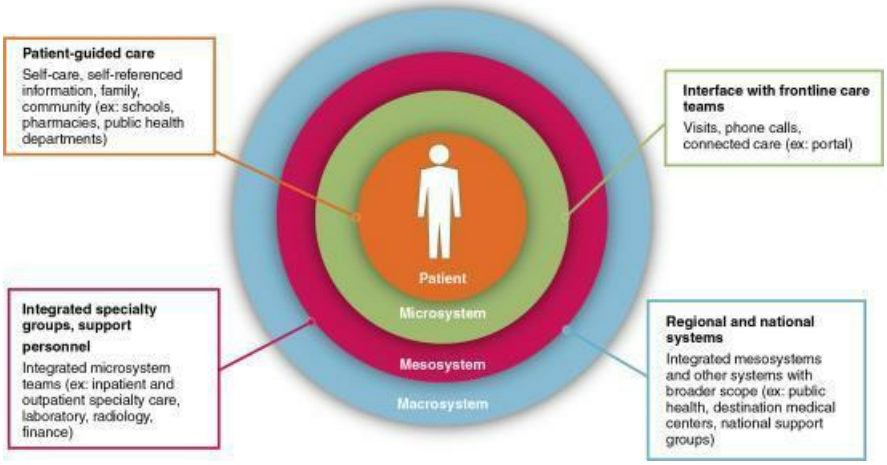
III. New models of health care delivery

As noted previously and in Chapter 5, mandates to improve the value of care and new payment models that seek to reward higher quality, lower cost, and better outcomes of care are changing the way medical groups deliver that care.

Health care professionals must understand where and how often patients actually encounter the health care system to ensure that the system is truly patient centered and designed to address the Triple Aim. Fig. 3.2 represents the percentage of US health care system encounters by one segment of patients (adults ages 55 to 64 years) over 12 months, by visit type.[20] Approximately 12% of adults in this age group had no physician visits whatsoever. This should not be a surprise because the United States focuses on ensuring a patient-centered health care system (Fig. 3.3), with patients and families working to achieve and maintain health via efforts that start at home. Next, patients and families are more likely to address health needs with community-based components of the system (e.g., schools and pharmacies) outside of traditional clinics and hospitals. Traditionally the greatest focus on costs and poor outcomes has been for those patients admitted to the hospital; this makes sense given the greater cost and acuity if hospitalized. It is critically important to note that for this age cohort, approximately 10% of all individuals in this age group were hospitalized. To achieve the Triple Aim, our system structures and processes must include all individuals, whether or not they directly interface with the medical portion of the system.



• **FIG. 3.2** Patient-reported (ages 55 to 64) encounters with the US health care system in the previous 12 months (2012–2013). Respondents were asked about their health care contacts in the past 12 months. Fewer than 1% had an emergency department visit or a hospitalization, but no doctor visits, in 2012–2013. "No visit" is no doctor visit, emergency department visit, or hospital stay in the past 12 months. *Source:* (Modified from Centers for Disease Control and Prevention. *Health, United States, 2014*. 2015. Available at: http://www.cdc.gov/nchs/data/hus/hus14.pdf. Accessed October 18, 2019.)



• **FIG. 3.3** A Patient-Centered Health Care Delivery System. *Source:* (Modified from Nelson EC, Godfrey MM, Batalden PB, et al. Clinical microsystems, part 1. The building blocks of health systems. *Jt Comm J Qual Patient Saf*. 2008;34[7]:367-378.)

An increasing number of integrated community care practices have begun to provide coordinated nonvisit patient care (such as via online patient portals). These and other new care models will continue to grow and align with ongoing care. PCMHs are medical groups that have achieved recognition and in many cases certification for their ability to provide coordinated ongoing care to include health maintenance, wellness, and acute and chronic care needs.[21] PCMHs may be primary care clinics within a variety of practice models, such as multispecialty group practices, integrated health care systems, or community health centers, but can also be care teams dedicated to patients with specific complex needs. These specialty medical homes can provide comprehensive care to patients with significant complex episodic or complex chronic conditions. Examples include care for patients with hemophilia, end-stage renal disease, cystic fibrosis, and cancer, as well as posttransplant patients.

In addition to the changes in traditional inpatient and outpatient settings, new models of outpatient care have developed. Retail clinics, often located in pharmacies and grocery stores, compete for patients who require routine care and vaccinations. Online practices offer medical advice and management and are readily available on the Internet. Concierge practices compete for patients who value personal high-service care delivery that is supported by extra fees for access and service. Hospitals are now delivering more complex care in an outpatient environment. While inpatient admissions have declined in recent years, the use of hospital-associated outpatient services for patients with acute medical needs has increased. Sophisticated imaging, such as magnetic resonance imaging, has increased the precision of diagnoses prior to admission. The numbers of outpatient surgery and infusion clinics have grown. It is critical to note that whether the structures of the system are existing (e.g., nursing homes) or new models of care (e.g., retail clinics), they are infrequently integrated well with other portions of the system.

The personnel who provide care and support the care delivery system are varied. In an integrated system, all personnel engaged in health care delivery are part of a team. Emerging models centered on high-value care and population health have highlighted

the importance of high-performance teams in care delivery and patient outcomes. The success of high-functioning teams hinges on the skill and reliability of all team members who work together.[22] Team-based health care is the provision of health services to individuals, families, their communities, or a combination of these by at least two health providers who work collaboratively with patients and their caregivers—to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality care.[23]

While past, training and practice has focused on the physician as the center of the team, now the patient is recognized as the central member of any high-functioning care team. All members of the team play a critical role to optimize patient health outcomes. The roles necessary for a high-functioning team at the clinical microsystem level will depend on the setting. For example, operating room teams include operating room nurses and technicians, anesthesiologists and nurse anesthetists, and surgeons. Neonatal intensive care unit teams include pediatric pharmacists and dietitians, neonatal nurses, neonatologists, neonatal nurse practitioners, social workers, and respiratory therapists as well as chaplains.

Given the growth of accountable care models, the composition of primary care delivery teams is changing dramatically to reflect their role as the "core" population health care teams. The roles and professions represented on traditional primary care teams (physicians, registered nurses [RNs], licensed practical nurses, desk staff, administrative assistants) have expanded to include nurse practitioners, physician assistants, RNs in care manager roles, social workers, and other integrated behavioral health professionals, such as psychologists. Many other roles may be selectively represented on expanded teams, including pharmacists, therapists, audiologists, dietitians, podiatrists, optometrists, oral health care providers, and community health workers. A primary goal of these population health care teams is to implement processes of care delivery that enable every member to perform at the maximum of his or her licensure.

There are many other health care professionals and members of health care teams not listed specifically in this chapter. For further reading, *The Health Care Handbook* has an expanded list of health care professionals, their training, and their common roles in the system.[24] The roles of health care professionals and the concept of teamwork are addressed in Chapter 8.

IV. Congruence of current delivery systems with accountable care and population health

To succeed in the new health care system, provider groups must develop a network of providers with aligned purpose that considers all contacts individuals may have with the health care system, as demonstrated earlier via one patient segment (adults ages 55 to 64 years) in Fig. 3.2. They can then use interdisciplinary teams to coordinate the care delivery supported by timely, actionable analytics and an aligned financial model. The CMS accountable care performance requirements are designed to foster a high-value system that meets the goals of patients and of the Triple Aim. New population health models seek to operationalize this system on the premise that the foundation of the ideal health system lies in PCMH.[17]

ACO performance relies on timely performance measurement to evaluate the quality of care that is provided. Alignment between the metrics for financial success and performance incentives can make provider teams aware of both potential overuse (i.e., in disintegrated systems) and underuse (e.g., in organizations that lack awareness of patient needs for preventive care).[17] The existing culture in many organizations and communities is entrenched in a narrow view of each service line (such as cardiovascular surgery) or in the structures, processes, and outcomes associated within or across microsystems, when evaluating value and cost. Significant change (with strong leadership) is required to transform these silos within the system into a coordinated and cohesive mesosystem or macrosystem with a focus on aligning incentives for high-value care models based on patient outcomes and costs of care over time.

The presence of a coordinated system of care for primary care needs (such as the PCMH model) is critically important to health system reform. The PCMH model can help increase value by providing higher-quality care at a lower cost over time in a coordinated way. It combines attention to the ongoing and acute care needs of patients in a patient-centered manner that is supported by practice innovations, including population health approaches to chronic disease, effective uses of information technology, new models of care delivery, and health care improvement.[17] This model focuses on the preferences and values of patients and their families as well as payment reform that rewards value over finite interventions and provisions of care.

The transformation to accountable care and the PCMH model is challenged by the current state of many health care systems. Current information technology systems (discussed in more detail in Chapter 10) are often insufficient to measure and provide real-time feedback to frontline teams and to help leaders anticipate whether the mesosystem or macrosystem is on track to meet ACO requirements. Clinical revenue systems have traditionally used production-based workflow and compensation models that do not align the systems to support collaborative discussions regarding transitions in care, much less high-value care or the Triple Aim.

Case study 1: Health improvement at the macrosystem level

A team responsible for the health of a large population of Native Americans identified multiple gaps in care delivery and health outcomes. How did they use health care improvement strategies at the organizational (macrosystem) level to help close the gaps they identified?

The Chinle Service Unit (CSU) serves 31 Navajo communities in the central region of the Navajo Nation as part of the Indian Health Service (IHS). The IHS is a federal agency in the US Department of Health and Human Services. After developing a patient-centered, culturally influenced improvement model in 2005 and engaging in primary care transformation via a collaborative in 2007, the CSU committed to further pursue the Triple Aim to provide higher-value care for their population of over 35,000 primarily Native American patients. They created and implemented a portfolio of projects to include a medical home model (including childhood immunizations, emergency department visits, and access to care), inpatient safety, diabetes, inpatient satisfaction, and collaboration of the IHS's community health improvement councils.

The CSU organized the projects based on the Triple Aim. Their project outcome measures included emergency department and urgent care visits, childhood immunization rates (medical home care), diabetes outcome bundle control (hemoglobin A_{1c}, low-density lipoprotein, blood pressure), hospitalization rates (diabetes), and coalition development scores (community health improvement council collaboration). The teams also followed population outcome measures for each dimension of the Triple Aim: population health (self-reported health status, childhood healthy weight, diabetes incidence and prevalence), experience of care (ambulatory care patient satisfaction, 30-day readmission rate, and diabetes outcome bundle), and per capita cost (estimated based on emergency department and urgent care utilization and hospital bed days). The teams made significant and sustained improvement in many of their measures; participation in the projects has positively impacted the long-term culture of quality improvement across their unit.[38]

V. Closing gaps in the health care delivery system

The breadth and speed of changes and the rapid emergence of high-value care models to meet the Triple Aim of care requires physicians and other health care professionals to reenvision and execute on specific opportunities to advance the system forward for patients and society.

A. Population management

The IHI defines population management as management of and payment for health care services for a discrete or defined population. Contrast this with population medicine, which IHI defines as the design, delivery, coordination, and payment of high-quality health care services to manage the Triple Aim using the best resources available.[25] Population medicine is discussed in more detail in Chapter 11.

Effective population management requires the stratification or segmentation of patients based on level of risk of poorer health outcomes. Roughly half of patients in a primary care population are healthy (bottom of the pyramid) and constitute 10% to 20% of total health care dollars spent. Thirty percent to 45% of the population has limited or stable chronic disease, or both; the cost of caring for this group is roughly 30% to 40% of total costs. The sickest patients are in the smallest percentage (5%) of the population and are often described as "super-utilizers." They are often elderly, frail, and disadvantaged socioeconomically and have psychosocial barriers to care, multiple health issues, many emergency department visits and hospitalizations, or a combination of these. They account for 45% to 50% of health care costs in the population.[26]

Health organizations seeking to meet the Triple Aim and improve outcomes while minimizing cost must target high-risk, high-cost subpopulations proactively and differently than those with lower risk. At the outset, this requires organizations to correctly identify these patients. For example, ACOs must be able to determine which patients are at high risk of readmission, with a focus on patients with a rising risk index, such as congestive heart failure patients with sudden weight gains or diabetic patients with worsening hemoglobin A_{1c} values.[27] Current risk prediction models lack precision and are difficult to generalize across a broad, diverse population. Ongoing study of internal performance and benchmarking to similar groups will allow a broader understanding of risk. Emerging systems are collecting and sharing de-identified data from EHRs and other sources to better characterize and predict risk to help ACOs with projections of patient outcomes and financial performance.[28]

Patient registries are organized systems that use observational study methods to collect uniform data (including clinical data) to evaluate specific outcomes (predetermined for scientific, clinical, or policy purposes) for a population of patients.[29] The population may be defined by a particular disease, condition, or exposure. The files derived from the registry are called the registry database. Registries are designed

according to their purpose, because different levels of rigor are required for registries used to support decision making as compared to those used for descriptive purposes. Registries may be used for determining clinical, cost, or comparative effectiveness of a test or treatment; they may be used to monitor or measure the safety of specific products and treatments; they may be used to measure or improve quality of care within a health care improvement initiative at the microsystem, mesosystem, or macrosystem level; and they may also be used to assess the natural history, magnitude, incidence, prevalence, and trend of a disease, or a combination of these, over time.[29] In the context of population management, patient registries are important tools not only for quality and process improvement efforts, but for active management or care of patients with specific diseases or conditions by frontline (microsystem) teams.

Case study 2: Use of patient registry and a community approach via crowdsourcing and technology to improve asthma outcomes

The mayor of a moderately sized city challenged by poor air quality considered a cross-sector partnership between city leaders and health providers to improve the health of the city's asthma patients. What structures and processes might be used to implement this population health approach?

The Louisville Metro Government in Kentucky recognized the significant health and economic burden of respiratory diseases and created a collaborative team (city leaders, a local nonprofit, and a digital health company) to launch the AIR Louisville project. Asthma patients were identified using a patient registry. All participants used electronic inhaler sensors that passively measured date and time of medication use; data were transmitted via Bluetooth (for patients with smartphones) or wireless hub technology (for patients without smartphones). Self-management strategies were enforced via smartphones giving feedback on medication use and asthma control. Data were shared with health care professionals, so medication changes could be made based on data trends (e.g., increasing medication use as a marker for worsening asthma exacerbation). Hot spots of poor asthma control were identified as highest-risk neighborhoods based on top quartile of asthma burden (asthma prevalence and expected short-acting medication use per person), highest air pollution, lowest tree canopy, highest impervious surface, and highest urban heat. Small focus groups and a large policy summit of partners were convened to generate ideas and provide feedback on the project and potential policy interventions.

Participants experienced significant improvement in clinical asthma outcomes, including a 78% reduction in rescue inhaler use and a 48% improvement in symptom-free days. Patients expressed increased confidence in avoiding asthma attacks and in asthma understanding. In addition to improving health outcomes for participants, the data (crowdsourced data on inhaler use and environmental data) led to local policy changes (such as enhancing tree canopy, recommended truck routes, and development of a community asthma notification system) that have the potential to improve respiratory health for other community members.[39]

B. Information systems

There are three fundamental prerequisites for an information system designed to support the Triple Aim: content, analytics, and deployment.[32] Content broadly includes "What should we be doing?", such as evidence-based decision making for diagnosis, treatment, and prevention, as well as the best practices (including care models) needed to provide optimal care to patients. Analytics refers to the system that answers the questions "How are we doing?" and "What is the system's performance on measures of importance?" For example, what percentage of children in a particular population is fully vaccinated at 2 years of age (process measure)? What is the inpatient mortality rate for patients admitted with a diagnosis of myocardial infarction (outcome measure)? Analytics that connect the processes of care to patient outcomes are particularly important and require a data source that transcends any particular structure in the system. Content includes extant evidence (knowledge, including practice guidelines) as well as the implementation of the evidence via health care improvement strategies to minimize delays between identifying what physicians and other health care professionals should do and actually ensuring that it happens consistently in practice. Deployment ("How do we transform?") ensures that improvements become part of routine care delivery through changes in culture, dissemination, leadership, and accountability.[32] Effectiveness depends upon how improvements are adapted or adopted by microsystems of care.

C. Data analytics

Data analytics that collate and display observational data from national and international billing data and de-identified clinical data is another critical tool for closing the knowledge gap between the current health care system and the system of the future. These "big data" collections consist of large integrated data sources accessed with alternate techniques such as machine learning. Data are often displayed as graphic analytics and "heat maps" of data that can link diagnoses and use of resources. The complexity and breadth of the data plus the need to access multiple databases simultaneously to develop a comprehensive observational data set require use of resources and software that is beyond the capacity or purpose of commonly available data management software that is used for internal process and outcomes analytics. Data analytics and patient registries are discussed in more detail in Chapter 10.

Although data analytics is a potential resource to better understand national care patterns and the natural history of diseases, it presents several limitations. Big data collections are generally limited to observational data, and decisions regarding specific clinical interventions may often require more detailed clinical studies. In addition, most providers are primarily interested in discovering and benchmarking the performance of their frontline team. This type of data analysis includes three phases: data collection, data sharing, and data analytics. Data analytics is the discovery and communication of meaningful patterns in data.[31] Institutions across the health care system have moved or are moving toward EHRs, but this intervention alone is not enough to significantly close system gaps, since they typically benchmark past performance. The full potential

of EHRs will be realized in a data-driven health care culture aligned with rapid cycle improvement. In this culture, data will be analyzed, exploited, and benchmarked to other providers to improve outcomes and align financial incentives via a value-based model to the work of clinical teams.[31]

It is helpful to consider how organizations might improve their awareness of unexpected practice variation and improvement of their performance through adoption of analytics. Many start by collecting and integrating data through use of standardized definitions to allow collation of information and develop patient registries. Analysis of internal data benchmarked to other providers can improve understanding of performance gaps and drive a response to waste and unexpected variation in care. Eventually the system will evolve to a higher level with population health management and predictive analytics. Predictive modeling is a statistical process that analyzes historical data in order to create an algorithm that can be used to determine the likelihood of a future event. Predictive modeling helps identify the risk of an outcome, based on an in-depth understanding and analysis of what has happened in the past.[32] At this more advanced level, organizations may seek to use clinical risk intervention and analytics to tailor patient care based on population outcomes and genetic data.[31]

Organizations that have achieved an evidence-based, patient-centered, data-driven culture with a consistent analytic feedback loop for understanding clinical outcomes can effectively execute population health management and likely move closer to the Triple Aim. These organizations are aligned with the goals of accountable care, sharing in the financial risk and reward of clinical outcomes; more than half of acute care cases are managed under bundled payments (payments based on the entire episode of care, not on fee-for-service for each health care intervention or encounter). Clinical teams (microsystems) have access to point-of-care analytics that are aligned with the Triple Aim.[31]

D. Displays of population data

To become successful in providing high-value care to a population of patients, provider groups must structure their practice to analyze data and intervene when needed to support the health and well-being of the population that they serve. The emerging model of team-based care is well aligned with this care model. Good intentions must be supported by sophisticated analytics that display the current status of the population with enough granularity and timeliness to support action, move forward, and proactively manage and predict risk for the population. With this in place, medical groups must develop data-based learning communities to accelerate adoption of new care models and adapt the system when confronted with unexpected outcomes or evidence of low-value care. EHRs will provide evidence and focus caregiver attention based on formal problem lists, reconciled medication lists, tests, and imaging. However, the clinical profile of patients at present is not fully captured by available risk scoring or formal documentation and coding.[33] Large databases that selectively navigate provider and payer databases are often supported by natural language processing and have large patient cohorts with the power to reach statistical significance for subsets of the

population that cannot be profiled by many groups. These systems offer health care providers the potential to use integrated data for detailed predictive care modeling and comparison with a national database of matched de-identified patients.

How can the health care system define and capture the promise of population health, and how does this differ from public health? Many authors have offered definitions of population health, including "the health outcomes of a group of individuals, including the distribution of such outcomes within the group."[34] Chapter 11 provides a detailed review of population health and its intersection with public health. Public health typically assumes a direct relationship with government health departments, whereas population health is a broader topic that includes the health care delivery system in total.[35] Currently most consider population health as a spectrum, wherein the population in any given context may be patients defined by specific characteristics such as their residence, their provider group, their disease, or their insurer.

Health care professionals in a typical clinical practice must improve population health one patient at a time; professionals in teams at all levels of the system (microsystem, mesosystem, and macrosystem) must proactively provide high-value care and promote health for individual patients as well as the group of patients they are responsible for. The system must include the structures (personnel, training, team composition, settings, means of communication) and processes that ensure the care provided is truly patient centered. Health care professionals must be facile in effective shared decision making and incorporate patients' preferences, values, context, and capacity for completing care recommendations with advanced information systems and analytics.[36]

E. Health care improvement strategies

Health care improvement is a broad term that encompasses traditional process and quality improvement and patient safety efforts to close gaps aligned with the six IOM dimensions of quality. Batalden and Davidoff defined it as

> the combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development.[37]

Chapters 6 and 7 provide detailed explanations of patient safety and quality improvement strategies and tools that are used up to the macrosystem (health care organization) level. Health care improvement empowers every member of the health care team to close gaps and hold gains in quality and value within the system. It also adds the challenge of change management and the work necessary to disseminate, adapt, and operationalize improvements across a system. Health care improvement is fundamental to both content ("What should we be doing?") and deployment ("How do we transform?").

Five types of knowledge must be applied in concert to drive system improvement: scientific evidence, context awareness, performance measurement, plans for change, and execution of planned changes. Scientific evidence informs plans for change (or interventions aimed to make the desired improvement) within a particular context (microsystem setting); knowledge related to system improvement (change management, leadership) is required to ensure that the needle successfully moves from baseline performance measure to desired performance measure. Quality improvement efforts occur at the microsystem, mesosystem, and macrosystem levels; successful initiatives include representatives from all roles in the process or work that is being improved.

All health care professionals should understand early in their education and training that they have two jobs: delivering high-value care to patients (doing the work) and improving the process and outcomes of care (improving the work).[37] Improving the work requires professionals to employ systems thinking skills in every aspect of health care (see Chapter 2). Although health care professionals (even within a single discipline) will have varying levels of expertise in planning and executing quality improvement projects, it is important for all team members to visualize health care delivery as a series of processes that become standard work. Systematizing care via this "standard work" will ensure better outcomes and provide capacity for individualizing care (based on patient preferences, value, and context) when needed. Chapter 7 describes rapid cycle changes—Lean, Six Sigma, and change management by leaders and the importance of measurement. Related chapters include Chapter 9 (a broad overview of leadership) and Chapter 14 (discusses health policy, a means for improving the system at a level higher than the macrosystem or health care organization level).

The remainder of this book elaborates additional approaches that are critical to closing gaps in current systems. To promote value, physicians must be trained in quality improvement methods and principles of patient safety. Successful systems will rely upon robust clinical informatics and a shift to greater emphasis on population health.

VI. Chapter summary

US health care is undergoing unprecedented and exponential change. Patients and society need the health care system to maximize the health of all individuals (population health) and ensure a patient-centered experience of care while minimizing unnecessary costs (i.e., the Triple Aim). To advance the Triple Aim, health care professionals must have a basic understanding of the current and anticipated structures and processes of the US health care system and the levels of a patient-centered system. They must appreciate the current dissonance between what patients perceive as the system of care and the reality of poorly integrated health care structures and processes that do not provide ideal outcomes, quality of care, or value for all individuals. They must also see the gap between the current US health care system and evolving new payment, population management, and care delivery models. They should understand how health care improvement strategies, population management, and data analytics must be used to close health care gaps. Together, these evolving efforts must be integrated with compassionate care that reflects the preferences, values, and context of individual patients.

Questions for further thought

1. How is accountable care changing the health care landscape?
2. What kind of measures would you use to improve the quality of care in an intensive care unit?
3. What type of data can be collected via the electronic health record for use in quality improvement and research?
4. What is your role in your health care mesosystem? How does this compare to your role in the microsystem and the macrosystem?

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[a]Note: the Institute of Medicine changed its name to the National Academy of Medicine in 2015.

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This white paper provides a high-level overview of how US health organizations can transform to close gaps in value (quality and cost) in the evolving environment.

Burton DA. A guide to successful outcomes using population health analytics. Health Catalyst Available at https://downloads.healthcatalyst.com/wp-content/uploads/2015/05/A-Guide-to-Successful-Outcomes-using-Population-Health-Analytics.pdf 2015; Accessed October 18, 2019.

This white paper gives a high-level overview of how population health and data analytics can be successfully used to improve health and health care outcomes.

Nelson EC, Godfrey MM, Batalden PB. et al. *Clinical microsystems, part 1. The building blocks of health systems* Jt Comm J Qual Patient Saf 7, 2008;34: 367-378.

This journal article provides a commonly used nomenclature for understanding and communicating the different levels of the health care system (microsystems, mesosystems, and macrosystems).

Rittenhouse DR, Shortell SM, Fisher ES. *Primary care and accountable care—two essential elements of delivery-system reform* N Engl J Med 24, 2009;361: 2301-2303.

This commentary article nicely summarizes the importance of primary care and accountable care as two necessary ingredients for US health care delivery reform.

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Health care structures and processes

Ami L. DeWaters, MD, MSc, Ryan Munyon, MD

CHAPTER OUTLINE

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In this chapter

This chapter defines the Donabedian model, as well as multiple different components of health care structures, including the different care settings that patients encounter in the United States. It also discusses processes that may be commonly encountered by physicians and other health care professionals. The effects of certain structural and process advancements are described. Finally, this chapter discusses the future directions of health care structures and

processes, including advancements in telemedicine and the shifting landscape of inpatient medicine.

Learning Objectives

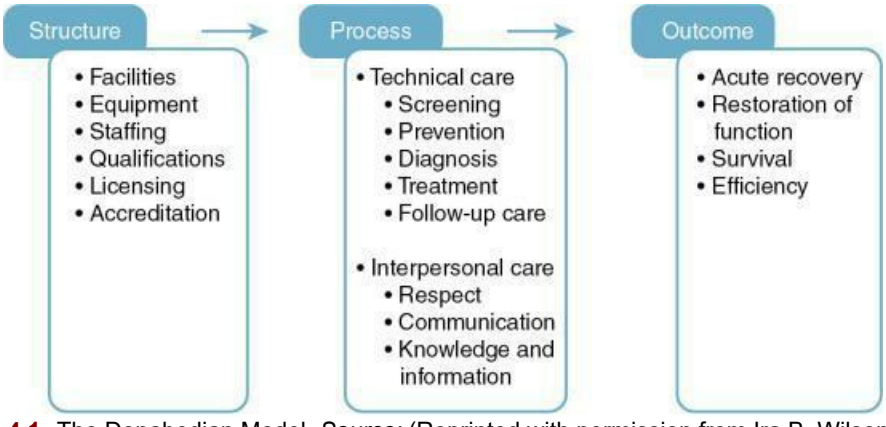
1. Describe the Donabedian model.
2. Discuss the components of health care structures and processes.
3. Evaluate how certain structural and process advancements have affected patient outcomes.
4. Discuss future directions for health care structures and processes.

I. Introduction to the donabedian model

A 78-year-old woman presents to her primary care physician with a cough and shortness of breath. Her oxygen saturation on room air is 86%, her pulse is 110 beats/min, and she has a fever of 101°F. On examination, the patient has crackles in the bilateral bases of her lungs. The physician discusses with the patient that evaluation in an emergency department would be best. The patient agrees. Per clinic policy, emergency medical services is called to transport the patient via ambulance to the nearest emergency department. The primary care physician calls the emergency department physician and relays the patient's history to her.

The preceding portion of the case presented throughout this chapter is just the beginning of one patient's journey into a complex health care system. As health care professional learners help their patients traverse this system, many of them naturally wonder what the components of the system are, as well as how to evaluate the quality of their patients' care. In the example case, what were the components of the system that affected the patient's care? Did the patient's care in the outpatient setting meet expected quality standards? For many years, medicine lacked an overarching framework to be able to adeptly answer those questions.

Enter the modern health care quality movement. Just over 50 years ago, a professor of medical care organization at the University of Michigan, Dr. Avedis Donabedian, began to work on a framework to assess health care quality.[1] In what would become a seminal work, Donabedian wrote an article in 1966 in which he outlined three components—structures, processes, and outcomes—that can be used to assess the quality of care provided in medical settings.[2] These three components became known as the Donabedian model (Fig. 4.1).



• FIG. 4.1 The Donabedian Model. *Source:* (Reprinted with permission from Ira B. Wilson, MD, MSc. Quality Measurement Presentation, April 4, 2014. https://slideplayer.com/slide/12342555/.)

To understand more fully the Donabedian model, there must be an understanding of the definition of each of the components. Structures are defined as the personnel, settings, facilities, and resources. This includes the equipment, financial, and

administrative structure present in a system. For instance, in the example case, there are two different facilities, the emergency department and the primary care office, which are part of the structure of the health care system. Likewise, there are multiple personnel at the clinic, including the physician, the emergency medical responders, the nurses, and the assistants. The pulse oximeter, thermometer, and heart monitor used to assess the patient's vital signs are all equipment that is part of the structure. The administrative structure that allows for quick response by emergency medical services to the office to take the patient to the emergency department is also included in the overall structure of the system.

Processes are defined as the actual work performed by physicians and other health care professionals, including physical examinations, laboratory tests, procedures, and coordination of care. The lung exam and communication between the primary care and emergency department physicians in the example case are both examples of processes. Interestingly, Donabedian also listed "acceptability of care to the recipient" as a process.[2] Therefore the shared decision-making conversation between the primary care physician and patient regarding transfer to the emergency department would also be considered a process in the system.

Outcomes are defined as the result of the care provided. Mortality, level of function, duration of illness, patient satisfaction, and recurrence of illness are all frequently reported outcomes. It is important to note that, historically, evaluating outcomes alone was the primary method of assessing quality of care. However, the Donabedian model helps avoid the pitfalls inherent in this single methodology. Using the example case at the start of this chapter, imagine if only an outcome measure such as admission to the emergency department were used to determine the quality of the clinic's care. Was the clinic's care low quality because a patient was transferred to the emergency department? Not necessarily. In this case, it was the appropriate medical choice. In addition, examining outcomes alone does not allow for an in-depth understanding of the contributors to poor-quality care. As Donabedian noted, "although outcomes might indicate good or bad care in the aggregate, they do not give an insight into the nature and location of the deficiencies or strengths to which the outcome might be attributed."[2]

The power of the Donabedian model therefore lies in its ability to comprehensively examine a health care system for its components, as well as assess the system for quality. This chapter identifies and defines certain prevalent structures and processes within the health care system. These structures and processes are necessary for understanding health care systems as a whole. In addition, commentary is provided on how certain developments have affected the quality of patient care.

II. Structures across the continuum of care

A. Personnel

1. Hospitalists

The 78-year-old woman is transferred from the primary care clinic to the emergency department. An emergency department physician examines her and verifies the same vitals and physical exam findings as were noted by her primary care physician. A complete blood count is obtained and a white blood cell count of 15,000/mm^3 is noted. A chest radiograph is obtained and shows bilateral, patchy infiltrates in the bases of both lungs. The emergency department physician calls the on-call hospitalist for admission to the hospital for this patient with a suspected diagnosis of sepsis secondary to community-acquired pneumonia.

Personnel are a large component of the structure in a health care system. One of the most interesting changes in personnel in the last 20 years has been the development of the hospitalist. The patient in the example case was admitted to the hospital by a hospitalist, a general internist or family medicine physician who specializes in inpatient care. A hospitalist typically spends greater than 90% of his or her time caring for patients working inside a hospital. While inpatient specialists have been a part of the British and Canadian health care systems for many years, the development of hospital-based physicians only began to grow in the United States in the 1990s. Drs. Bob Wachter and Lee Goldman popularized the term *hospitalists* in 1996.[3] The field has steadily grown. Prior to the development of hospitalists, primary care physicians would follow their patients into the hospital, prior to a workday in clinic, or designate one of the practice members to manage the inpatient workload. To change physicians to someone outside the practice at such a critical time would have seemed irrational and dangerous in the 1980s and before. Nonetheless, hospitalist medicine has become the dominant style of inpatient general internal medicine in many locations. Over 50,000 hospitalists now work at greater than 75% of hospitals,[4] with even higher percentages at hospitals with more than 250 beds. The mental model of being assigned a new physician on admission to a hospital is becoming widely accepted.

This dramatic and rapid change in health care delivery has come about due to several pressures. The first is workforce. With the average complexity of patients increasing, the ability of primary care physicians to complete work in two locations, sometimes switching multiple times a day, is limited. Primary care physicians are also under constant pressure to see more patients, take on larger panels, and respond to increasing amounts of indirect patient care, such as electronic messages, phone calls, and electronic prescription refills. Adding complex inpatient care with pressing issues and hospital system demands could be untenable.

Second, hospitalist-driven care models have shown decreased length of stay for patients and decreased cost of hospitalizations, while having no worse outcomes in regard to 30-day mortality or readmissions.[5-8] In comparison, a study by Dr. Stevens

and colleagues compared hospitalist care with inpatient care provided by primary care physicians or "covering" nonhospitalists and found that primary care physicians caring for their patients had the lowest 30-day mortality and 30-day readmission rates. However, hospitalists performed better than "covering" physicians, which in any larger practice can be the reality. In essence, patient care can be improved with physicians who either know the patient or know the system.[9]

Finally, hospitalists are well positioned to help with inpatient quality improvement projects. The growth of hospitalist medicine coincided with growing interest in safety culture, quality improvement attempts, and accountable care initiatives on the heels of the Institute of Medicine report *To Err Is Human: Building a Safer Medical System*.[10] This report focused on medical errors in the hospital and the resulting outstanding cost to human life and to medical systems. The change that followed in hospital culture and medical service lines viewed hospitalists as a natural source of improvement ideas, implementation specialists, and leaders.

2. Advanced practice providers

Once the patient is admitted to the hospital, she is seen on a daily basis by a physician assistant.

A second major shift in personnel in recent years has been the increasing integration into daily clinical practice of nurse practitioners and physician assistants, often referred to collectively as advanced practice providers. One study noted that by 2006, 77% of emergency departments reported the use of advanced practice providers, as opposed to 28% in 1997.[11] According to the Bureau of Labor Statistics, there were 118,000 physician assistants in 2018. An additional 37,000 jobs for physician assistants are expected to be created by 2028.[12] As of 2019, there were more than 270,000 nurse practitioners, and more than 28,000 nurse practitioners finished their academic programs in 2018.[13] Advanced practice providers are trained to assess patient needs, diagnose illnesses, prescribe medications, and form treatment plans in collaboration with a physician or, in some states, as independent clinicians. Physicians work alongside advanced practice providers in every clinical setting, from the emergency department to the hospital to the primary care clinic.

There are a number of reasons for this trend. First, quality of care has been comparable between advanced practice providers and physicians in multiple settings. In a study of over 1000 patients at a large, urban primary care clinic, patients were randomized to treatment by a physician or a nurse practitioner. Patients in both groups had similar physiologic measures, such as blood pressure and blood glucose, after 6 months of treatment. Likewise, the patient satisfaction scores were similar for both groups of patients.[14] A systematic review on the subject noted that advanced practice providers had been found to have patient care outcomes equivalent to those of physicians in acute and critical care settings.[15] A second reason for the growing utilization of advanced practice providers is that they may be more cost-effective than physicians, due to relatively higher physician salaries.[16] As a result, physicians practicing medicine today and in the future can expect to be working with advanced practice providers daily.

3. Care coordinators, social workers, and patient navigators

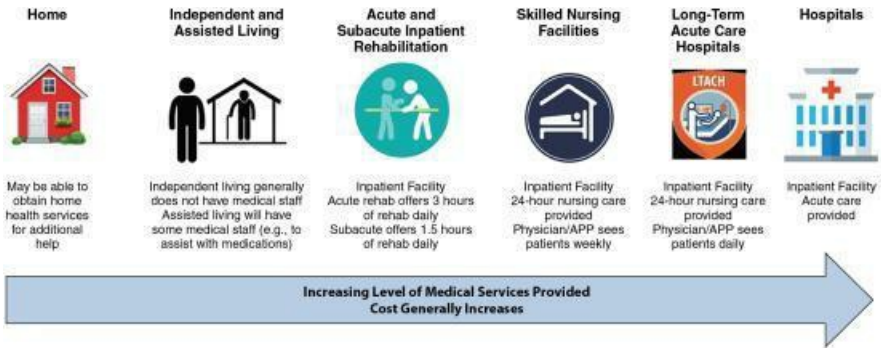
While admitted, the patient mentions to her nurse that she needs help applying for Medicare Part D insurance to help pay for her medications. The nurse calls a social worker to come and assist the patient.

The complexity of the current health care system in the United States has necessitated the development of roles for individuals to help guide patients through the system. Social workers, care coordinators, and patient navigators have filled these roles. A social worker usually has a bachelor's or master's degree and can help patients interact with their employers, find housing, and find placement in other health care facilities, such as skilled nursing facilities. A care coordinator is usually a registered nurse who helps manage care by coordinating with a patient's insurance company, finding affordable medications, setting up home health care, and contacting other health care professionals to ensure that all members of the team are aware of the treatment plans. Patient navigators build longitudinal relationships with patients in order to help support them and their communication with their health care team, and, therefore, facilitate the development of patient-centered treatment plans. These roles are essential to the health care system, and the integration of these roles is further discussed later.

B. Settings

During the patient's third day in the hospital, she walks to the bathroom, has an episode of orthostatic hypotension, and falls. She develops immediate pain in her right hip, and she is sent for an urgent CT scan of her right hip and femur, which shows a right proximal femoral neck fracture. She requires surgery. After her surgery, she is evaluated by a physical therapist who recommends that discharge to a rehabilitation center would be best. The patient agrees and asks if she can get help investigating independent or assisted living facilities for after her rehab stay. She states she no longer feels comfortable at home alone.

Health care is provided in a multitude of different settings (Fig. 4.2). The most fundamental difference is between inpatient and outpatient settings (Table 4.1). Inpatient facilities include hospitals and mental health facilities where patients stay overnight and are receiving active medical treatment. They also include inpatient rehabilitation facilities, skilled nursing facilities, and long-term acute care hospitals; these facilities are referred to collectively as post–acute care facilities. Outpatient facilities are offices where patients are seen by physicians and other health care professionals, receive treatment, but do not stay overnight.[17] The patient in the example case is transitioning from one inpatient facility (the hospital) to another (an inpatient rehabilitation facility) before attempting to transition to home. As in this patient's case, each individual's needs will dictate which setting is best when the time comes to leave the hospital.



• **FIG. 4.2** The Settings of the United States Health Care System. *APP*, Advanced practice provider.

TABLE 4.1

Post–Acute Care Settings

	Subacute Care	IRF	LTACH
Type of care provided	Skilled nursing services or skilled rehabilitation services for the short term on a daily basis in an inpatient setting after an inpatient stay of 3 or more days	Intensive rehabilitation therapy in an inpatient hospital environment; patient requires and is expected to benefit from 3 hours or more of therapy at least 5 days per week	Continued hospital level of care
Typical medical conditions treated	• Heart failure and shock • Hip and femur procedures • Joint replacement • Kidney and urinary tract infections • Septicemia	• Brain injury • Lower extremity fracture • Major joint replacement • Neurological disorders • Stroke	• Complex medical conditions • Complex wounds/burns • Mechanical vent weaning
Daily therapy requirements per person	1-1.5 hours	>3 hours	N/A
Average length of stay	27 days	13.1 days	26.6 days
Average cost of care per patient	$10,808	$17,085	$38,582

IRF, Inpatient rehabilitation facility; *LTACH,* long-term acute care hospital; *N/A,* not available.

Reprinted from Stefanacci RG. Admission criteria for facility-based post–acute services. *Ann Long Term Care Clin Care Aging.* 2015;23(11):18-20, with permission.

If patients are able to care for their medical conditions and navigate their home independently or with strong family support, they will be discharged to their home. Those patients will return to seeing their physicians in the outpatient, also called ambulatory, setting. If a patient who is being discharged is without a home, a social worker may assist him or her in locating transitional housing. Transitional housing, such as a shelter, is usually time-limited, meaning individuals are generally not allowed to stay beyond 24 months.

Individuals who are mostly independent but have specific additional needs may be able to be discharged home with home health care. Home health care is ordered by a physician and involves a licensed nurse going to the patient's home on a regular basis.

For instance, if a patient requires assistance organizing his or her medications or requires frequent blood work, a nurse may come to the home and help distribute the medications into a pill box and draw blood every week. Alternatively, in-home care is available for non–health care needs. A professional, such as a home health aide who is not a nurse, may come to the home to help with light housekeeping, prepare meals, and so on. It is important to note that in-home care and home health care are expensive, and most individuals will require insurance to cover the cost. According to an annual cost-of-care survey performed by Genworth Financial, the average cost of a home health aide was $52,624 annually in 2019.[18]

The patient in the example case no longer feels comfortable at home, and she wants to investigate other options such as independent or assisted living. Each facility that offers independent or assisted living will have its own set of care options available. It is important to advise patients to look into each facility to see what is specifically offered. In general, people in independent living communities have their own apartments or condominiums and perform all their own activities of daily living (cooking their own meals, medication management, housekeeping). But they have access to an on-site cafeteria, and the community offers social activities and gatherings. There are no medical services provided in independent living facilities. At an assisted living facility, people still have their own apartments or condominiums; however, medical staff are available. Medical staff may assist community members with taking and organizing their medications and are available for emergencies. Meal preparation and assistance with housekeeping may also be offered. Cost remains a prohibitive factor for many individuals exploring this option, with the average assisted living facility charging $48,612 annually.[18]

For individuals who have more complex medical needs, post–acute care facilities may be the best option. Skilled nursing facilities, also called nursing homes, provide 24/7 licensed nursing care. In a skilled nursing facility, individuals have rooms, not apartments, and the rooms may be semiprivate or private. Physicians visit individuals in nursing homes usually on a weekly basis to review their medical conditions. For patients who have medical conditions requiring regular monitoring throughout the day, a long-term acute care hospital may be the best option. At a long-term acute care hospital, a licensed nurse and physician care for each patient daily; the setting is very similar to that of a hospital. Patients in these facilities may require mechanical ventilation, tube feeding, frequent intravenous medication treatments, or extensive wound care.

Some patients, like the patient in the example case, may require a short stay in a rehabilitation facility to gain more independence and function before transitioning back to home or another facility. Both acute and subacute rehabilitation facilities are available. Acute rehabilitation facilities generally require patients to participate in therapy 3 hours a day, and the average length of stay is about 12 days. Subacute rehabilitation facilities generally require patients to participate in therapy for an hour a day. Complicating the picture is the fact that many skilled nursing facilities have combined with subacute rehabilitation facilities to form one facility that functions as a nursing home with subacute rehabilitation options.

As an example of how a setting may relate to an outcome per the Donabedian model, a recent comparison between skilled nursing facilities and inpatient rehabilitation facilities found that patients who received rehabilitation at skilled nursing facilities had higher mortality within 2 years after discharge, though costs were lower.[19] Overall, it is not clear if one setting is truly superior to another, but as investigations into health care costs continue to garner interest, additional research into settings that provide quality patient outcomes at low cost will be performed.

In addition, there is no doubt that health care settings have dramatically changed in certain ways over the last 50 years. Post–acute care facilities grew in both the number of facilities and costs to Medicare, though both have slowed over the last decade.[20] Per the Centers for Disease Control and Prevention, the number of hospitals in the United States declined by about 22% between 1975 and 2014. This translates to a decrease of about half a million hospital beds.[21] Concurrently, the number of outpatient visits to practices associated with hospitals has quadrupled.[22] With this shifting landscape, it is important to keep in mind that the majority of health care is delivered in the outpatient setting. A study by Green and colleagues estimated that, while a fifth of the US population will visit a physician in the ambulatory setting, less than 1% of the population will be hospitalized. Notably, less than 0.1% will be hospitalized in an academic health center or a hospital associated with a medical school.[23]

With the predominance of health care occurring in the outpatient setting, it is imperative to examine some of the changes that have occurred in that setting in the United States that have affected quality of care. Private practices are defined as professional businesses that are independently owned and not owned by a larger company, such as a hospital, or by the government. The total number of private practice organizations has been decreasing for decades. By 2016, the percentage of physicians working in private practices was less than 50% for the first time.[24] The reason for this shift "has likely been accelerated by recent policy changes, such as quality and outcomes reporting, health information technology requirements, and the scale requirements needed to participate in accountable care organizations and other value-based purchasing programs."[25] In other words, the degree of administrative tasks necessary to prove that high-quality care is being delivered may be shifting physicians away from private practice. This does not mean that private practices provide lower-quality care. In fact, data suggest that smaller private practices have lower hospital admission rates compared to larger hospital-owned practices.[25] Many physicians continue to find independent practice highly rewarding. See the sidebar in this chapter by Dr. McAneny and the sidebar by Dr. Kridel for more perspectives on the rewards of private practice.

A second change is the interplay between the settings and personnel components of health care structure. While outpatient office visits are increasing and the majority of care continues to occur in the outpatient setting, the number of primary care physicians is also decreasing.[26] Primary care physicians are physicians who care for the general medical and preventive needs of the population; they can be family medicine, pediatric, or internal medicine physicians. Some include obstetrician-gynecologists in this group.

There is growing concern that the primary care medical needs of the US population will outgrow the ability of the medical workforce to provide care.

However, this concern has not gone without response. The need for more general medical ambulatory care combined with the need to broaden medical care beyond the scope of biogenetic factors alone led to the development of the patient-centered medical home. Recognition is growing that social and environmental factors, as well as individual behaviors, contribute to 60% of premature deaths.[27] The patient-centered medical home movement is the result of over 40 years of effort to redesign the primary care setting to help address these social and environmental factors, as well as provide more comprehensive ambulatory care. Theoretically, a coordinated effort to treat patients on multiple levels will create a healthier population and allow for a shrinking workforce of physicians and advanced practice providers to manage a larger population of patients. Patient-centered medical homes are defined as a medical office that provides (1) team-based care, defined as two or more clinicians working together to provide care; (2) a partnership and personal relationship developed and maintained over time and directed toward care for the whole person; and (3) enhanced access to care, coordinated care, comprehensive care, and a systems-based approach to improving quality of care.[28] This model has also expanded to include some specialty care practices.[29]

It should be noted that in order to develop patient-centered medical homes, many clinics began to incorporate care coordinators, social workers, and patient navigators into their clinical sites to fulfill the requirements of providing comprehensive, coordinated care that included care for social determinants of health factors.[30] Therefore, major personnel changes were required to make the development of patient-centered medical homes possible. While it is not entirely clear that the medical home has resulted in better patient outcomes, it is clear that patients and staff are more satisfied with the care being delivered.[28] Today, patient-centered medical homes have become integrally embedded in the outpatient setting.

C. Financing

The patient is medically ready for discharge, and the social worker is now contacting inpatient rehabilitation centers to determine which ones are in-network with the patient's insurance.

The financing of health care is a major structural component that should not be overlooked. Consider again the example case in this chapter. The patient has Medicare insurance. Medicare is a federally funded insurance program for individuals who are older than 65 or who are younger than 65 and permanently disabled or diagnosed with amyotrophic lateral sclerosis, end-stage renal disease, or a condition that resulted due to a hazard exposure from an emergency declaration area after 2009.[17] Since the patient in this chapter's example case is older than 65, she has qualified for Medicare.

There are multiple different components of Medicare. Part A will provide financial coverage for inpatient stays. Part B will provide insurance for outpatient visits. Part C allows individuals to get additional private insurance, which may give them even better insurance coverage. Part D provides financial support for prescription drugs.[17] It is not

unusual for individuals to have certain parts of Medicare but not all. Parts A and B of Medicare are considered "original" Medicare, but part D is additional coverage that requires an additional cost per month. Therefore, not all individuals can afford Part D Medicare and may not receive insurance to help pay for prescription medications. This is a substantial problem given that in 2015 the average annual cost of one drug used to treat a chronic condition was $5807.00.[31] The example case describes a common scenario of a patient needing to apply for Medicare Part D in order to help cover the costs of medications.

Separate from Medicare is Medicaid (Table 4.2). Medicaid is a jointly funded federal and state insurance program. Americans who are parents with dependent children, pregnant women, seniors, children, and individuals with disabilities who have incomes below a certain threshold will be eligible for Medicaid. Each state is allowed to choose its own threshold, which is some percentage below the federal poverty line.[17] When the Affordable Care Act was passed, it attempted to mandate an expansion of Medicaid to any individual with an income less than 138% of the federal poverty level. However, that was ruled to be unconstitutional, and therefore each state was allowed to decide whether or not to expand Medicaid.[32]

TABLE 4.2

Medicare and Medicaid Compared

Medicare	Medicaid
• Federal program • Basically the same everywhere in the United States • Run by the Centers for Medicare & Medicaid Services	• Federal-state program • Varies based on location • Run by state and local governments within federal guidelines
Insurance program	Assistance program
Medical bills are paid from trust funds that those covered have paid into	Paid for by public funds collected through taxes
Serves primarily people over age 65 years regardless of income. Also serves younger people with disabilities and those with certain medical conditions	Serves low-income people of every age
Patients pay part of costs through deductibles. Small monthly premiums are required for nonhospital coverage	Patients usually pay no part of costs for covered medical expenses. A small copayment is sometimes required

From: Department of Health and Human Services. What is the difference between Medicare and Medicaid? Available at: https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html. Accessed November 7, 2019.

Alternative to state and federal insurance, many Americans receive insurance from their employers via private insurance companies. Private insurance companies may have a specifically defined network. The network is composed of hospitals and ambulatory offices, including private practices, that have made contracts with that specific insurance company for certain rates of reimbursement for each service

provided. An out-of-network provider would be a hospital or ambulatory office that has no contract with that particular insurance company, potentially resulting in higher costs. The cost of health care in the United States is covered in more detail in Chapter 14.

In an effort to combat rising costs, insurance companies have attempted several different plan designs. Health maintenance organizations (HMOs) are insurance plans that allow beneficiaries, or individuals with that insurance, to see only physicians who are in-network. Primary care physicians may be assigned by the HMO, and access to subspecialists is only via referral from a primary care physician. Alternatively, preferred provider organizations (PPOs) are insurance plans that allow individuals to see physicians who are out-of-network but at a higher expense than those physicians who are in-network. In addition, referrals to subspecialists do not have to go through a primary care physician. Medicare beneficiaries may be a part of an accountable care organization (ACO), which is a group of health care providers that is accountable for the quality, cost, and care of the beneficiaries.

Overall, it is not clear that any of these organizational structures actually improve patient outcomes,[33] but it is clear that individuals without insurance have significantly worse health outcomes compared to those who do.[30] While the number of uninsured Americans has decreased since the Affordable Care Act, according to the United States Census Bureau there remained over 28 million uninsured Americans in 2017.

D. Equipment

The patient is transferred from the hospital to the rehabilitation center via ambulance. A discharge summary accompanies the patient. There is no communication between the hospital's electronic health record (EHR) and the rehabilitation center's EHR.

The largest change in equipment in the health care setting in recent history has undoubtedly been adoption of the EHR. With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act of 2009, health care facilities in the United States were mandated to transition away from paper medical records and to institute EHRs. According to the National Center for Health Statistics, by 2017, 86.9% of office-based physicians and 96% of hospitals used some sort of EHR compared to 34.8% and 50%, respectively, in 2007.[30] The hope was that the implementation of the EHR would be a structural change that would significantly improve patient outcomes by reducing medical errors made as the result of documentation that was sloppy and difficult to track and transmit. However, the data are not clear. According to one systematic review, EHRs improved the structure aspect of primary care clinics by eliminating records that were illegible; however, it was not clear that any patient outcomes actually improved.[34]

At this point, the systems thinker will likely see an emerging theme. While advancements in one component of structure may be intended to have large, positive effects on patient outcomes, without adjustments in other areas of structure or process to help facilitate the change, the effects are likely to be limited.

III. Processes within the health care system

A. Transitions and coordination of care

At rehab, the patient has another fall. There is concern she may have re-fractured her hip. She is transferred back to the hospital. An urgent consult is placed to orthopedic surgery, and surgery is planned for the next morning at 7:00. The patient is admitted to the orthopedic surgery service, with internal medicine as a comanagement service.

Comanagement is a model of care that allows surgical teams to take care of patients with multiple medical issues and continue to remain the primary service for admitted patients. In this type of care, the hospitalist follows the patient as a consultant throughout the hospitalization but is permitted to place orders directly, based on an agreement between departments. Such agreements also typically involve protocols for common, high-risk situations, such as traumatic hip fractures in the elderly. In this example, the hospitalist will not be limited to treating a particular medical issue from a narrow consultation but rather will ensure that the patient's multiple medical issues are appropriately transitioned from outpatient, through the stress of surgery and recovery, and back to outpatient again. At the same time, any acute issues that could have a significant effect on surgical outcomes can be addressed. On the surgical side, coordination of care between teams that typically work together is not fragmented. The surgical team continues to have the same physical therapist, nursing staff, and care coordination team members as it would normally. Various populations have shown differing effects of comanagement, but typical benefits are shortened length of stay[35-37] or increased likelihood of return to the community,[38] and surgeon satisfaction.[39]

B. Shared decision making

After surgery, the patient recovers well. She did not like the rehabilitation center she was sent to and requests to be allowed to go straight home. Her physicians and other health care professionals express hesitation about her safety given her history of two serious falls. The patient is steadfast that she will not go to a rehabilitation center, though she certainly understands the risks of falling. She asks if she could go to her nephew's house, where she can receive 24-hour care and home physical therapy. The physician agrees to this plan.

Shared decision making is the process by which clinicians and patients "share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences."[40] Shared decision making has become a foundational component of patient-centered care over the last 2 decades; however, it was not always a process that was part of the health care system. Previously, paternalistic medicine, or physician-driven decision making, was a more common practice. While there is significant debate about the role of medical paternalism,[41] there is no doubt that shared decision making is a process that is actively present in today's health care system. Future physicians and other health care

professionals will undoubtedly encounter scenarios, such as the one described in the example case, in which shared decision making will be utilized.

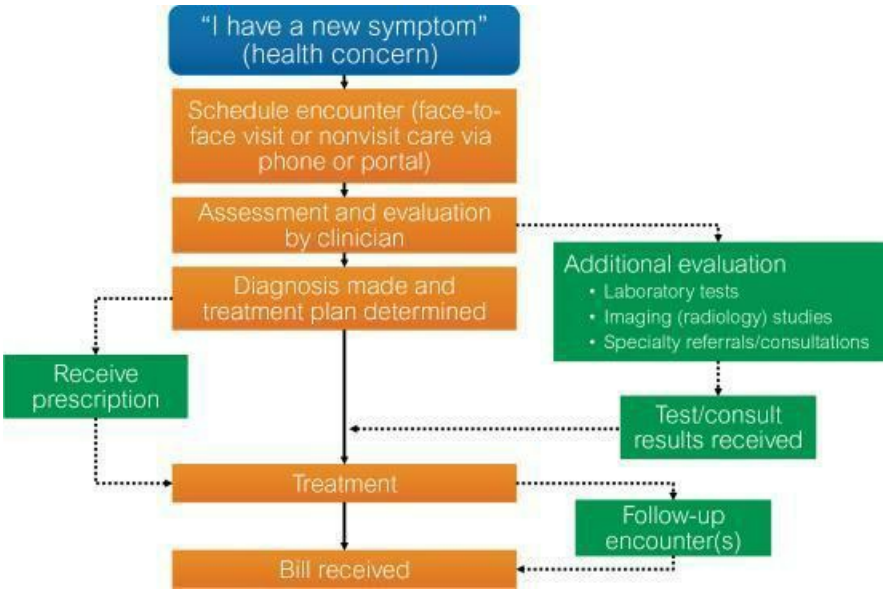
As the patient prepares for discharge, the provider is working with the care coordinator and social worker to ensure that home physical therapy is set up and that she will be able to afford all her medications at discharge. The provider also speaks with the primary care physician to update her on the patient's condition.

C. Coordinated care

Coordination of care is a necessity. Physicians and other health care professionals are working on interdisciplinary teams daily to ensure that patients' medical care is continued safely after moving from one medical setting to the next. As already discussed, care coordinators, social workers, and patient navigators have been integrated into innovations such as the patient-centered medical home to ensure that these transitions between settings are successful. In addition, ACOs are now employing care coordinators to help provide quality care and reduce costs. As of 2017, 76% of ACOs had already implemented care coordinators as a strategy to help reduce costs, and another 19% planned to implement care coordinators.[42] The ACOs described the top five reasons care coordinators were employed as (1) to follow up after hospital discharge, (2) to coordinate with post–acute care providers, (3) to coordinate with community resources (such as transport resources), (4) to coordinate with family and caregivers, and (5) to schedule follow-up care.[42] There is hope that significant investment in coordinated care will produce a positive effect on health outcomes, but it is not yet clear if that is the case.[43-45]

IV. Clinical microsystems

In addition to the basic structures and processes of care, health care professionals must be able to visualize the delivery system as four levels, or as four concentric circles. Patients (the population for whom the system is responsible) and their families are appropriately in the center of this model. The subsequent levels (larger circles beyond the center) are microsystems, mesosystems, and macrosystems (see Fig. 3.3). The microsystem most familiar to patients is the team of physicians and other health care professionals who provide care and support for patients in a clinic or during a hospitalization. This clinical microsystem (commonly called the care team) typically consists of physicians, nurses, therapists, and other professionals who directly contact patients. These microsystems also include administrative support (desk staff, secretaries) as well as the processes (e.g., ensuring results of laboratory tests are provided to patients) needed to ensure good care. Mesosystems are the collection of microsystems; they include the clinical programs and centers that are often part of larger organizations. For example, there are often many individual microsystems or care teams within one hallway of a larger mesosystem (outpatient family medicine clinic). Macrosystems (such as hospitals, multispecialty group practices, and integrated health systems) are the larger collection of mesosystems. The ideal is for patients to interact with each level seamlessly as they engage the system from start to finish.

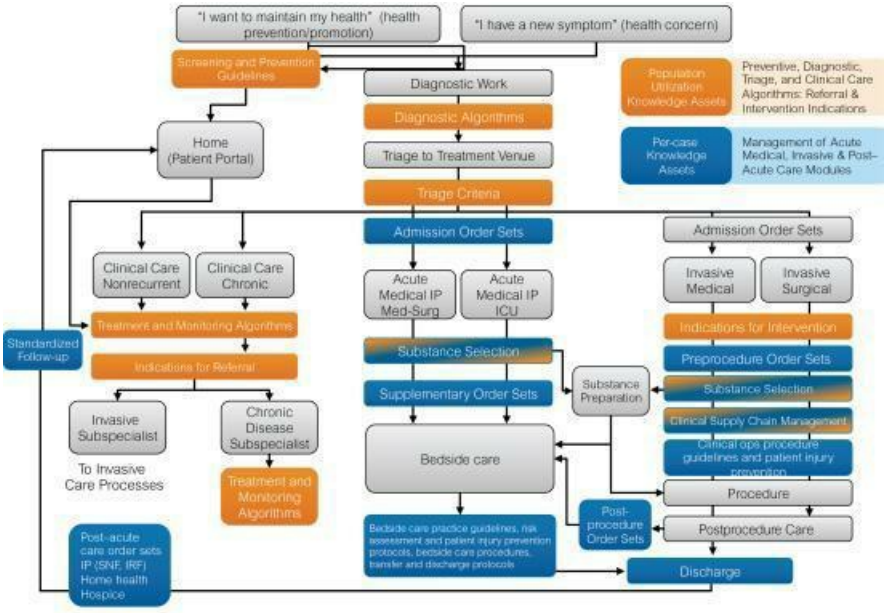


• **FIG. 4.3** Patient's View of the Health Care Encounter. *Source:* (Created by Stephanie R. Starr, MD, and Robert E. Nesse, MD. Reprinted with permission.)

Consider this common example as a way to better understand one of many processes in health care and the different levels of the system. A woman decides to contact her primary care clinic because she has a new symptom and wants to schedule a visit with

her physician. She starts by calling the desk staff (or sends an Internet-based portal message) to schedule an appointment. On the day of the appointment she is greeted by a receptionist and escorted to a room by another team member, who often obtains vital signs and clarifies the reason for the visit. Next, the physician conducts the office visit and, if needed, orders additional tests and images or a consultation or both to make an accurate diagnosis and appropriate treatment plan. If a prescription is written, the patient next encounters the pharmacy team (another microsystem) to get information regarding the drug and have the prescription filled. If her symptoms resolve, she may not reconnect with the system until the next time she has a health concern or preventive services are due. If tests are ordered, she needs to learn the results of the tests, and how to best manage her condition and (if necessary) schedule follow-up care. If she requires hospitalization, her physician will transfer her immediate care to an inpatient care team (another new microsystem involved in her episode of care).

The steps in the process of contacting a primary care clinic to be seen for a visit, have testing completed, fill a prescription, and make plans for follow-up care may appear relatively straightforward to many patients. Fig. 4.3 is one representation of our patients' view of processes across our current health care system. However, health care professionals and the nonclinical teams that constitute the mesosytems and macrosystems of care delivery must cope with the complexity of the current system in a way most patients do not see. Fig. 4.4 is one representation of the current health care delivery system as seen by many individuals working within the system. This chaotic flow diagram is representative of most current systems, which were not deliberately designed and do not align with patient priorities or the Triple Aim. It is understandable that the complex system represented by Fig. 4.4 often frustrates and baffles professionals as they deliver care. Even where exemplary health care professionals or microsystems exist, they are often not optimally integrated with other microsystems.



Modified with permission from Health Catalyst.

• **FIG. 4.4** A System View of the Anatomy of Health Care. *ICU,* Intensive care unit; *IP,* inpatient; *IRF,* inpatient rehabilitation facility; *SNF,* skilled nursing facility. *Source:* (Modified with permission from Burton DA. The anatomy of healthcare delivery model: how a systemic approach can transform care delivery. Health Catalyst; 2014. Available at: https://www.healthcatalyst.com/anatomy-healthcare-delivery-model-transform-care.)

One common example is poor integration across microsystems during times of patient handoffs (such as dismissal from the hospital team to the outpatient team or from the emergency department to the intensive care unit). Those who receive care must be supported as they navigate in this system or their care will suffer. While health care will remain complex, those within the system can only improve it if the system is oriented around patients. Health care professionals must work in multidisciplinary teams to modify processes to center on patients and their quality of care. Chapter 7 provides more detail regarding methods used in process improvement.

Each microsystem has numerous processes or flows of work that are part of daily work and routines. Health care improvement projects (discussed in detail in Chapter 7) often focus on these processes of care, especially when decreased variation in the process has been linked with better patient outcomes. Transitions of care processes across clinical microsystems are particularly important to address to improve the patient experience and identify and close gaps in care delivery. Many clinicians and patients have experienced and understand typical transitions such as the transition from hospital care to home care. These transitions often occur within an established health care setting (e.g., from an emergency department to an intensive care unit). Transitions also occur across health care settings (e.g., from a hospital inpatient unit to the outpatient setting or from a provider visit to ongoing nonvisit care conducted between patients and population health care teams). Patient-centered medical home models also generate transitions between traditional health care, individual care locations, and community partners (such as public health departments, schools, and health clubs). Patients are often more vulnerable to errors and unsafe care by the system during these times of transition due to poor exchange of information and the complexity of transitions that accompany an integrated high-value health care system; diligent attention is needed to deliver seamless care. New information systems such as EHRs that share information simultaneously across multiple settings are increasingly essential to prevent errors and duplication of work.

V. Future directions

Many have noted that physicians are progressively being asked to spend more time as coordinators of the total care provided. In the short term, it is unlikely that this role, or the time spent on coordination of care, will decrease. While many of the processes of care, such as coordination of care, will always be a part of the clinician's role, the settings in which medical care is delivered may change significantly. In the past 10 years, the role of inpatient medicine has faced several experiments in care delivery. One of the most promising has been "hospital at home," a return to physician care models from the early 20th century. In this style, a general practitioner, generally a hospital-based physician, sees a patient in the emergency department and allows the patient to go home to receive daily care, or if the patient worsens, to be transported to the hospital. Similar to home health nursing or outpatient parenteral antimicrobial therapy, there are significant benefits to having daily physician and nursing care in a patient's home: decreased risks of hospital-acquired infections, delirium, and falls. Multiple small observational studies in select populations have shown safety, but large meta-analyses[46,47] have been limited due to significant variation in the studies. To date, this remains an intervention on the vanguard of development.

Likewise, telemedicine, or medical care delivered virtually, continues to increase. Telemedicine is particularly appealing because of its ability to bring medical care to previously unreachable areas and the potential for it to help reduce health care costs.[48] With the progression of telemedicine and innovations like the Hospital at Home, developed by the Johns Hopkins University Schools of Medicine and Public Health and tested at medical centers across the country, it is possible that the setting of health care will return more toward patients' homes, and away from physical offices.

VI. Chapter summary

The patient arrives at her nephew's home. In the last 2 weeks, she has been cared for by 10 physicians, two advanced practice providers, one care coordinator, one social worker, and a dozen nurses and physical therapists. She has received medical care in four different settings: a primary care office, the hospital, the rehabilitation center, and her home. Through shared decision making and coordination of care, she is on her way to a successful recovery.

In the Donabedian model, structures and processes combine to have effects on patient health outcomes. Various structures and outcomes have been defined, but the overarching theme has been that innovations in one component of the Donabedian model are not necessarily sufficient to create a large, positive effect on health outcomes. It is far more likely that by understanding each of the individual components, the systems thinker can combine innovative components into a comprehensive model that generates an innovative health care system—one that can improve outcomes for patients across the United States.

Case study

You are working with a primary care physician. One of the patients you see that day has just been discharged from the hospital 2 days prior. The patient is not clear what occurred during his hospitalization, and he brings a discharge summary with him that states "Primary diagnosis: atrial fibrillation—please discuss anticoagulation with PCP." The patient asks you what anticoagulation is and whether or not he needs it. You explain the reasoning behind anticoagulation, and the risks and benefits, and after hearing from the patient that he does not want frequent blood draws, you decide together to start apixaban. You inform the attending of this conversation, who then talks with his care coordinator to ensure that the patient's insurance will cover the cost of apixaban.

Questions for further thought

1. This case study provides an example of paternalistic medical decision making. True or False?
   Answer: False. This case demonstrates shared decision making, which is a process in the health care system that leads to management/treatment decisions. What would this interaction look like if it was an example of paternalistic medical decision making?
2. Explain why discussing this example case with a care coordinator is essential.
   If the patient is unable to afford the medication, then he will not be able to take a medication that could have significant positive effects on morbidity by preventing stroke. Therefore, it is essential that the cost factor be explored prior to the patient leaving the office. Consider how and in what situations you would work with a care coordinator. When is a care coordinator necessary? When is a care coordinator not needed?
3. The discharge summary is an example of a
   a. Structure
   b. Process
   c. Outcome
   d. A and B
   Answer: D. The discharge summary is an example of communication between the hospital clinician and the primary care physician, and therefore would be a process. However, it is also a part of the EHR and therefore is a part of structure. Not all components of a system may fit neatly into one category. Consider what other components of the health system may fit into more than one category. How does this change your view of these components?
4. Do you think this visit could have been completed via telemedicine?
   It is possible that conversations like this could take place via telemedicine since they do not necessarily require anything that has to be done in person, such as a physical exam or labs. What do you think this visit would look like if it took place via telemedicine? However, it is important to note that some patients may prefer in-person visits.

ASK AN EXPERT ABOUT PRIVATE PRACTICE

Barbara McAneny, MD

What is independent (private) practice like?

An independent practitioner must want to be in charge of their own life and work. It helps to have an entrepreneurial spirit, since you become an owner of a small business. With the ability to design your work environment to best suit your patients and your partners, you also gain direct responsibility for your own actions and your patients' outcomes. Team-based care is more natural, since you select staff members who share your vision, then train and collaborate with your employees to serve your patients

well. You have to trust your partners and share best practices, so that you know your patients receive consistent care when you cover for one another. You have to treat partners, staff, and patients the way you want to be treated.

Innovation is easier in an agile independent practice. I recognized that hospitalizations related to side effects of treatment resulted in lower quality of life and posed financial hardships for my patients. I created processes to intervene early in the development of side effects and avoid hospitalizations. I realized that I was saving a lot of money for the system, and I was able to frame those processes as the COME HOME program. This garnered a financial award for health care innovation from the Centers for Medicare & Medicaid Services and helped to change oncology practices of other groups as well. That would never have happened if I didn't have partners who trusted me or if I had been bogged down getting approvals from hospital committees!

When you run your practice effectively, independent practice can offer your patients several benefits. These doctors are readily accessible to their patients and know them well, so patients may avoid visits to the emergency department for issues that can be managed in the office, and handoffs between providers (a potential source of error) are minimized. Independent practitioners are highly aware of the impact that accurate documentation and preauthorization have on what insurers cover, so they are careful to avoid having patients getting stuck with bills. Due to differences in reimbursement, patient copays are often lower, hospital facility fees are avoided, and costs of testing may be lower in the independent setting. You can refer patients to whomever you think will do the best job and get along best with a given patient. If a patient has a financial hardship, you can often write off copays or chose to deliver free care, as long as these actions are in compliance with applicable insurance contracts. Such independence allows you to form strong relationships with your patients and fosters a sense of connection to your community.

You set your own priorities. Your salary as an independent practitioner is what you earn after expenses. No one gives you raises or bonuses, you have to earn them. If you want more money, work harder and take less vacation; if you want to have more vacations, or if you want to reduce your caseload so you can spend more time with each patient, be prepared to earn less. Other than licensure and insurance companies, you only answer to your partners for your actions, and no one else. As a partner, you gain equity in the practice, which has to be paid to you if you relocate or retire. You also gain job security—you cannot be fired without a supermajority of the partners, unlike contracted employment, which often has a surprisingly short-term termination clause by which you can be fired without cause (for instance, if an organization is downsizing). You can be creative and agile in advancing care delivery. If an independent practice wishes to buy new equipment or add a new service, they just evaluate their options, figure out if they can afford it (e.g., develop a business plan), and then do it.

Do I need different skills in health systems science to be successful in independent practice?

I think you have to like business to do a good job, but it grows on you! Developing

negotiation skills helps you to reach common decisions with your partners and to contract effectively with affiliated health care systems and insurers; these skills are also useful in your personal life. You will need an accountant to help with taxes and setting up the cash flow, and an office manager to develop and monitor effective processes. If you are joining an established practice these roles will already be in place, but it is important to understand operations for yourself. These are similar skills that you would need if you wanted to assume a management role in an academic department or hospital.

There are lots of places to learn these skills—local medical societies, night courses, the Medical Group Management Association, the AMA, and so on. Join groups of practices in your specialty and share best practices. Participate in the Contractor Advisory Committees so that you understand Medicare. Take a course on billing and coding. I think it is wise to take some basic business courses—health law, accounting, human resources. You don't have to do it all at once, and you do not necessarily need to pursue a degree. You certainly need to focus on leadership skills, since your partners, staff, and patients are all relying on your vision and execution.

Essentially, independent practice is just that—you have greater independence (and responsibility) to structure your part of the health care system to optimize the experiences of your patients, your team, and yourself. If you have a vision about how to provide better care to patients and their families, independent practice offers you the flexibility and control to bring your ideas to fruition.

Barbara McAneny, MD, is a medical oncologist who served as the 173rd president of the American Medical Association (AMA) from 2018 to 2019, has been a member of the AMA Board of Trustees since 2010, and is the founder and board chair at the National Cancer Care Alliance. McAneny is a managing partner of the New Mexico Cancer Center in Albuquerque, where she pioneered the Community Oncology Medical Home (COME HOME) model to give cancer patients medical services when and where they needed care, rather than when or where it was convenient for the people providing the care. She has embraced her role in physician leadership as the health care sector shifts from fee-for-service medicine to value-based care models.

IS PRIVATE (SOLO OR GROUP) PRACTICE FOR YOU?

Russell W. H. Kridel, MD

As reimbursements decline, red tape and daunting regulations increase, and external interferences interpose themselves between patients and their physicians, physicians have to decide whether private (solo or group) practice is where they will blossom or whether they might be happier in an employed model with a hospital or integrated system. Whether in a private or an employed situation, physician burnout and decreased practice satisfaction are major issues. Physicians spend more time in complex documentation and administrative interactions and less time with patients, despite the fact that more patients have multiple chronic diseases demanding face-to-face physician-patient time.

Numerous surveys have shown that physicians have greater satisfaction in their practice if they have enough time to spend with patients, have an impact on the health

of their patients, and retain autonomy in decision making with patients and in the management of their practice circumstances. Physicians as a group do not want policymakers or administrators to dictate medical decisions. Physicians know what will work best for their patients. All physicians are losing some of that autonomy today and feel somewhat powerless in coping with the red tape, regulations, and documentation required by insurance companies and the government. Some of those administrative hassles are diminished in an employed practice, but there is a great loss of autonomy as administrators, deans, and hospitals control hours, numbers of patients seen, where referrals go, whether or not purchases will be made, and the like. There may be a guaranteed income/salary in an employed situation, but that can be ratcheted down when contracts come up for renewal. And if the new figures are not favorable, a noncompete clause can force the doctor to leave town rather than set up practice in the same city.

Running a practice is not a walk in the park and requires attention to fine details as well as keeping a focus on short- and long-term goals. But there are rewards for the successful practice, and it's not just financial; it's what I call "freedom from arbitrary power." I have been in private practice for over 30 years, and I still enjoy what I do immensely because of the autonomy that I have built into my practice. My colleagues employed in academic centers or by hospitals voice to me the frustrations they meet daily, where bureaucracy, resistance to change, slowness to act, and hesitance to innovate are rampant. If I want to buy a special instrument or device in my private practice, I don't have to go through a committee and months of meetings before I get the go-ahead. With online retailers, I can have that instrument or camera or device in my office in just a few days. True, I am not insulated from the potential that the purchase may not produce income, and true, the money left over to pay me at the end of the month will be less—but the choice was mine.

In private practice, I am free to refer my patients to any doctors I choose in the community based on their quality of care; I am not restricted to only refer to those in my hospital or system. If I can get an MRI done for a patient for $500 in one radiologist's private office, I don't need to send the patient to the hospital for an MRI that costs the patient $2500! If I want to take 4 weeks' vacation or take a day off next month, I don't need to ask permission and apply months in advance. On the other hand, if the computer goes down, I have to pay to get it fixed.

In private practice, I can act quickly, and I live or die by my decisions. I can hire a new employee or fire a nonproducing employee today. I can accept or reject an insurance contract without having to agree with what the institution has decided. I can correct an intraoffice system error today. My salary is determined by how hard I work; once I have paid all the expenses, some months I may not earn as much as others. Yes, I made many mistakes as I started out, but through trial and error and with training and assistance from qualified practice managers, I have learned the wise tenets that make a private practice thrive.

Sure, there are hassles in running a private practice, and it is true that most physicians have little training in running a business, which is so important and integral in a private practice setting. Success in practice involves so much more than expertise

in medicine. Just as we as physicians realize that lifetime education in our medical or surgical disciplines is essential, we must keep up to date in recognizing and adapting to the myriad of external changes foisted upon us by third-party payers, the federal and state governments, and their legislators. We must learn from the successes of consultants in medical and nonmedical fields who provide different perspectives that can successfully be applied to medical practice models.

Teams in health care delivery work well in the hospital and in the office. Through delegation of tasks and leveraging the abilities of nonphysician providers, a physician's time can be optimized. Similarly, to make a practice work, an office team must be developed and coordinated, and all staff must have a feeling of ownership and mutual respect. All employees must be superstars, and the selection process is key. Prospective employees must have the passion, the personality, the initiative, and the desire to grow and learn on the job. As the old adage goes, a great staff can make a mediocre physician shine, and a mediocre staff can make a great physician look ordinary. There have to be mission goals and action plans that all team members understand and embrace. In my practice, we have weekly team meetings to briefly reiterate a few of our guiding principles on a rotating basis so we all maintain a clear picture of our obligations to patients, their safety, their satisfaction, and our practice goals.

In private practice, many decisions need to be made but you make the call, not someone else—not the dean or department chair if you are in academics and not the administrator if you are working for the hospital. Some of the administrative demands created by external regulations are daunting and resource-intensive for an independent practice. The AMA advocates for physicians and provides resources to help physicians understand regulatory requirements. Interactive practice transformation tools such as the AMA's Steps Forward (https://edhub.ama-assn.org/practice-transformation-topics) provide pragmatic tips for successful practice management.

For me and for many, the freedom that private practice affords and the autonomy it preserves are more than enough reason to not be employed by a system that tells me what to do and makes medical decisions for my patients.

Russell W. H. Kridel, MD, is a Houston-based double board-certified facial plastic and reconstructive surgeon in private practice with more than 30 years of experience. Dr. Kridel serves as a clinical professor of the Division of Facial Plastic Surgery at the University of Texas, Houston, and is a past president of the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS). He serves on the American Medical Association (AMA) Board of Trustees and is secretary of the board, which places him on the Executive Committee. In Texas Dr. Kridel has held numerous leadership positions at the state and local levels.

Dr. Kridel's interests have always been community-oriented. In 1995 Dr. Kridel founded The Face Foundation, which provides surgical care at no fee to financially disadvantaged individuals who are survivors of domestic violence. During his tenure as president of the Harris County Medical Society, Dr. Kridel created the Committee on Personal Responsibility and the "Shut Out Sugar" campaign to support physicians in addressing obesity. He also served for 2 years as president of the Texas Medical Association Foundation, which has improved outcomes for many through its immunization programs, science teacher awards, and minority scholarships.

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Value in health care

Neera Agrwal, MD, PhD, Steven Yuen, MD, Natalie Landman, PhD

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In this chapter

Value in health care is a strategic priority in the United States. All members of society want a health system that provides care that is highly effective, safe, patient centered, and affordable. This chapter defines value in health care, explores what value means to all stakeholders in society, and discusses the barriers to high-value health care. While on average the US health care system falls short on value, many institutions and health care systems in the United States are championing high-value initiatives. This chapter highlights some of these high-value systems that are providing much-needed innovations in the field of health care delivery and strategies physicians can use to promote high-value care.

Learning Objectives

1. Explain the concept of value and how it applies to health care.
2. Review the essential components of a high-value health care system.
3. Summarize the current state of value in US health care.
4. Discuss key barriers to patient-centered, high-value health care.
5. List strategies physicians can use to promote high-value care.

"Achieving high value for patients must become the overarching goal of health care delivery. This goal is what matters for patients and unites the interests of all actors in the system. If value improves, patients, payers, providers, and suppliers can all benefit while the economic sustainability of the health care system increases."

—Michael Porter, PhD[1]

I. Introduction to value in health care

As described in Chapter 3, payment for health care is moving from the traditional fee-for-service and volume-based reimbursement to one that is value based, in part because of mandates from the Department of Health and Human Services. The National Academy of Medicine (NAM; formerly called the Institute of Medicine, or IOM) has defined high-value care (HVC) as the "best care for the patient, with optimal results for the circumstances, delivered at the right price."[2] All health care stakeholders want HVC, regardless of whether they are patients, health care professionals, health care delivery institutions, or payers. Therefore HVC needs to span the full health care continuum from the macrosystem (national and local health care systems) to the microsystem (the team providing care at the individual patient level). Much of medical training and practice has historically focused on acquiring medical knowledge, ordering and interpreting tests, and prescribing medications. With the ongoing changes in the health care delivery environment described in Chapter 3, there is a growing call for HVC education models and competencies for health professions training.

II. Knowledge and education gaps in high-value care

In order to improve value in health care delivery, we must improve the education for those providing health care. Gaps in this knowledge base exist throughout the spectrum of health care professionals and across the continuum of physician training. The gaps in undergraduate medical education and graduate medical education have been widely recognized and are described by Skochelak[3] and others. Fifteen US and Canadian reports published over a decade uniformly called for a significant change in education practice to align with the goals of high-value health care delivery. The gaps in HVC education have become wider over time as the pace of change in medicine becomes steeper, and educators are working to modernize their curricula.[4]

Ryskina and colleagues conducted a survey of US internal medicine residents' knowledge of HVC. While the residents felt they were aware of the principles of HVC, only one in four reported knowledge of cost information, and fewer than one-half discussed costs of care with patients.[5] A study from Kaiser Permanente surveyed leaders regarding the ability of newly graduated physicians within their divisions to practice within a highly organized care delivery system. The survey included competence in care coordination, continuity of care, clinical information technology, leadership, management skills, and systems thinking. Thirty percent to 50% of those surveyed felt that this cohort of physicians showed significant deficiencies in these core competencies, indicating a lack of training in health systems science in graduate medical education.[6]

The training environment appears to be critical in the development of physicians who can practice HVC. Sirovich and colleagues assessed the ability of first-time test takers of the American Board of Internal Medicine certifying examination to recognize HVC practices. They noted that internists trained in lower-intensity medical practice regions were more likely to recognize when conservative management was appropriate, although they remained capable of choosing appropriate aggressive therapies when indicated.[7] A similar analysis by Chen and coworkers demonstrated that physician training location and local practice patterns determined how physicians spent resources throughout their careers. Those who trained in lower-spending regions continued to spend up to 7% less during the first 15 years of their practice, compared to their counterparts who trained in higher-spending regions. This difference did decrease with time, and by 16 to 19 years of practice, there appeared to be no spending differential.[8]

Ryskina and associates found that one determinant of internal medicine resident trainees who participated in HVC practices was their institutional leaders' investment in and support of HVC teaching. Those residents who trained in a program with a formal HVC curriculum were more likely to report involvement in HVC quality improvement (odds ratio, 1.83). Likewise, residents were more likely to discuss HVC principles such as harms, benefits, and cost of care if the faculty had undergone training in HVC faculty development (odds ratio, 1.21).[9] The influence of learning environment

and awareness of HVC practices is observed at the undergraduate medical education level as well. Leep Hunderfund and colleagues surveyed 3395 medical students, examining their attitudes toward cost-conscious care. They found that 90% of the students believed containing costs is the responsibility of the physician, although many also reported barriers in doing so. Not surprisingly, students who trained in regions of higher health care intensity (defined by medical specialty visits as well as hospitalization days) also reported observing fewer cost-conscious role-modeling behaviors in their mentors.[10] These studies underscore the importance of training health care professionals early in their careers about health care policy, health care costs and financing, and the financial burdens to patients and society.

Another key message in health professions training should be that HVC is not simply a formula for cost containment. It is a recipe for improved health care outcomes.[11,12] The Accreditation Council for Graduate Medical Education has defined six general competency domains for physician education: medical knowledge, patient care, professionalism, interpersonal and communication skills, practice-based learning and improvement, and systems-based practice. Weinberger proposed that providing high-value, cost-conscious care should be a critical seventh general competency for physician training.[13]

Educating health care professionals to provide HVC is not a simple task, in part because it requires mastery of many competencies. The University of California, San Francisco, Center for Healthcare Value Training Initiative proposed 21 competencies in health care value that should be considered in the education of all health care professionals. These are defined by learner levels and include the core principles of health care delivery, financing, and organizations.[14] The American Hospital Association noted "that to work in a reformed health care environment, physicians need to develop skills to both lead and facilitate a care team, understand and use systems theory and information technology to improve quality and patient safety."[15] In order to meet these goals, the American Hospital Association recommends lifelong learning in HVC, starting in the medical school curriculum and continuing through residency and postgraduate practice.

One such curriculum that spans the entire educational and practice career has been developed as a collaborative effort by the Alliance for Academic Internal Medicine (AAIM), the American Board of Internal Medicine, and the American College of Physicians (ACP).[16] The AAIM-ACP HVC curriculum was launched in 2012, and although initially intended for internal medicine residents and fellows, it has been adapted for medical students and practicing physicians and could serve as a model for additional health care professionals. Other institutions are moving forward with curricula that address rising health care expenditures,[17] suboptimal health care metrics, overtesting, and shared decision making.[18] McDaniel and coworkers published a high-value rounding tool that may be used in teaching HVC principles at the bedside. Using a Delphi method, the authors identified 10 items that may be discussed at the bedside to promote HVC topics that focus on both costs of care and patient-centered goals.[19] As eloquently stated by Parikh and associates, "Tomorrow's physicians will find it difficult

to serve their patients and the public without understanding the economic effects of their decisions on all stakeholders."[20]

III. Defining value

Individuals expect value in their lives, whether buying consumer goods, such as a car, or purchasing a service from an airline or hospital. While some have argued that it is impossible to measure value in health care, there is increasing recognition that it can be measured and improved.

What constitutes high-value health care, and how is it defined? A widely accepted approach was proposed by the NAM in 2001 and includes six health system goals. Health care should be safe, timely, effective, efficient, equitable, and patient centered (STEEEP)[21]:

- *Safe:* Medical errors account for between 44,000 and 98,000 deaths per year,[22] and there is much room for improvement. Avoiding injuries to patients and eliminating medical errors is a crucial component of any high-value system.
- *Timely:* Patients should be able to access care as expeditiously as possible, with a premium set on reducing waiting times and potentially harmful delays in both evaluation and treatment.
- *Effective:* Health care organizations should provide the most up-to-date services following established guidelines and best practices. These services should be evidence based. Care that does not provide a clear benefit should be withheld to avoid unintended harm.
- *Efficient:* Waste in US health care is an important issue, with some estimates ranging between $500 billion and $900 billion of wasteful care provided each year.[23] Avoiding duplication and other sources of wasted equipment, supplies, and other resources is crucial to improving quality.
- *Equitable:* Care should be provided without prejudice to all patients regardless of individual characteristics such as gender, ethnicity, socioeconomic status, geographic location, or sexual orientation.
- *Patient centered:* Patients should be at the center of decisions affecting their health and well-being. Care should be taken to ensure that individual patient preferences and values are accounted for at each step in the decision-making process. Consumer-directed values of accessibility, service, effectiveness, and costs should be upheld whenever possible.

A system that is able to improve care in all of these domains will go a long way toward achieving HVC. As the NAM stated:

> A health care system that achieves major gains in these six areas would be far better at meeting patient needs. Patients would experience care that is safer, more reliable, more responsive to their needs, more integrated, and more available, and they could count on receiving the full array of preventive, acute, and chronic services that are likely to prove beneficial. Health care professionals would also benefit

through increased satisfaction from being better able to do their jobs and thereby bring improved health, greater longevity, less pain and suffering, and increased personal productivity to those who receive their care.[21]

The formidable goals put forth by the NAM have since been distilled into an actionable framework, known as the Triple Aim, by the Institute for Healthcare Improvement (IHI)[24]:

1. Improve the health of a defined population.
2. Enhance the patient care experience, including quality, access, and reliability.
3. Control and reduce the per capita cost of care.

The Triple Aim in practice would support a defined population, with a system optimized to do so. The system would provide coordinated care for individuals in the population, with access to up-to-date knowledge and evidence on effective care. The costs of doing so should be transparent, especially the costs over time both for the individual and for the population.

After establishing what kind of health care is desired by all (NAM STEEEP), as well as the high-level tactics to get there (Triple Aim), a common framework is needed to translate the vision and aspirations into a set of measures to (1) determine the size of the gap between the current and desired states, (2) create a plan for closing this gap, and (3) monitor the progress on the path toward a high-value health care system for all. This is where the concept of a value equation becomes particularly useful. While the specific metrics to measure value will vary depending on whose perspective is considered (e.g., patient, payer, provider) and the exact population of patients in question (e.g., asthma patients vs. diabetes patients), in the simplest terms, value can be defined as quality relative to costs.

Fig. 5.1 shows an example value equation. Quality forms the numerator of the equation and has at least three key elements: outcomes, safety, and service. Each of these elements is a multidimensional term that can include a variety of specific metrics that reflect stakeholder perspectives and the population of patients being addressed:

- Outcomes may include patient mortality, complications, functional status, and workplace productivity or consistent school attendance. The measures that fall under this term aim to capture the "effective" and "patient-centered" components of the NAM STEEEP vision. "Equitable" care also implies the goal of similar outcomes regardless of social determinants of health or other factors known to negatively impact health equity.
- Safety, one of the most important determinants of HVC, may include metrics such as infection rates, accidental falls, and medication errors. The measures included here are meant to reflect the "safe" component of STEEEP.
- Service may include patient satisfaction; waiting times to be seen by a given health care provider; access to a physician, a given treatment, or a procedure; and access to affordable insurance. The "timely" and "equitable" care

components of STEEEP are reflected in the measures that fall under the service term of the value equation.[25] "Efficient" is represented because service also includes minimizing unnecessary use of resources (including patient time).

$$\text{Value} = \frac{\text{Quality}\ (\text{Outcomes} + \text{Safety} + \text{Service})}{\text{Total cost}}$$

• **FIG. 5.1 The Value Equation.** *Source:* (Included with permission from Dr. Denis Cortese, Mayo Clinic Health Policy Center.)

The denominator of the value equation, "total cost," can be defined in various ways, for example, per line item of service, per visit, per episode, per disease, or per year. However, to determine greatest value, cost must be defined as the total amount spent per patient over the length of the condition being treated. This long-term view is essential, as in some instances higher costs in the short term actually lead to lower overall costs of treatment. Thus value in health care is defined as quality achieved per dollar spent for the entire course of the disease over time.

The following are examples of HVC that have initial higher costs but lead to higher quality and lower overall costs in the long term[26]:

- At the Intermountain Medical Group, outpatient mental health care is combined with primary care. Primary care physicians are empowered to provide treatment for more common mental health conditions such as mild or moderate depression, and several types of mental health professionals are integrated into primary care practices. Patients receive coordinated behavioral care, leading to improved outcomes. Although costs are higher up front, overall costs are lower due to reductions in emergency department visits and other care.
- The Mayo Clinic studied teams who analyze pathology evaluations of frozen specimens during breast cancer surgery to ensure that surgical margins are cancer free. While this process adds time in the operating room initially, it may prevent a second surgery. In a study of breast cancer lumpectomy surgery at 5 years after the procedure, the 30-day reoperation rate was 3.6% at the Mayo Clinic, compared with 13.2% nationally. Short-term costs were higher but overall costs were lower, thus promoting HVC.
- The MedStar House Call Program (MSHP) is a mobile care intervention that provides a "single, comprehensive source of home-based medical and social services for frail elders and their families" in the Washington, DC area. Core MSHP services include home-based primary care, 24/7 on-call medical staff, physician continuity to the hospital, intensive social services, and coordination of needed specialty and ancillary services. Despite intensive (and thus higher-cost) primary care services, a comparison of MSHP patient outcomes and overall costs with a matched set of controls showed that MSHP patients have similar survival outcomes at a 17% lower cost than control elders.[27]

The Centers for Medicare & Medicaid Services (CMS) Hospital Value-Based Purchasing Program uses a version of the value equation, with very similar dimensions (clinical care ≈ outcomes, safety ≈ safety, patient- and caregiver-centered experience of care ≈ service, efficiency and cost reduction ≈ total cost) to determine the value of care provided by a given hospital and, consequently, the size of the year-over-year update in hospital payments[28] (Box 5.1).

• BOX 5.1

Value-Based Health Care vs. Cost-Effectiveness Analysis

As high-value care (HVC) becomes a more prominent feature of the US health care system, it is often conflated with cost-effectiveness, a relative value analysis of different medical interventions. While both concepts focus on determining what we get (outcomes) for the money spent (cost), there are some key differences that warrant clarification. Those differences include the types of costs and outcomes considered by each approach but also, and most importantly, the frame of reference that characterizes each approach. As stated by Tsevat and Moriates, "CEA [cost-effectiveness analysis] generally considers costs and benefits from the societal or health care sector perspectives, whereas HVC is intended to adopt the patient perspective. As such, CEA is intended to inform coverage decisions at a group or population level and HVC is intended to be implemented at the level of clinician–patient interactions."[29] A detailed comparison between the two approaches is provided in their article ("Value-Based Health Care Meets Cost-Effectiveness Analysis").

IV. Value from stakeholders' perspectives

Physicians and other health care professionals who strive to provide HVC must consider the perspectives of the various stakeholders in the health care system. The health care system is a large ecosystem, ranging from the macrosystem to the local microsystem. An action by a specific entity in the system, whether a provider, a payer, or the patient, may lead to outcomes affecting quality and cost and have an effect on other stakeholders. Given the currently fragmented nature of the US health care system, the integration across components of the system is not optimized. The lack of synergy across systems means the definition of health care value can vary widely depending on whose perspective is being considered.[30]

Who are the players in our health care system, and what do they value? The health care system can be defined as a complex, intertwined organism comprising five key domains (Table 5.1). The *knowledge domain* includes research and education. Stakeholders include a variety of institutions, including universities, research institutes, academic medical centers, and pharmaceutical and medical device manufacturers, as well as the agencies that fund their activities, such as the National Institutes of Health.[25] Maximizing return on investment by these organizations can contribute to increasing health system costs.

TABLE 5.1

The Five Domains of Health Care

	Care Delivery Domain	Knowledge Domain	Payer Domain	Medical-Legal Domain	Regulatory Domain
Current roles played by each domain	• Diagnosis • Treatment • Rehabilitation • Prevention	• Medical-related education • Clinical training • Research • Innovation • Medical technologies • Data collection • Measurement	• Reimbursement • Patient coverage	• Confidential and undiscoverable malpractice procedures • Compensation for patients and families • State-specific policies	Numerous policies and regulations related to the following: • Health • Medical documentation • Billing codes • Payments • Use of information technology • Clinical certification and licenses • State-specific scope of practice for providers • State-specific insurance rules
Roles for each domain in a future high-value, continuously learning health care system focused on the patient	• Create high-value care on a continuously improving basis • Develop a continuously learning organization as an output of the health care delivery system	• Discover and generate new knowledge, novel diagnostics, and novel therapeutics that improve value	• Pay for value	• Compensate injured patients and families • Generate safety data and information for continuous improvement by the care domain	• Develop policies and regulations that foster the self-organization of a high-value, continuously learning health care delivery system

Stakeholders	• Patients • Physicians • Nonphysician providers (pharmacists; physician assistants; nurses; social workers; registered dietitians/nutritionists; community health workers; physical, occupational, and speech therapists; public health workers) • Health care administrators • Public health departments • Community health centers • Subacute care facilities • Ambulatory surgery centers • Hospitals • Home health agencies • Rehabilitation centers • Skilled nursing facilities • Nursing homes • Hospices • Integrated networks • Diagnostic clinics • Imaging units • Laboratory services • Health information technology • Nonprofit/special interest organizations	• Medical schools • Dental schools • Nursing schools • Pharmacy schools • Physician assistant programs • Physical, occupational, and speech therapy programs • Researchers • Universities • Private foundations • US Department of Health and Human Services (AHRQ, ATSDR, CDC, FDA, HRSA, IHS, NIH, SAMHSA) • State health departments • Professional associations • Trade associations • Medical equipment manufacturers • Biomedical suppliers • Pharmaceutical companies • Biotechnology companies • Nonprofit/special interest organizations	• Commercial insurers • Self-insured employers • Government payers (Medicare/Medicaid, Veterans Affairs, Tricare, IHS, Federal Employees Health Benefits, State Children's Health Insurance Program) • Individuals/consumers/patients	• Lawyers • State government • Justice system	• Congress • The White House • Federal government agencies • State government agencies • State legislatures • State medical licensing bodies • Accreditation agencies, including professional specialty boards for providers

AHRQ, Agency for Healthcare Research and Quality; *ATSDR*, Agency for Toxic Substances and Disease Registry; *CDC*, Centers for Disease Control and Prevention; *FDA*, Food and Drug Administration; *HRSA*, Health Resources and Services Administration; *IHS*, Indian Health Service; *NIH*, National Institutes of Health; *SAMHSA*, Substance Abuse and Mental Health Services Administration.

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The *care delivery domain* is the primary place where patients and their families reside. It includes the broad range of health care professionals and institutions across the patient care continuum, from primary care to postacute and long-term care. In defining value, the patient's perspective includes outcomes of mortality, survival, complications, return to normal activity, and access to care. The health care professional is concerned with mortality, survival, complications, and patient satisfaction. Neither group has historically focused on the cost of care, although awareness of costs of care is changing as patients share an increasingly higher proportion of costs as out-of-pocket payments for health care.

The primary function of the *payer domain* is to pay for health care services provided; it

includes individuals, private insurance companies, employers, and state and federal government agencies. Private payers want to keep the bottom line solvent, as many must report to stockholders, while self-insured employers look for satisfied employees and their rapid return to work, as well as a healthy bottom line.

The *medical-legal domain,* which includes the malpractice system, often exists in an adversarial relationship with the care delivery domain. Although this domain often may serve a watchdog function, under the current structure it also has the ability to profit from the health system's mistakes.

Finally, the *regulatory domain,* the domain of legislative enactment and associated administrative interpretation, derived from national, state, and local actions, exerts a powerful influence across the other domains. Regulatory efforts may increase or decrease costs, sometimes through unintended or unanticipated consequences.

Although understanding the value from the perspective of all stakeholders in the health care system is important, the most important perspective to be considered is that of the patient. Thus defining value (and paying for value) requires measuring what actually matters to patients.[31] Ideally, a high-value health care system would identify each individual's priorities and measure the extent to which these priorities are met. Despite the need for a patient-centric definition of HVC, the vast majority of current quality metrics reflect professional standards. For example, outcomes of interest to people living with frailty or advanced illnesses may not be well represented in the current set of quality metrics used by the CMS. Among the elderly, priorities include maximizing physical comfort, avoiding delirium, receiving care at home, maintaining independence, and maintaining relationships with family and friends. Younger disabled persons may have a different set of priorities: restoring function, returning to work, earning a living, supporting a family, and being in control of their own lives. Thus HVC may be a moving target and must be defined for each patient in a manner that meets his or her needs.

Case study 1: Direct contracting

Data from the National Business Group on Health reveal that the average annual cost of health care coverage per employee continues to rise at a consistent rate of 5% per year.[32] Consequently, several alternative models of care have arisen in an effort to maximize value and trim unnecessary expenditures. One such model is direct contracting, wherein self-insured employers and provider organizations directly negotiate the terms under which health care is provided to an employer's beneficiaries and dependents, bypassing traditional commercial payers. These arrangements may be limited to specific high-cost and high-volume services, such as joint replacement, or may involve the entire spectrum of health care services for a given patient population.[33]

These direct health system–to-employer contracts allow for the design and delivery of health care in ways that maximize value for patients and purchasers (employers). By changing provider incentives away from fee-for-service and reducing the administrative burden of billing and preauthorization for every diagnostic or therapeutic decision, this model affords providers with the flexibility to practice in a patient-centered manner. Providers are free to deploy the most appropriate services and

health care providers to achieve the best patient outcomes at the most reasonable costs. In turn, health care organizations are assured a group of beneficiaries with a known and predetermined health risk profile, allowing them to more accurately forecast costs and anticipate the health care needs of a particular population.[34]

According to the National Business Group on Health, only 3% of employers currently use direct contracting. However, this model is expected to grow in popularity given current trends in increasing costs of providing care to patients. Several large Fortune 500 companies, including Amazon, Boeing, General Electric, General Motors, and Walmart, have embarked on various direct contracting models aimed at increasing value and reducing overall cost.[35] Some of these are more limited in scope, with contracted bundles for specific high-cost and high-volume interventions, such as total joint replacement, cardiac catheterization, oncologic care, or organ transplantation, while other arrangements are more comprehensive in nature and include primary care provider services and case management, as well as care coordination.

1. The definition of value can vary widely among health care ecosystem participants and may at times conflict. How, then, can payers and care delivery organizations find common ground to provide the highest value to the patient?
2. What potential challenges will delivery organizations face as they embark on the road to providing HVC?

V. Assessing the current value of US health care

Much has been written about rapidly rising costs, uneven access to health care services, and patient outcomes that consistently place the United States at the bottom of the developed world when ranked against other nations' health care systems.[36] Beneath the surface there is a more complex story, however, which is not surprising given the sheer size and heterogeneity of the US population. A deeper look at US health care data suggests that value is variable and often falls short on basic dimensions of quality and cost.

As the NAM stated in its 2013 report *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America:*

> If banking were like health care, automated teller machine (ATM) transactions would take days or longer as a result of unavailable or misplaced records.... If home building were like health care, carpenters, electricians, and plumbers each would work with different blueprints, with very little coordination.... If shopping were like health care, product prices would not be posted, and the price charged would vary widely within the same store, depending on the source of payment.... If airline travel were like health care, each pilot would be free to design his or her own preflight safety check, or not to perform one at all.... If automobile manufacturing were like health care, warranties for cars that would require manufacturers to pay for defects would not exist. As a result, few factories would seek to monitor and improve production line performance and product quality.[2]

So where does the United States stand in terms of achieving high-value health care for all? This section examines each of the components of the value equation individually.

A. Outcomes

The US health care system produces some of the best and some of the worst patient outcomes in the world, as measured by mortality amenable to health care. The measure of "deaths... before age 75 potentially preventable with timely and effective health care" is often used to assess the performance of health care systems.[37] Data collected by the Commonwealth Fund show that the United States consistently ranks last in mortality amenable to health care among developed nations. However, a more detailed review highlights a more than twofold variation in this measure across the United States, ranging from 54.7 deaths per 100,000 people in Minnesota (the best-performing state) to 142.4 in Mississippi (the worst-performing state).[38] This variation within the United States is more extensive than what has been observed across Organization for Economic Cooperation and Development (OECD) member nations. Moreover, the top five states in the United States consistently rank among the best OECD nations, while the bottom

five states trail all of the OECD nations. The variability in mortality outcomes holds true, even when we look at a smaller subset of health care providers (e.g., teaching hospitals). We might expect that teaching hospitals would consistently show the best patient outcomes in the country given their access to the latest in medical technology and use of best practices. However, analysis of Medicare Provider Analysis and Review (MedPAR) data shows that in 2009, mortality outcomes in teaching hospitals varied approximately threefold between the best and the worst facilities.[39]

B. Safety

Safety is a major factor contributing to poor-quality care. The NAM's landmark 2000 report *To Err Is Human: Building a Safer Health System*[22] estimated that avoidable medical errors account for between 44,000 and 98,000 deaths annually in the United States. Despite numerous initiatives over the past 10+ years, medical errors remain a major system issue. A 2010 Department of Health and Human Services report showed that nearly one in seven (or 13.5%) hospitalized Medicare beneficiaries experienced an adverse medical event, while an additional 13.5% experienced temporary harm. The same study determined that nearly one-half of these events were clearly or likely preventable.[40] A 2011 study of a broader patient population by Classen and colleagues found that one in three patients in the United States experiences an adverse event during a hospital stay.[41] Medical errors also increase health care costs. Van Den Bos and colleagues estimated that medical errors cost the United States approximately $17.1 billion in 2008.[42]

The Hospital Safety Grade, published by the Leapfrog Group, has become a key measure of patient safety. A single score is calculated based on 28 approved performance measures and represents a hospital's overall performance in relation to preventable harm and medical errors. The spring 2018 Hospital Safety Grade report showed that only 30% of over 2500 hospitals across the nation received an A grade. The data also showed significant variability in hospital safety scores across the nation. For example, the percentage of hospitals that received grade A scores in a given state ranged from 72.7% in Hawaii to 0% in Alaska, Delaware, and North Dakota.[43,44] Variability in patient safety is also found when examining specific individual procedures. For example, a 2012 study of total joint procedures by the High-Value Healthcare Collaborative (a consortium of 17 health care delivery systems and the Dartmouth Institute) showed "substantial variations across the participating health care organizations in... in-hospital complication rates."[45]

C. Service

Patient satisfaction, one metric of service, also varies greatly across the nation. The Hospital Consumer Assessment of Healthcare Providers and Systems survey is a national, standardized, publicly reported survey of patients' perspectives of hospital care. The July 2018 survey release showed that 88% of patients were highly satisfied with their experience at the best-ranked hospitals, while only 56% reported the same

level of satisfaction in facilities ranked in the bottom 5%.[46] At the state level, the percentage of patients who "would definitely recommend the hospital" ranged from 79% in Nebraska (the best-performing state) to 63% in New Mexico (the worst-performing state in the continental United States).[47]

It should be noted that while patient satisfaction continues to play a role in Medicare's Value-Based Purchasing Program, a growing number of quality experts and health services researchers are moving away from patient satisfaction to patient experience of care metrics. In contrast to patient satisfaction surveys, which focus on patient "opinion" of care received, patient experience surveys are designed to collect information on what patients actually did or did not experience in their interactions with the health care system. For example, instead of asking whether the patient would recommend a given facility (a measure of patient satisfaction), a patient experience of care survey may inquire about ease of scheduling appointments or transparency regarding the costs of care. Thus surveys of patient experience are presumed to provide not only more accurate but also more actionable information toward understanding and improving the value of health care.

D. Cost of care

> *"Price is what you pay, value is what you get."*
>
> **WARREN BUFFETT**

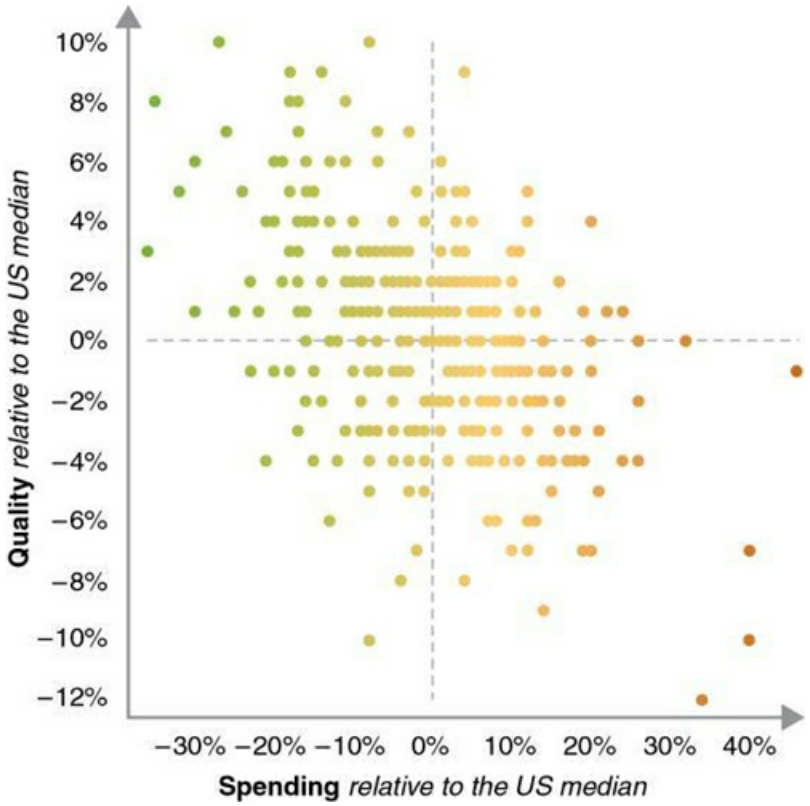
The United States spends significantly more per capita and a higher percentage of its gross domestic product (GDP) on health care than other countries spend.[48] In 2016, the United States spent 17.1% of its GDP on health care. In contrast, the next highest spender, Switzerland, saw 12.2% of its GDP go to health care, while the United Kingdom spent 9.8% of its GDP on financing the health of its citizens. Per capita spending in the United States stands at $9832, more than double that of the United Kingdom ($4164).[49] Private health care spending, which includes both insurance premiums and out-of-pocket spending, is also highest in the United States. All of these observations are sources of concern in assessing value in US health care.

Due to high (and rising) costs, health care in the US is becoming increasingly unaffordable for the average citizen[50] and, as one of the major contributors to US debt, may be putting the financial health of the nation at risk.[51] Federal spending on health care has grown from 5% of the federal budget in 1970 to nearly 25% of the federal budget in 2013. Some have estimated that if the current trends continue, federal spending on Social Security and health care, plus payment for interest on the national debt, may exceed total US revenue by 2025. Thus no federal funding would be available for other government initiatives, including education, infrastructure, social services, and defense.

Does higher US spending on health care translate to higher-quality care? Unfortunately, many studies demonstrate that the higher spending does not necessarily

translate into better quality of care (and thus higher value). For example, when compared with other developed nations, OECD health data show that Americans have fewer physician visits (4 vs. 6.5 average for member nations), fewer practicing physicians (2.6 per 1000 population vs. an average of 3.4 across OECD countries), and poor population health despite the high level of health care spending. In 2016, the US life expectancy at birth was 78.6 years, whereas the average life expectancy of OECD member nations was 80.8 years.[49] One explanation for why higher health care spending in the United States does not lead to higher life expectancy is that the majority of health care dollars in the United States are spent on a relatively small population of highly sick patients[52] and on acute interventions that have limited impact on life expectancy of the overall population. Comparatively little funding goes to primary prevention and health promotion, addressing lifestyle, environmental, and social circumstances that have a much greater impact on overall population health than health care delivery.[53]

The limited correlation between quality and cost of care also holds true when we examine specific patient populations or conditions. Fig. 5.2 provides an illustration of quality of care and costs of care for Medicare beneficiaries.[54] The near-zero correlation between the dollars spent and hospital quality of care suggests significant waste and room for improvement. Analysis of coronary artery bypass grafting (arterial grafts for blocked coronary arteries) outcomes and costs in California hospitals has resulted in similar observations and set of conclusions.[55] An estimated 15% to 30% of all health care spending is either low value or of no value at all to the patient. To put this degree of waste into perspective, the 30% estimate (approximately $750 billion in 2010) is greater "than our nation's entire budget for K-12 education."[56]



• **FIG. 5.2** Higher hospital spending does not correlate with better outcomes, suggesting system waste and opportunities for improvement. Spending Indicator Source: Data Year: 2015—Geographic Variation Public Use File, April 2017 (CMS Office of Enterprise Data and Analytics). Spending Indicator Notes: Spending estimates are for inpatient acute care hospitals paid under the prospective payment system and reflect only the age 65+ population with traditional fee-for-service Medicare. Spending estimates are standardized to account for local wage differences using the CMS hospital wage index. Payments for engaging in medical education and treating a disproportionate share of low-income patients have been excluded. *Source:* (Printed with permission of The Commonwealth Fund.)

The NAM defines six categories of health care waste; two (unnecessary services and inefficient care) are under the influence of health care providers and account for nearly one-half of overall estimated waste. Geographic variation in the cost of care for Medicare beneficiaries has been well documented over the past 20 years by the Dartmouth Atlas Project (https://www.dartmouthatlas.org). In 2011, the NAM released its own set of standardized and risk-adjusted Medicare data that corroborated Dartmouth's findings. While Medicare spent $7500 per beneficiary on average in 2008, there was a 40% difference in spending between the geographic areas with the 10% lowest-cost providers and those with the 10% highest-cost providers.[57]

In his much-discussed article in *The New Yorker*, "The Cost Conundrum," Atul Gawande, MD, MPH, examined two Texas towns, McAllen and El Paso, which despite similarities in location and demographics cost Medicare vastly different amounts of money. In 2006, McAllen cost $14,946 per Medicare enrollee, essentially double the cost of $7504 per enrollee in El Paso.[58] Data from the Dartmouth Atlas Project suggest that the difference is driven to a large extent by the amount and type of care ordered for patients and is a reflection of physician practice style and system incentives.

VI. Key attributes of a high-value health care system

The experience of select health care organizations such as Advocate Aurora Health, discussed in detail later, suggests that high-value health care in the United States is both feasible and occurring in some parts of the country. Which health care system features need to be in place to support the STEEEP aims put forth by the NAM and create HVC for all? The key components of a high-value health care system include the following characteristics[25,59]:

1. A clear, shared vision, with the patient at the center, to deliver the highest-value care possible
2. Leadership and professionalism on the part of health care professionals, with corresponding training that emphasizes teamwork, systems engineering, and process improvement
3. A robust information technology (IT) infrastructure that supports the development and maintenance of a learning health care system, one characterized by seamless information exchanges, stringent peer review, use of best practice, and evidence-based medicine
4. Insurance for all, wherein individuals own their insurance and have the means to choose and access appropriate medical care
5. Reimbursement models that remove incentives for volume-based care and instead promote integration and coordination, prevention, and health promotion

In the absence of a carefully designed national system that supports HVC, it is not surprising that the focus on HVC often falls to organizations under the umbrella of "integrated" systems. There is confusion regarding what constitutes an integrated delivery system, and in our view simple vertical integration wherein a hospital purchases a physician organization (or vice versa) does not ensure meaningful integration that promotes value. We endorse Shortell and colleagues' definition of an integrated delivery system as "a network of organizations that provides or arranges to provide a coordinated continuum of services to a defined population and is willing to be held clinically and fiscally accountable for the outcomes and health status of the population served."[60] This authentic integration may be vertical (as in the case of Kaiser Permanente, in which payers and providers are all part of a single entity) or virtual (e.g., Grand Junction, Colorado, where payers and providers make contractual arrangements to function as a single integrated system while remaining independent organizations).

The key is to align the incentives of health care professionals with delivery of value-based care for patients and establish a culture of integrated and coordinated care that is supported by evidence-based medicine and a robust IT infrastructure (for a detailed

discussion of integrated delivery systems, see Enthoven[61]). A 2009 Commonwealth Fund survey of health care leaders endorsed promoting the growth of integrated delivery systems as the best way to reduce the growth in US health care costs.[62]

Case study 2: Advocate health care/physician partners comprehensive population health program

(Updated case study courtesy of Advocate Aurora Health)

Advocate Physician Partners (based in Rolling Meadows, Illinois) is part of Advocate Aurora Health, the 10th largest not-for-profit, integrated health system in the country. The organization's clinical integration program, which began in the early 2000s to align what would otherwise be a fragmented group of thousands of independently practicing physicians, has evolved into a comprehensive population health program to provide value-based care.

The collaborative brings together 5000 physicians and 12 partnered hospitals to drive targeted improvements in health care safety, quality, efficiency, and outcomes. Composed of a common set of quality goals and measures across all insurance carriers, the program incorporates the most current standards of evidence-based medicine and has successfully driven high-quality outcomes across more than 1 million lives. More than 150 clinical performance metrics are tracked in a robust, web-based patient registry system that provides physicians with robust, actionable information to manage patients in real time. This online tool is used to measure and monitor patients, identify gaps in care, and offer recommended targeted interventions. Physicians are also provided personalized support, from integrated care managers to patient-centered medical home advisers, to help manage patients with standardized protocols, toolkits, and targeted action plans.

Through the program in 2017, an asthma initiative resulted in $6.1 million in annual savings while preventing 56,000 days of lost productivity and absenteeism. A diabetes initiative led to $7.3 million in savings and 29,000 years of additional life. A childhood immunization initiative saved nearly $6 million in avoided hospitalization costs for rotavirus-related diseases, and a generic prescribing initiative reduced out-of-pocket expenses by $93 million. One of the most powerful measures of success going forward will be to track how many days per year patients are at home.

In recent years, Advocate has kept costs under control for payers, employers, and individuals participating in the CMS's Medicare Shared Savings Program, despite hikes in US health care spending. This has been achieved by reducing congestive heart failure hospitalizations through better postdischarge follow-up care, expanded partnerships with its postacute network, and increased primary care services with a sharper focus on preventive health and wellness visits. Using the same care model that delivers quality outcomes and cost savings to the commercially insured, Advocate's affiliated accountable care organization has saved the federal government $165 million through the Medicare Shared Savings Program since 2012.

VII. Barriers to high-value care

The previous sections have described ways to achieve HVC in the United States at the macrosystem level and, as highlighted in Table 5.1, how each of the domains of the health care system plays a role in promoting HVC. Health care professionals seeking to promote and provide HVC need to understand the key barriers that stand in the way of high-value health care delivery being the US norm.

A. Conflicting stakeholder incentives

> *"In any field, improving performance and accountability depends on having a shared goal.... In health care, however, stakeholders have myriad, often conflicting goals.... Lack of clarity about goals has led to divergent approaches, gaming of the system, and slow progress in performance improvement."*
>
> **MICHAEL PORTER, PhD**[1]

One barrier that precludes full adoption of HVC practice is conflicting incentives across various health care stakeholder groups. Health care professionals play a pivotal role in determining health care spending because of their responsibility for ordering services, medications, and treatments. It has been estimated that physicians are responsible for more than 80% of health care costs, based on the decisions made about patient treatment plans.[63] Certainly, much of this spending is necessary to provide appropriate care; however, the amount of overuse is substantial. Health care in the United States has historically been permeated by the idea that more care is better care, and this concept has been reinforced over generations of training.[64] More recently, physicians and other health care professionals have started to actively combat the challenge of health care waste through initiatives such as Choosing Wisely[65] and the Do No Harm Project.[66]

Patients also sometimes assume that more medical care is better, despite the potential harm of unnecessary testing and interventions. Direct-to-consumer advertising by pharmaceutical, medical device, and other health care companies may lead patients to request specific tests, drugs, and procedures that may be unnecessary. Direct-to-consumer advertising in the form of television and magazine advertisements may be used to promote the sale of newer, more expensive medications that may not necessarily increase value or safety over other, lower-priced medications.[67] It has been suggested that advertisements for medications should include cost information or a notation that generics may be cheaper; however, this is not current practice.[68] Moreover, with the rise of third-party payers, patients with health insurance became increasingly insulated from true costs of care and have few incentives to be prudent consumers of health care services. The introduction of high-deductible health plans, as well as copays and co-insurance structures, aims to bring at least a portion of health care costs to light for patients.

In contrast, the payers (whether private insurers or the government) are interested in decreasing the use of health care services and the corresponding cost of health care. Over the past few decades, insurance companies have tried a variety of ways to contain costs and spending, including setting prices (government payers), negotiating discounts, aggressive gatekeeping of services, bundled payments to hospitals based on specific diagnoses, and financial incentives to physicians for their ordering habits.[69]

B. Lack of shared reality

In order to improve health care value, all stakeholders need to openly and honestly appraise the current state of US health care. This shared reality is pivotal to dispelling deeply ingrained assumptions and generalizations and helps drive actions and prioritization of opportunities. Yet the fragmented nature of the health care system and the current state of health care IT systems make it difficult to measure and improve health care value. Ideally, health care professionals would make assumptions and create strategies based on reliable, relevant, and meaningful data. However, lack of a national health data infrastructure, poor health IT interoperability, and health IT systems designed primarily for billing rather than patient care purposes limit the ability to collate data, study outcomes, and publish results. Design and implementation of patient-centered IT is vital in providing safe and effective care for all patients and mandatory if the US is to generate new strategies for HVC. In an ideal state of health IT, all information about an individual's health care would be immediately available to both physician and patient, anywhere in the world, with the simple click of a computer key. Currently, this ideal is far from realized.

These inherent challenges in measurement have encouraged an explosion of quality metrics, quality measuring agencies, and a focus on what is easy to measure (process) instead of what is meaningful (outcomes). As stated by Porter:

> Since value depends on results, not inputs, value in health care is measured by the outcomes achieved, not the volume of services delivered.... Nor is value measured by the process of care used; process measurement and improvement are important tactics but are no substitutes for measuring outcomes and costs.[1]

The future of quality measurement may lie in harnessing the "big data" available in electronic health records (EHRs) across systems to identify areas in which better value can be achieved. An article by Bates and colleagues suggested that there are six practical areas in which big data can be used to reduce costs of health care: high-cost patients, readmissions, triage, decompensation, adverse events, and treatment optimization for diseases affecting multiple organ systems.[70] Through this approach, organizations may have an opportunity to increase the quality of care while decreasing costs. A more in-depth discussion of quality improvement and measurement is included in Chapter 7.

C. Poor integration and coordination

Increasing specialization and the growing number of health care professionals involved in a given patient's care, combined with insufficient communication among them and a fragmented payment system, have resulted in health care that is complex and lacking in care continuity and coordination. In the worst examples, this is a system of duplicated tests, confusion about care plans, and not surprisingly, poor patient outcomes at higher costs.[50] This is particularly true for patients who are the highest cost and highest need and tend to see a multitude of providers for their complex care needs. The current system is discussed in additional detail in previous chapters.

Improvement is possible; the integrated delivery systems discussed earlier show both higher quality and better cost containment than the status quo.[60,71] On average, true integrated delivery systems engage in more prevention and health promotion than nonintegrated groups and score better on a variety of Healthcare Effectiveness Data and Information Set measures. In these organizations:

> Care is integrated across settings (inpatient, outpatient, home, doctor's office, etc.)... handoffs between settings are smooth, with all necessary information transferred to the providers in the receiving setting.... And decisions are made with the total results, i.e. patient outcomes and total resource use, in mind, and not sub-optimization in one or another silo.[61]

These organizations accomplish their results through a combination of aligned incentives, deployment of evidence-based medicine, robust and patient-centered IT infrastructure, and the greater use of team-based care.

D. Inadequate education of health care professionals

It has been said that the most expensive piece of medical technology is the physician's pen.[58] After all, providers "are the ones who order the expensive new drugs, tests, and procedures, often unnecessarily or inappropriately, and at times indiscriminately."[72] Despite this, most health professions training programs lack formal education on methods to systematically improve care delivery. Health care professionals may have some exposure to these concepts as part of their training, but often it is not at the level of rigor that includes how value is measured and monitored, and how data can be used for continuous improvement. Despite the growing recognition that team-based care results in higher value for patients and the health care system overall, health professions training programs are still in the early stages of developing meaningful interprofessional training.[73]

It is important to understand the role of physicians (and, increasingly, other independent health care professionals) in contributing to wasteful spending in health care. It starts with the development of ordering habits in medical school and residency and leads to the formation of practice patterns following training. Indeed, on traditional rounds in a hospital medicine ward, errors of omission (e.g., missing tests that could have been ordered but were not) are more likely to attract the criticism of attending

physicians than errors of commission (e.g., ordering too many unnecessary tests). This problem is compounded by the lack of easily accessible costs of laboratory tests and images. It has been shown that making fee information available to providers at the time the order is placed results in decreased ordering.[74]

E. Serial nature of health insurance coverage in the united states

The United States is the only developed nation that currently lacks universal health insurance coverage, with 8.8% of the population uninsured as of 2017.[75] Moreover, unlike other developed nations that cover their populations in a single insurance scheme "from cradle to grave" (either government-based like the United Kingdom's National Health Service or private insurance with government oversight such as in the Netherlands), health insurance coverage in the United States comes "in series." In this arrangement, private insurers cover the younger and healthier working-age population, while the government finances the coverage for the elderly and the disadvantaged. This coverage structure creates limited incentives for private payers to manage the health of their insured population because (1) primary, secondary, and even tertiary prevention and health promotion efforts pay off only in the long term, thus private payers are not likely to reap significant savings from their young insured population as it matures, and (2) the majority of health care spending occurs in the age 55+ population and thus becomes the problem of the government/taxpayer.[76]

F. Perverse provider reimbursement structures

Despite the recent moves toward pay-for-value, the majority of health care providers continue to be paid fee-for-service, which in combination with 30+ years of Medicare price controls tends to incentivize volume over value:

> Fee for service [FFS] theoretically aligns providers and patients' interests by removing any incentive to deny or refuse potentially beneficial care.... The downside is that FFS creates incentives to provide ever more narrowly defined, specialized, and higher priced services, even when expected clinical value added is doubtful or non-existent. Providers gain from delivering more care, but are not rewarded [for], and will often lose revenue from evidence-based parsimony.[77]

Moreover, the providers are often paid in silos, with conflicting incentives, and there is no financial downside to physicians and other health care professionals for providing unnecessary care. For example, consider the case of Elena, a 70-year-old Medicare patient with congestive heart failure who is admitted to the hospital with a broken hip. At the end of the hospital stay she is discharged to a nursing home for rehabilitation.[78] Table 5.2 summarizes how some of the providers in her care will be paid and the incentives for each.

TABLE 5.2

Health Care Providers Are Paid in Silos and Often With Conflicting Incentives

Provider Type	Payment Type	Incentive
Hospital	One bundled fee (DRG) to the hospital to cover room and board, nursing services, prescription drugs, etc., during the hospital stay.	Use fewer resources, discharge quickly, drive more admissions
Skilled nursing facility	A per diem payment amount to skilled nursing facility to cover room and board, nursing services, prescription drugs, and rehabilitation services during the patient's nursing home stay.	Keep the patient as long as possible
Physicians	Separate fee-for-service payments are made for services provided by the physicians who care for the patient during the hospitalization.	Perform many services

DRG, Diagnosis-related group.

Additional examples of perverse incentives include but are not limited to:

- Site-of-care differential payments for oncology services that favor hospital outpatient facilities versus free-standing physician clinics, and not surprisingly lead to a shift toward more hospital-based care[79]
- Relative value units (RVUs) that have resulted in a proliferation of specialists and a dearth of primary care physicians

While both the CMS and private payers have been making attempts to pay for value for several years now, with the most recent examples being accountable care organizations, bundled payments, and the Medicare Access and CHIP Reauthorization Act, these initiatives often fail to deliver on their promises due to several implementation shortcomings, which include the following[80]:

- Patient attribution methodology and patient engagement
- Provider access to timely and actionable data
- Continued payment of frontline providers on a fee-for-service basis, even when the parent organization is under a value-based contract
- Shifting metrics and targets that often penalize already-efficient providers while rewarding those that are historically high cost
- Administrative complexity
- Volunteer nature of programs and a multitude of opt-out opportunities

"What may seem to be a sound strategy from Washington's perspective can run into problems if it is overly prescriptive, poorly designed, and implemented without sufficient regard for conditions in local health markets."[80]

It is of interest to note that true integrated delivery systems (such as Kaiser

Permanente, Geisinger, and Intermountain Healthcare) have found a way to deliver HVC within the constraints of the current payment system. Perhaps the focus of further regulatory efforts should shift from payment demonstration programs to creating market conditions that promote the formation of such systems nationwide.

VIII. What can health care professionals do to promote high-value care?

Thus far, this chapter has focused at a high level on the national macrosystem and the dynamics that contribute to the value of health care. Health care professionals need to have a basic understanding of the forces occurring at this level so they can understand how and when those forces impact patients. Health care professionals have a responsibility to promote value, and need the knowledge and skills to promote HVC by improving outcomes, decreasing cost, increasing safety, and increasing patient satisfaction through application of principles presented in this chapter (i.e., by increasing the numerator and decreasing the denominator in Fig. 5.1).[81]

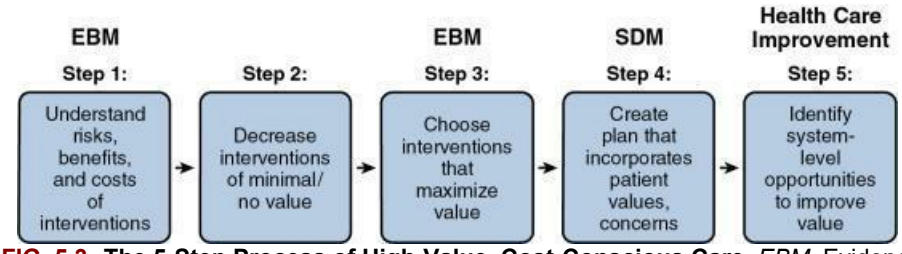
A. Identify and classify value gaps

In order to avoid the unabated growth in health care spending, health care professionals must serve as leaders in identifying and minimizing care that is inappropriate and focusing on delivering care that is appropriate and necessary.[82] An important first step is to "see" (identify) and classify gaps in HVC. The most common value gaps include overuse, misuse, underuse, and overdiagnosis. Overuse and misuse refer to the waste that occurs when care is provided that cannot help patients, such as ordering advanced imaging to evaluate acute low back pain without concerning findings.[23] Underuse occurs when screening opportunities are missed, such as early detection of colorectal or cervical cancer in at-risk individuals. On the other end of the spectrum, overdiagnosis refers to detection of cancers that will not become symptomatic in a patient's lifetime.[83]

Increasingly, physicians and health care professionals are leading the charge to decrease health care waste and increase value. One example is the Choosing Wisely campaign, which launched in 2012 as a collaboration between the American Board of Internal Medicine and *Consumer Reports.* In this forum, societies of medical specialists developed lists of tests, treatments, and services that often are used but should be questioned by both health care providers and patients.[84] As of late 2015, over 70 professional societies are represented in the Choosing Wisely campaign. The overarching goal of the Choosing Wisely campaign (https://www.choosingwisely.org) is to decrease the utilization of services that provide harm or little benefit; the next steps include evaluating the effect of the campaign on ordering practices of providers.[85]

Education of future health care professionals is a key focus in the drive toward HVC. It has been shown that internal medicine residents demonstrate inconsistent stewardship practices in hypothetical situations.[86] One way to combat inconsistent education in HVC is to provide a national curriculum in this area. In 2012, the ACP collaborated with the AAIM to launch a national curriculum for internal medicine residents that introduces a five-step framework for HVC delivery and promotes evidence-based, thoughtful, patient-centered care that adds value.[64] The curriculum was updated in 2014 and again in 2016; materials are available at

https://www.acponline.org/clinical-information/high-value-care. The five-step framework (Fig. 5.3) is discussed in detail in the following sections.



• **FIG. 5.3 The 5-Step Process of High-Value, Cost-Conscious Care.** *EBM*, Evidence-based medicine; *SDM*, shared decision making.

B. Understand the benefits, harms, and relative costs of interventions

It is critical that all health care professionals understand the benefits and harms of any test, procedure, or medication that they order. All health care professionals must do their best to practice evidence-based medicine, which refers to the thoughtful consideration of scientific evidence in application to patient care and is integral to this first step. Although it is tempting to consider each test we order as a yes-or-no answer to assist with a specific complaint or diagnosis, this is not often the case. Each test has its own sensitivity and specificity that help increase or decrease the pretest probability of disease. With this framework in mind, understanding the characteristics of a test and thinking ahead provide high value. When ordering a test, health care professionals should be able to answer the following questions:

- What will I do with the results of this test?
- Will these results change the diagnosis, management, or prognosis for my patient?
- If this test is positive, how will the care plan change?
- What if the test is negative?

If the test results will not change the care of the patient, the test should be reconsidered.[87]

Similarly, the cost of the test must be taken into consideration. The cost of the test includes not only the financial costs, which may be substantial, but also downstream effects such as radiation exposure, contrast reactions, implications of false-positive or false-negative tests, anxiety or worry for the patient, and incidental findings. When considering downstream costs, downstream savings must also be considered. Sometimes a medication that is more costly per pill (such as certain oral anticoagulants) may cost less in the long run due to greater effectiveness and fewer complications.[88] Comparative effectiveness research can assist health care professionals in making such

determinations; this exciting body of literature continues to grow and gain momentum.

C. Decrease or eliminate the use of interventions that provide no benefit, may be harmful, or both

Once the benefits, harms, and costs of the intervention have been considered, it becomes simpler to eliminate those that do not provide benefit to the patient. For example, the concept of decreasing or eliminating interventions that provide little to no benefit can be applied to stroke evaluation and workup. A study published in the *Journal of Hospital Medicine* in 2016 has suggested that the use of transesophageal echocardiography (TEE), despite its high diagnostic yield, may have little impact in changing the course of medical management in patients over the age of 50 who present with strokes of undetermined etiology and already have a normal transthoracic echocardiogram (TTE).[89]

In this study, 263 patients meeting inclusion and exclusion criteria were screened with a TEE after having a normal TTE. More than 42% were discovered on TEE to have cardiac findings that could explain the cause of the infarct. While the dramatic increase in diagnostic yield would lead one to believe that TEE is superior to TTE, an interesting fact noted in the study was that in only 0.4% of cases (i.e., one patient) did a TEE finding alter the course of medical management. While other studies have shown similar yields in detecting cardiac sources of stroke on TEE, there has been significant variation with regard to the percentage of findings that subsequently changed management, with some studies suggesting 16% to 33%. Furthermore, it is uncommon for such findings to be present without structural heart disease or arrhythmia, and it is known that detection rates for arrhythmias such as atrial fibrillation, which is an indication for use of anticoagulation in stroke patients, increase significantly with duration of continuous electrocardiographic monitoring.

What is clear in this case is that the routine use of TEE in the workup of cryptogenic ischemic stroke is highly controversial, given the previously mentioned data and the increased risks associated with an invasive (vs. noninvasive) diagnostic procedure. Therefore an emphasis on judicious use of TEE for further elucidation of stroke etiology and management should be paramount. Providers of high-quality health care are challenged to practice evidence-based medicine and to provide care that is patient centered while eliminating interventions that provide no positive benefit.

D. Choose interventions and care settings that maximize benefits, minimize harms, and reduce cost

The setting of care is also important when discussing health care value. When clinically necessary, hospital-based care adds value due to concrete benefits from specific treatments not available outside the hospital. However, there is a growing body of evidence-based and comparative effectiveness literature regarding certain conditions for which inpatient care does not add value and may in fact increase harm. One such example is the inpatient (hospital-based) treatment of uncomplicated deep vein

thrombosis (DVT). Traditionally, patients with DVT were admitted to the hospital for intravenous heparin administration while bridging to oral warfarin for anticoagulation therapy. Since the advent of low-molecular-weight heparin and other agents, outpatient treatment is safe and cost saving compared to inpatient treatment in selected patients with uncomplicated DVT.[90] Harms of unnecessary hospitalizations include not only financial harm but exposure to hospital-associated infections such as *Clostridioides difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and others. Hospital-acquired infections such as MRSA have been associated with higher costs as well as increased utilization of care.[91] With this in mind, it is reasonable to aim to reserve hospital care for only those patients who truly require it in order to avoid unnecessary complications and cost, both short term and long term. It is critical to use shared decision making as a tool for considering the best interventions and care settings for individual patients given their own values and concerns.

E. Customize care plans with patients that incorporate their values and address their concerns

Open and honest communication with patients is critical to achieving HVC. Shared decision making occurs when the provider understands and articulates a clear vision of each patient's individual goals and values. This approach can then assist health care professionals in delivering care that is both medically appropriate and consistent with patients' wishes. For example, consider a chronically ill 85-year-old female smoker presenting to the emergency department with fever, shortness of breath, and cough. An initial chest radiograph reveals pneumonia but also shows a mass concerning for lung cancer. Should she have a lung biopsy? Should she receive chemotherapy if she has cancer? Should she be referred to hospice to focus on quality of life? Thoughtful discussion with this patient and her family will help her clinical team choose interventions that are appropriate for her ongoing care. Patients with underlying medical conditions who are found to have cancer may choose not to pursue aggressive treatment such as surgery or chemotherapy. If an open and honest discussion is not undertaken regarding the risks and benefits of aggressive treatment, patients may start down a road of high-cost, highly morbid care that may not provide benefit. The 2016 High Value Care curriculum from the ACP-AAIM presented the "High Value Care Conversation Guide" (https://www.acponline.org/system/files/documents/clinical_information/high_value_ca resouces/hvc_conversation_guide.pdf), a tool to assist in clear conversations aimed at customizing care. This tool includes tips on specific phrases to use to elicit patient values, customize the plan, and confirm patient understanding.

On the other side of the coin, some patients may request care that is unnecessary due to underlying fears of cancer, disability, or other concerns. For example, a young man who presents to a clinic complaining of low back pain after helping his friend move to a new apartment 1 week earlier reads on the Internet that he could have a "slipped disc," so he wants the physician to order magnetic resonance imaging (MRI) to be sure. A complete history and physical are performed, and no alarming symptoms or

examination findings are identified. In this case, skilled communication is necessary to reassure the patient that his concern (slipped disc) is highly unlikely or at least unlikely to cause disability and that the MRI is unnecessary and potentially harmful. Resources such as Choosing Wisely (http://www.choosingwisely.org) offer patient handouts on challenging topics such as these to encourage thoughtful communication in the provision of patient care when patients request tests or studies.

F. Identify system-level opportunities to improve outcomes, minimize harms, and reduce health care waste

Institutional leaders have the responsibility to harness the culture of their organizations and use it to forward the mission of HVC.[92] This mission is often accomplished through health care improvement (quality improvement [QI] and patient safety) initiatives driven by those who are on the ground seeing patients and working in the health care system directly. QI efforts are critical in the quest to provide health care with increased quality at decreased cost, thereby decreasing the denominator of the value equation. One QI success story is found at the Everett Clinic, a physician group practice in Snohomish County, Washington, that employs 500 providers and cares for 300,000 patients. A multidisciplinary team recognized the high expense and minimal benefit of advanced imaging studies (such as computed tomography, MRI, and positron emission tomography scans) when they are not clinically indicated and developed a set of criteria that health care providers must use to order such studies. As a result, unnecessary imaging was reduced by 39% in 2 years, saving the system $3.2 million annually.[93] Chapter 7 provides more details about the role of QI in institutional change.

Patient safety efforts, as addressed in Chapter 6, play a key role in both individual and system-level efforts to minimize harms and thereby increase both quality and value. The NAM report *To Err Is Human* brought patient safety initiatives to the forefront of medical care.[22] Most institutions have patient safety reporting systems in which any individual who has patient contact may anonymously report witnessed patient safety events. These observations are then investigated in a nonjudgmental fashion and, in many cases, lead to improved patient safety throughout the system. The goal of safety reporting systems is to encourage a culture of safety throughout the system.

Overuse of diagnostic and therapeutic medical modalities is a well-recognized problem in health care.[56,94-96] It results in high costs for patients and health systems and is a leading cause of low-value care. Some suggest that excess resource utilization may be considered an adverse medical event, since it subjects patients to pain, excess radiation, phlebotomy-associated anemia, risk of secondary infections from antibiotics, and high costs.[97] Korenstein and colleagues have developed a conceptual model of overuse, showing that there are not only short-term consequences of excess use of medical care but long-term consequences as well. These encompass physical, psychological, social, and financial realms of a patient's life.[98]

Reducing low-value care and excess health care has been difficult.[99] The United States

has had a hard time changing traditional patterns of care, even after newer treatments have been shown to be more effective or previous treatments are found to be wasteful. The process of letting go of low-value care has been referred to as "de-adopting" or "de-implementation."[100,101] Because physicians and other health care professionals have individual biases preventing de-implementation of low-value care, health care systems are developing system-level improvements to deliver high-value, cost-conscious care. Technology has become a useful partner in assisting with HVC endeavors. Computer order entry systems allow clinicians to order multiple tests simultaneously and very easily, and thus are low-hanging fruit for decreasing overuse. Daily reminders to reduce tests, visual aids to make providers aware of overuse, and checklists are useful tools.

Unnecessary and excessive testing in the intensive care unit has been part of the culture. Using Choosing Wisely initiatives, several groups have published decision tools built into EHRs that (1) raise clinician awareness of the impact of unnecessary testing, (2) require mandatory indications for daily routine testing, and (3) create provider quality metrics. Using these types of system decision aids, Mount Sinai St. Luke's Hospital in New York City saw a 22% drop in its intensive care unit laboratory testing.[102,103]

The Los Angeles County-University of Southern California Medical Center entered a checklist into the EHR to identify which patients did not need expensive preoperative testing. With these additional keystrokes, unnecessary preoperative medical visits for certain surgeries fell by 64%, reducing the wait time for surgery as well as saving approximately $1200 per case.[104]

Another type of EHR innovation has been the addition of patient photographs to the patient's electronic chart. Using this tool, the Children's Hospital Colorado was able to significantly reduce near misses and errors from wrong-patient ordering of tests and medications. These types of initiatives are being carried out across the country and internationally, in order to improve the delivery of HVC.

IX. Chapter summary

Over recent years, health care reimbursement in the United States has been shifting from a system based on volume to one based on providing value. Despite this important change, gaps remain in teaching value-based care to health care professionals at all points in training. Encouragingly, multiple new initiatives are currently underway to combat these deficiencies in the education of HVC, and excellent resources are readily available.

HVC is best defined by the value equation, or the quality of care divided by cost of care over time. Other ways to understand value-based care include analyzing various domains in the health care ecosystem and determining value from the perspective of these stakeholders. Finally, the NAM's STEEEP model, which says that health care should be safe, timely, effective, efficient, equitable, and patient centered, provides another way of defining value. This model has been crafted into a framework for action by the IHI's Triple Aim, which aspires to improve the health of a defined population, enhance the patient care experience, and reduce the per capita costs of care.

Despite the efforts of organizations such as the IHI and the NAM, the United States as a whole continues to struggle to provide HVC, as evidenced by the variation throughout the country regarding patient outcomes, safety, satisfaction, and costs of care. This may be due to barriers such as poor integration and coordination of services, fragmented and volume-based provider reimbursement, conflicting stakeholder incentives, and social determinants of health. Fuchs addressed two types of inefficiencies: "micro-inefficiencies," which relate to individual patient-provider interactions, and "macro-inefficiencies," which relate to health policy and the larger system. He argued that the United States may actually have good micro-efficiency but rather suffers from macro-inefficiency.[105] It is therefore heartening that despite the variability in health care quality and value across the United States as a whole, examples of HVC systems, including some integrated systems highlighted in this chapter, have demonstrated the ability to produce high-quality care at low costs.

What can health care professionals do to promote HVC? Health care professionals should understand the relative benefit, harm, and cost of every intervention undertaken. An evidence-based approach should be used to assess options, and if an intervention provides no benefit or is shown to be harmful, it should not be used. Care plans should be customized to each patient's values and address all concerns, placing the patient and his or her family in the center of the decisions made with the care team. Finally, because health care professionals are uniquely positioned to affect change on a systemic level, they should provide leadership in identifying opportunities to improve outcomes, minimize harms, and reduce health care waste.

Exercise

A patient is admitted for sepsis and respiratory failure to the intensive care unit at your hospital. Your supervisory staff reminds you to order daily labs and radiographs. How should you respond? Could your patient experience harm from daily testing? Why do

clinical providers have a difficult time de-adopting low-value care? How could your institution assist you in providing HVC?

Questions for further thought

1. Among the six NAM goals for quality health care, what are the specific meanings of “effective” and “equitable”?
2. Within the health care system, what are the knowledge and payer domains, and how do their value goals differ?
3. How do health care quality and cost outcomes in the United States compare to quality and cost outcomes in other developed countries?
4. What are the key components of a high-value health care system?
5. What are the key barriers to delivery of high-quality care? What can you do to improve the value of the care provided to patients?

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Patient safety

Luan E. Lawson, MD, MAEd, Jesse M. Ehrenfeld, MD, MPH, Timothy Reeder, MD, MPH

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In this chapter

Patient safety rose to the attention of patients, physicians, payers, and the public after the Institute of Medicine's landmark report To Err Is Human: Building a Safer Healthcare System, was released in 1999. Despite significant technological and clinical advances, understanding how to deliver safe care in a complex, rapidly changing environment with tremendous time constraints is one of the greatest challenges in health care today. Too often, errors have been attributed to the mistakes of individuals, instead of focusing on how the health care system contributes to making health care delivery prone to error. This chapter aims to teach the key principles of patient safety and provide foundational learning for health care professionals to effectively change the culture and systems in which they care for patients. Understanding the epidemiology and types of errors is essential to investigating solutions. Clinical examples are utilized to demonstrate the types and etiologies of medical errors. This chapter also discusses the importance of error disclosure and care of "second victims," both of which are essential in promoting a "Just Culture. " Finally, reporting systems and analysis of errors and near misses are described as an opportunity to prevent and correct system failures in a nonpunitive manner. Understanding these concepts will provide health care professionals with the requisite knowledge and skills needed to change the future of health care and patient safety.

Learning Objectives

1. Describe the history of the patient safety movement as it has evolved into a priority for high-value care.
2. Describe the classification of medical errors and analyze the epidemiology of common errors.
3. Discuss the elements of full disclosure and apology when dealing with the victims

of medical errors.

4. Discuss the importance of human factors, systems thinking, Just Culture, and other components that can contribute to improved patient safety.

I. Introduction

Patient safety has received increasing focus over the past several decades as the impact of medical errors in health care has drawn increasing attention from the public and the medical community. The World Health Organization defines patient safety as "the reduction of risk of unnecessary harm associated with health care to an acceptable minimum."[1] Others have described patient safety as

> a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events.[2]

The importance of patient safety came to the forefront of public discourse in 1999 after the **Institute of Medicine** (IOM; renamed the National Academy of Medicine in 2015) published the landmark report *To Err Is Human: Building a Safer Healthcare System,* which estimated that between 44,000 and 98,000 people die each year in US hospitals from medical errors and that over half of these deaths are preventable.[3] Until this report was released, the inherent high-risk environment of medicine that includes complex patient conditions and tasks coupled with time and workflow pressures was largely unrecognized by the general public. This greater transparency prompted the public, who are essentially the patients advocating for their own health, to hasten the systematic evaluation of the problem.

While there is clear evidence that adverse events and medical errors in our health care system are compromising the safety of patients, there remains inconsistency from study to study and ambiguity in terminology as to what constitutes a medical error. This has created significant debate as to the most reliable estimates of errors, near misses, and patient harm. The death estimates reported by the IOM were drawn from over 45,000 discharge records in New York, Colorado, and Utah in the mid-1980s to the early 1990s.[4-6] Another study indicated that 142,000 people die globally each year from medical errors.[7] Using broader definitions, yet another study suggested that over 400,000 patients die prematurely each year due to preventable medical errors, making medical errors the third leading cause of death in the United States.[8] In addition, patients experience harm 10 to 20 times more frequently than death, demonstrating significant morbidity.[8] Staggering accounts of wrong-site surgeries, missed diagnoses, poor discharge processes, retained surgical sponges, incorrect patient procedures, transfusion and transplant mishaps, and medication errors have been reported. Yet medical errors continue to impact patients and clinicians regularly and represent a leading cause of injury and mortality in the United States. In addition to the impact on patients, families, and clinicians, medical errors and preventable deaths cost approximately $20 billion annually in lost income and health care expenditures.[9] Health

care professionals, who pursued a career in medicine with a desire to help others, also suffer emotionally from their role in untoward events and may have their careers potentially derailed. Patients and health care professionals alike are united in the call to improve the safety of health care through a nonpunitive culture aimed at creating systems less prone to error.

II. Basic principles of patient safety

A. Nomenclature and definitions

While many patients experience adverse outcomes relative to their underlying medical condition, an **adverse event** is defined as "harm caused by medical treatment," whether it is associated with an error or considered preventable.[4] An **error** is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."[10] Although the term *error* may have a negative connotation, it is not meant to imply judgment, blame, or fault. A **preventable adverse event** is "an adverse event that is attributable to error."[4] Preventable adverse events that satisfy the legal criteria for negligence, in which the care provided to the patient did not meet the standard of care an average physician would provide, are known as **negligent adverse events**.[4] Criteria to determine medical **malpractice** include occurrence of a negligent adverse event and demonstration that the physician or other health care professional had a duty to care, that negligence contributed to an injury, and that the injury led to specific damages.

Not all errors result in adverse events or harm to the patient. However, even **near misses**, in which an unplanned event or close call did not reach the patient or cause an injury or damage to the patient, can impact the patient-clinician interaction and serve as valuable learning opportunities to evaluate potential safety risks within the health care system. Historically, the majority of serious, recognized adverse events occurred in hospital-based settings, with the operating room, hospital room, emergency department, intensive care unit, and labor and delivery unit being the most common locations for errors.[5] Initial patient safety efforts focused largely on the inpatient setting, but increased awareness that the majority of health care occurs in the ambulatory setting has called for increased attention to patient safety across all health care settings.

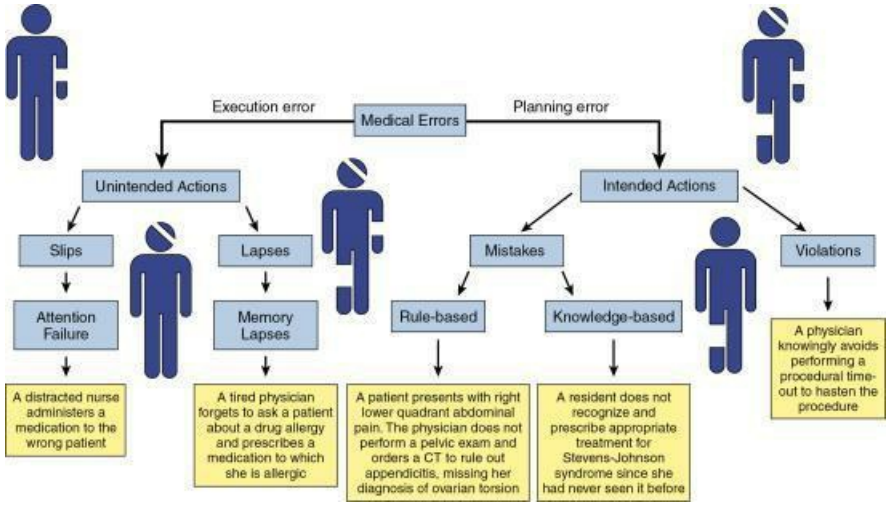
Understanding patient safety nomenclature is critical to interpreting and applying evidence-based patient safety interventions to clinical scenarios. Unfortunately, there is no standard nomenclature accepted throughout all health systems, so general concepts are discussed in this chapter. Consider the following patient scenario to illustrate the subtle differences in patient safety nomenclature. Mr. Jones is a 56-year-old male with a history of coronary artery disease who is prescribed daily aspirin to decrease risks of vascular complications. Unfortunately, Mr. Jones develops a gastrointestinal hemorrhage requiring transfusion, even though he does not have a history of peptic ulcer disease. Mr. Jones experienced an **adverse event** as a result of the recommended treatment; the gastrointestinal hemorrhage would not be considered preventable in this situation. If Mr. Jones has a history of gastrointestinal bleeding, but in a thorough risk-to-benefit analysis it is determined that the potential benefit of the treatment outweighs the risk and he is prescribed aspirin, then this scenario may be described as a **preventable adverse event**. However, if Mr. Jones has a documented history of anaphylaxis to aspirin and has recent gastrointestinal hemorrhages requiring blood

transfusion, then prescribing aspirin to this patient could be considered negligent and the resulting hemorrhage a **negligent adverse event**.

B. Slips, lapses, mistakes, and violations

Another way of looking at errors relates to the level of intent that underlies the action of a physician or other health care professional (Fig. 6.1). Understanding the intent can be useful when trying to understand the nature of an error. One can ask the following questions to further understand the nature of an error:

1. Was the action intentional? Was it a conscious or unconscious action?
2. Did the action occur as planned?
3. Did the action bring about the expected outcome?



• **FIG. 6.1** How medical error classification works based on cognitive intent, including examples of common medical errors.

Slips and lapses result from an unconscious, automatic action at the execution stage (either action or memory), making them easier to detect. A **slip** occurs when an action does not occur as planned. For example, a physician breaks a suture when she is tying it because she pulls too hard on the material. A **lapse** occurs when an action is missed or a person forgets to do something. For example, a nurse forgets to turn on a patient's intermittent pneumatic compression device as indicated to prevent a venous thromboembolism during surgery. Slips and lapses often occur because the routine action is being performed at a subconscious level. These familiar tasks may not engage conscious thoughts. A **mistake**, either rule based or knowledge based, occurs during conscious problem-solving activity when someone does something he or she thought to be correct but it was not. A mistake could result from using the wrong rule, such as evaluating a patient with chest pain for acute coronary syndrome instead of pulmonary embolism, or misapplying a rule, such as applying an evidence-based guideline for head trauma in adults to a pediatric patient suffering head trauma. Mistakes may also

be knowledge based and result from incomplete education, experience, or familiarity with a particular environment or equipment. A **violation** occurs when a deliberate, illegal, or otherwise unsanctioned action is undertaken.[11] An example would be knowingly skipping a mandatory surgical time-out that is a requirement of both a hospital and **The Joint Commission** (the largest international accrediting body for health care organizations).

Not all harms are the result of error. Multiple harms exist in health care related to the underlying condition of a patient, known complications of a therapy, or expected natural course of a disease process. Assessing harm in health care is more difficult than in many other industries. Patients frequently present to physicians and other health care professionals in a poor state of health, and it is difficult to separate the impact of an error from consequences related to the underlying medical condition. Further complicating this separation is that some treatments, such as chemotherapy or radiation, are understood to cause some harm in the process of treating an underlying illness. In a patient-centered approach, physicians and other health care professionals must weigh the risks and benefits of various testing and treatment options to determine the best approach for each individual patient. Many medical errors may not have immediate obvious negative outcomes, and it may be difficult to attribute the later injury to a specific error.

Despite the intentions of physicians and other health care professionals to deliver excellent care to every patient, adverse events due to medical errors occur in health care settings on a daily basis. When an error occurs, it is human nature to try to identify "the fall guy," the person who will be individually held responsible for the event. It is tempting to simply say the caregiver most culpable should be reprimanded to prevent further errors. In fact, one of the principles of "quality assurance" was to identify the outlier and change his or her individual behavior. At the same time, physicians and other health care professionals do not come to work intending to do harm. Well-trained, well-meaning professionals still make mistakes and can inadvertently cause patient injury simply because humans are imperfect. In fact, a good mindset and organizational culture are to assume that mistakes will be made and develop systems and processes to prevent them or minimize their impact. Human errors are frequently a warning sign that the systems around the individual are broken and require further evaluation. In fact, a study of medication errors and near misses found that at least 78% of the issues were attributable to system issues, not human errors.[12]

C. Systems approach to error

Because defective systems have been identified as the most predominant source of error, health care must adopt a systems approach to eliminate preventable errors.[13] Focused on improving and redesigning the environment and care processes, a systems approach promotes the anticipation and evaluation of errors instead of focusing on the behavior of individuals. Other industries, such as aviation, nuclear power, and the military, have made significant improvements in safety; their containment of errors can serve as a conceptual framework for reducing medical errors in health care.

Organizations in these fields also successfully operate under complex, hazardous conditions for extensive periods of time without serious accidents. **High-reliability organizations** (HROs) emphasize safety by maintaining an environment of collective mindfulness in which all workers identify and report small problems before those issues pose a significant risk and result in harm.[14] Safety is prioritized over other performance measures, and each individual in the organization has the authority, responsibility, and expectation to make adjustments to maintain safety and avoid error.

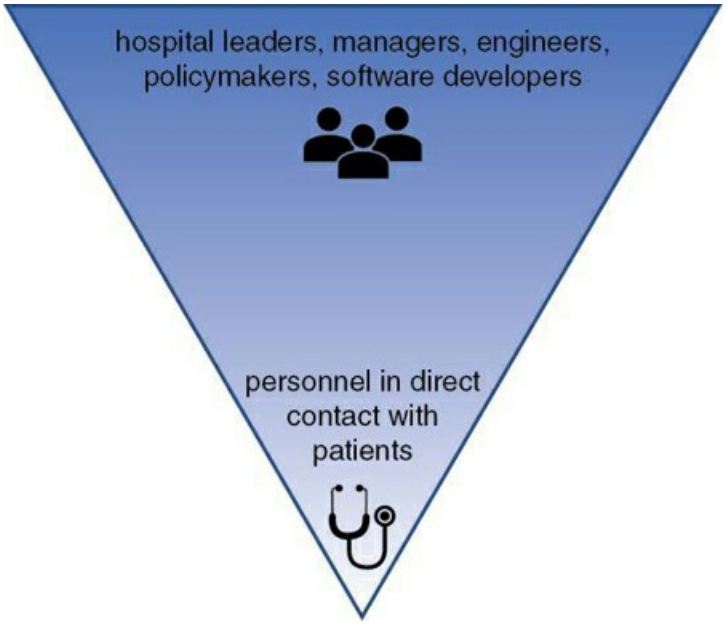
Weick and Sutcliffe articulated five characteristics that allow HROs to manage the unexpected[15,16]:

1. *Preoccupation with failure:* Everyone is continuously aware of and thinking about the potential for failure and maintains vigilance for subtle signs of potential problems. Near misses are viewed as opportunities to evaluate and improve systems.
2. *Commitment to resilience:* HROs recognize that systems are unpredictable and at risk for errors that could threaten safety despite efforts to anticipate and mitigate them. HROs regularly practice risk assessments and potential responses that would contain errors before they are compounded. The hallmark of an HRO is not that it is error free but that errors do not disable it.
3. *Sensitivity to operations:* A high awareness of operational conditions is maintained and the environment is constantly monitored for small changes or deviations that suggest a potential problem.
4. *Reluctance to simplify:* Work is complex and dynamic. HROs seek to explore complex explanations and processes instead of simplifying or relying on superficial explanations.
5. *Deference to expertise:* Decision-making authority is delegated to the individual with the most expertise, not necessarily the most senior or highest-ranked person.

The traditional health care culture that emphasizes "error-free practice" tends to create an environment that precludes open discussions of error and organizational learning, limiting the ability to improve care. Much of the framework of HROs can be transferred to health care, leading to opportunities to improve patient safety and health.

Dr. James Reason, a British psychologist and leader in the study of accidents and unintended events, described errors as circumstances in which planned actions fail to achieve the desired outcome.[13] He explained that human error can be viewed in either a persons approach or a systems approach. The **persons approach** focuses on the errors of individuals at the bedside, or the sharp end of the system, such as the physician, nurse, or other caregiver in contact with the patient (Fig. 6.2).[13] The "**sharp end**" refers to any personnel or components of the health care system that directly contact the patient in the provision of care. Such human errors are often attributed to forgetfulness, lack of knowledge, and carelessness. Methods such as poster campaigns, training, and disciplinary measures are utilized to counteract these errors, viewed as the responsibility of individuals. In contrast, the "**blunt end**" refers to the many layers of

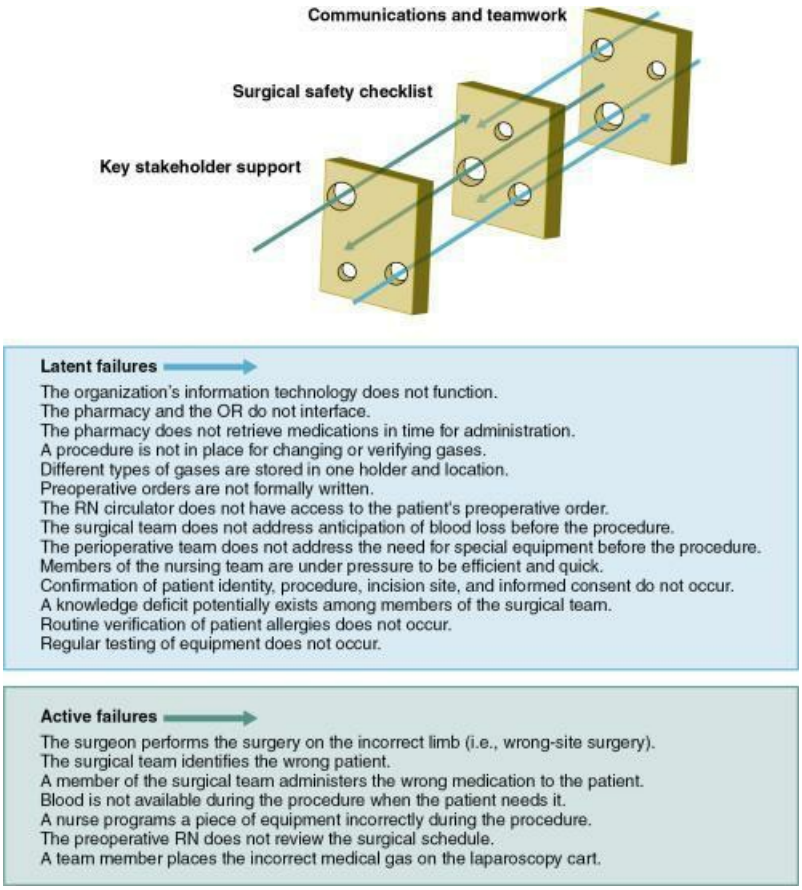
the health care organization removed from direct patient contact but directly influencing what happens to the patient.[13] Organizational leaders and managers, biomedical engineers, clinician administrators, policymakers, and software developers all reside at the blunt end, away from the patient's bedside. In a **systems approach** to error, one assumes that humans are fallible and human error is likely to occur, even in the best organizations, and that the system of care surrounding the caregivers must be assessed and improved.[17] It is important that physicians and other health care professionals providing care at the bedside (sharp end) become systems citizens to more effectively and efficiently improve health care. Using a systems approach, countermeasures to prevent error focus on system defenses, barriers, and safeguards to error.



• **FIG 6.2** The relationship between a systems ("blunt end") perspective and a persons ("sharp end") perspective. *Source:* (Image courtesy J. Ehrenfeld.)

Dr. Reason performed an analysis of errors and determined that most accidents occur as the result of multiple, small errors occurring in an organization with system flaws, rather than from the singular errors of individuals.[13,17] He went on to describe the **Swiss cheese model** of system failure, which recognizes that error is inevitable and every step in a process (such as health care delivery) has the potential for failure (Fig. 6.3).[17] Each layer of the system can serve as a defensive barrier to identify and catch the error before harm reaches the patient.[13] In the Swiss cheese model, the medical system is envisioned as a stack of Swiss cheese slices, with the slices representing the system defenses and the holes representing a process failure or system error. In order for harm to reach the patient, the error must pass through holes in multiple defense mechanisms represented by the slices of cheese. Ideally, errors will be prevented through the application of multiple defenses and safeguards (additional layers of cheese) and

improved processes (smaller holes in the cheese) that will function as a safety net to prevent errors and subsequent harm from reaching the patient.



• **FIG. 6.3** **The Swiss Cheese Model of System Failure** *Source:* (Reproduced with permission from Collins SJ, Newhouse R, Porter J, Talsma A. Effectiveness of the surgical safety checklist in correcting errors: a literature review applying Reason's Swiss cheese model. *AORN* J. 2014;100[1]:65-79.)

The holes in the cheese are the result of both latent and active failures. **Latent failures** (or **latent errors**) occur at the blunt end as the result of system or design flaws removed from the patient's bedside that allow active errors to occur and result in harm.[13] Latent failures are less obvious than active failures and may include equipment design flaws, decreased staffing for fiscal reasons, and software interface issues. Addressing latent flaws requires an understanding of how the complex system interacts with individuals; flaws in leadership, work environment, or institutional policies may be identified as the source of error. **Active failures** (or **active errors**) involve frontline personnel at the sharp end and occur as the result of an individual's failure.[13] These types of errors normally occur as the result of mental lapses, errors in judgment, or procedural violations. Examples of active errors include administering the incorrect medication, performing surgery on the wrong site, or lacking knowledge of the treatment for a particular illness.

Case study 1

You discharge a patient from the hospital who goes home with a prescription intended for a different patient. The patient takes the medication, and it cross-reacts with one the patient is already taking and causes an anaphylactic reaction requiring readmission to the intensive care unit.

A systems review of this case reveals contributing factors. An administrator had called you shortly before the event, asking that as many patients as possible be discharged right away to open beds for patients coming out of surgery. You had been up all night with critically ill patients and were trying to discharge three patients simultaneously but the EHR "went down." You resorted to handwritten prescriptions instead, and the nurse of one of the patients was helping you by putting patient labels on the prescriptions. The incorrect patient label was placed on the prescription in question. The pharmacy filled the prescription without identifying the potential drug interaction.

1. Can you identify both the latent and active errors in this case?
2. What was the nurse's responsibility? What was the pharmacist's responsibility?
3. Should you or the nurse be reprimanded or fired?
4. How can this be prevented in the future?

III. Specific types of medical errors

Medical errors are ubiquitous in the existing complex health care system. There are a number of classification systems and taxonomies for categorizing medical errors. Since medical errors often fall into a specific area or activity, one can organize them as demonstrated in Table 6.1. Common types of medical errors include those related to medications, surgical/procedural errors, diagnostic errors, errors in transitions of care, and teamwork/communication errors.

TABLE 6.1

Examples of Common Medical Errors

Type of Medical Error	Examples
Medication errors	• A physician writes a prescription for 5.0 mg of lisinopril, and the order is misread as 50 mg. • A physician orders Zyban for smoking cessation, not realizing the patient is already taking the drug Wellbutrin for depression—which contains the same active ingredient, bupropion. • A pharmacist mistakes a prescription for eribulin for epirubicin (both are drugs used to treat breast cancer).
Surgical/procedural errors	• An elderly patient's left kidney is removed instead of the right kidney. • A physician places a central line in a sedated patient in the intensive care unit. However, it was the wrong patient. • During an emergency laparotomy procedure for a teenager involved in a motor vehicle crash, a surgical sponge is left hidden behind the spleen.
Diagnostic errors	• A 19-year-old patient with abdominal pain, vomiting, and loss of appetite is diagnosed with acute gastroenteritis rather than appendicitis. • A lung nodule on a chest radiograph is not recognized by a radiologist. • A 63-year-old woman arrives in the emergency department with shoulder pain and palpitations after lifting a set of heavy boxes. She is diagnosed with a shoulder strain rather than a myocardial infarction.
Transitions of care errors	• A 72-year-old woman was readmitted to a hospital for heart failure 2 weeks after being discharged for treatment of the same condition. Upon reviewing her medication list, the admitting physician discovered that the patient's diuretic and ACE inhibitor were not prescribed at discharge. • A 63-year-old man was transferred from a long-term care facility to an emergency department with an acute decline in mental status and shortness of breath. Laboratory analysis revealed that the patient was in acute renal failure. On arrival at the hospital, medication reconciliation was completed between an emergency

	department nurse practitioner and a pharmacy technician at a local drugstore. The patient was restarted on a digoxin, a medication that was stopped by the patient's internist a year prior. The patient was subsequently diagnosed with digoxin toxicity.
Teamwork/communication errors	• A medical intern decides not to wake up her attending physician at 2:00 AM for a patient who has taken a turn for the worse, exposing the patient to unnecessary risk. • A patient is started on an antihypertensive medication that has a known side effect of increasing potassium levels. The prescribing physician schedules a potassium level to be drawn 2 weeks after the medication is started but fails to notify the follow-up physician. A month later the patient is hospitalized with hyperkalemia.
Health care–associated infections	• A patient develops pneumonia after being intubated for asthma. • A patient develops a urinary tract infection after having an indwelling bladder catheter placed to monitor urine output during an exacerbation of congestive heart failure.
Documentation errors	• A patient's medical record contains erroneous information that documents that she has had a hysterectomy. In evaluating her for pelvic pain, the physician fails to confirm the accuracy of that surgical history and does not order a pregnancy test. As a result, the patient has a delayed diagnosis of ectopic pregnancy. • An EHR contains erroneous documentation that a patient has an allergy to aspirin. Failure to confirm this information upon his presentation with acute myocardial infarction results in the patient not receiving aspirin as clinically indicated.
Patient identification errors	• Patients with similar names are located in rooms beside each other. Failure to confirm the patient's identity leads to the wrong patient having surgery. • A patient has a Pap smear performed for routine health screening and the specimens are mislabeled with another patient's name. As a result, the patient has a delayed diagnosis of cervical cancer and another patient undergoes unnecessary invasive testing.
Device-related errors	• In a medical ICU, an infusion pump was reprogrammed from 2.1 to 209 mL/hr, when the intention was 2.9 mL/hr. As a result, the patient receives a 100-fold increase of the intended medication.

ACE, Angiotensin-converting enzyme; *EHR*, electronic health record; *ICU*, intensive care unit.

A. Medication errors

The exponential increase in prescription and over-the-counter drugs has led to a tremendous increase in complexity of prescribing and administering medications. An **adverse drug event**, experienced by at least 5% of hospitalized patients, is harm that is experienced by a patient either from a side effect or as the result of a medication error.[18] It is estimated that over 7000 patients die each year due to preventable medication errors.[19] The costs of medication errors have been estimated to waste over $21 billion dollars annually.[19,20] While previous discussions focused on illegible handwriting as the cause of medication errors, errors can occur in any of the ordering, transcribing,

dispensing, and administration stages.[21] Now that most medications are ordered electronically, the underlying cause of many medication errors has shifted to other etiologies that may include inappropriate entry into the electronic ordering system. Errors include prescribing the wrong medicine or the wrong dose, or failure to consider interactions or contraindications. Even if ordered properly, the wrong medication may be administered either by the pharmacy, a physician, or another health care professional. Patient response to medications may be inappropriately monitored, such as failure to monitor liver function in a patient with mild hepatic insufficiency who is prescribed glyburide (which interacts with the liver) for his or her diabetes. Patients may take medications inappropriately due to insufficient or incomplete instructions, inadequate numeracy, challenges of dosing schedules, financial concerns, or poor design. For example, during evaluation of the ease of use of a new inhaler among patients, one study demonstrated that 24 hours after being shown how to use the device, 65% of elderly patients could not use the inhaler.[22]

Medication errors continue to be a surprisingly common and costly source of error across all clinical settings and were the focus of a 2007 IOM report, *Preventing Medication Errors: Quality Chasm Series*.[20] In this report, the authors estimated that 1.5 million preventable adverse drug errors occur in the United States each year, representing $3.5 billion in unnecessary cost to the health care system.[20] To reduce the likelihood of certain types of medication errors, it is recommended to avoid the use of abbreviations for dose designations, which are often misinterpreted.[22] Examples include the abbreviation "μg" for microgram, which is often mistaken as "mg" (milligram). Instead, one should use "mcg." It is also recommended to avoid the use of a "naked" decimal point; for example,.25 mg can be easily mistaken as 25 mg if the decimal point is not recognized. Instead, one should always write a zero before a decimal point (0.25 mg). Finally, drug abbreviations such as "HCTZ 50 mg" for hydrochlorothiazide can be mistaken as hydrocortisone by someone who reads "HCT250 mg." The Joint Commission has developed a "Do Not Use" list of problematic abbreviations (Table 6.2).[23]

TABLE 6.2

The Joint Commission's "Do Not Use" List

Do Not Use	Potential Problem	Use Instead
U, u (unit)	Mistaken for "0" (zero), the number "4" (four), or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
Q.D., QD, q.d., qd (daily) Q.O.D., QOD, q.o.d, qod (every other day)	Mistaken for each other Period after the Q mistaken for "I" and the "O" mistaken for "I"	Write "daily" Write "every other day"
Trailing zero (X.0 mg)[a]	Decimal point is missed	Write X mg

Lack of leading zero (.X mg)		Write 0.X mg
MS MSO_4 and $MgSO_4$	Can mean morphine sulfate or magnesium sulfate Confused for one another	Write "morphine sulfate" Write "magnesium sulfate"

[a]**Exception:** A "trailing zero" may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

From The Joint Commission Fact Sheet: Official "Do Not Use" list. http://www.jointcommission.org/facts_about_do_not_use_list/. Accessed June 4, 2019. ©The Joint Commission, 2019. Reprinted with permission.

In addition, there are specific medications that are referred to as high-alert or high-hazard agents because they are thought to be the most likely to cause harm to patients, even when used as directed. The Institute for Safe Medication Practices has published a list of high-alert medications, with insulin, opioids, potassium chloride, albuterol, heparin, vancomycin, cefazolin, acetaminophen, warfarin, and furosemide being some of the most common drugs associated with medication errors.[24] Special consideration should be given to implementing safeguards to reduce risks and minimize harm when using these medications. Strategies include mandatory patient education, improving access to drug information, using automated alerts, implementing bar code administration, and standardizing prescribing, dispensing, and administration practices. Geriatric patients are particularly predisposed to adverse drug effects due to age-related changes in pharmacodynamic response and increases in the number of medications used. The most common drugs causing harm for geriatric patients include heparin, insulin, morphine, potassium chloride, and warfarin.[25] Finally, it should be noted that all forms of insulin, subcutaneous and intravenous, are considered a class of high-alert medications. The highly concentrated form, insulin U-500, has been singled out for special emphasis on the need for distinct preventive strategies.

B. Surgical/procedural errors

The risk of errors associated with surgery and procedures is somewhat unique. The perceived sense of urgency in the operating room environment and other procedural suites (e.g., interventional radiology, endoscopy, or cardiac catheterization suites), the use of interchangeable teams, and the pressure to complete procedures on time bring together a variety of environmental and systems factors that can promote errors.[26] Successful procedures require a mixture of technical skills, good communication among teams, and adequate decision making. "**Wrong surgery/procedure**" (meaning the surgery or procedure was performed on the wrong patient or the wrong site, or the wrong surgery or procedure was undertaken) is surprisingly common, despite national efforts to eliminate this problem. Other problems include retained objects (i.e., surgical sponges or instruments) and failure to take appropriate precautions to prevent surgical site infections using established guidelines for care (i.e., giving antibiotics prior to

surgical incision). While many factors contribute to procedural errors, a number of studies have identified risk factors. One such study found that the leading system factors were inexperience/lack of technical competence (41%) and communication breakdown (24%).[27] The same study reported that cases with technical errors (54%) involved safety challenges in multiple phases of care, multiple personnel, lack of technical competence/knowledge, and patient-related factors.[27]

C. Diagnostic errors

Despite advances in imaging and laboratory evaluation, diagnostic errors have remained common. **Diagnostic error** is defined as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient."[28] It is estimated that 5% of patients receiving outpatient care in the United States will experience a diagnostic error, and postmortem examination research suggests that diagnostic errors contribute to 10% of patient deaths.[28] Diagnostic errors have been reported to account for 17% of preventable errors and represent the most common reason for paid malpractice claims in the ambulatory setting.[5,6,29]

According to the 2015 comprehensive report by the National Academies of Sciences, Engineering, and Medicine, Improving Diagnosis in Health Care, diagnostic errors will affect nearly every person at some point during his or her life, warranting increased attention as a major cause of significant morbidity and mortality.[28] As newer and more sensitive diagnostic modalities become available, increasing emphasis has been placed on addressing overdiagnosis, overtesting, and overtreatment. Abnormalities may be identified that are not clinically significant; diagnosis and treatment in such cases exposes patients to unnecessary treatment with the inherent risk of morbidity and mortality. Failures of communication and teamwork are major contributors to diagnostic errors. The report outlined eight goals for reducing diagnostic errors[28]:

1. Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families.
2. Enhance health care professional education and training in the diagnostic process.
3. Ensure that health information technologies support patients and health care professionals in the diagnostic process.
4. Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.
5. Establish a work system and culture that support the diagnostic process and improvements in diagnostic performance.
6. Develop a reporting environment and medical liability system that facilitate improved diagnosis through learning from diagnostic errors and near misses.
7. Design a payment and care delivery environment that supports the diagnostic process.
8. Provide dedicated funding for research on the diagnostic process and diagnostic

errors.

Implementation of these core goals would not only reduce diagnostic errors but also reduce many other medical errors and go a long way toward improving patient safety.

D. Transitions of care errors

Transitions of care, times when patients are moved from one setting of care or practitioner to another, are high-risk times for errors to occur (additional details are discussed in Chapter 8). Whether this involves physical movement of a patient (i.e., from the intensive care unit to a surgical-floor bed) or a handover of responsibility from one team or practitioner to another, a transition point is a time when information about a patient can be lost or misinterpreted. Challenges around ensuring successful transitions of care highlight that our health systems have not been designed for high reliability. To ensure information is not lost, experts recommend the use of a structured handoff process or checklist.

One such structured process, I-PASS, has been tested at multiple institutions and found to improve communication and result in decreased preventable adverse events. I-PASS reinforces the bidirectional nature of a handoff, with designated expectations for both the provider and the recipient of patient information. Adapted from I-PASS handoff curricular materials (http://www.ipasshandoffstudy.com), best practices to ensure a high-quality handoff include:

1. Unambiguously transfer both information and responsibility.
2. Identify a protected time and space to initiate the handoff.
3. Use a standardized format or a shared mental model.
4. Ensure that patient information is up-to-date, accurate, and relevant.
5. Establish clear roles during the handoff.
6. Use closed-loop communication to ensure receipt and understanding of knowledge.[30]

E. Teamwork/communication errors

As health care has become increasingly complex, effective teamwork and communication are becoming even more essential for the delivery of safe, high-quality health care. In a review of sentinel events from 2005 to 2018, communication errors have been identified as the root cause of the majority of all reported sentinel events, with 50% of these events resulting in a patient death.[31] Multiple obstacles can contribute to ineffective team performance, including frequent changes of team membership, time pressures, varying communication styles, fatigue, inadequate information sharing, lack of role clarity, and intensity and volume of workload.

Medicine has traditionally functioned in a rigid hierarchical system, but increasing attention is being placed on valuing the contributions of, and input from, all team members. The aviation industry overcame many of these challenges by a process known as crew resource management. Emphasis was placed on decreasing the

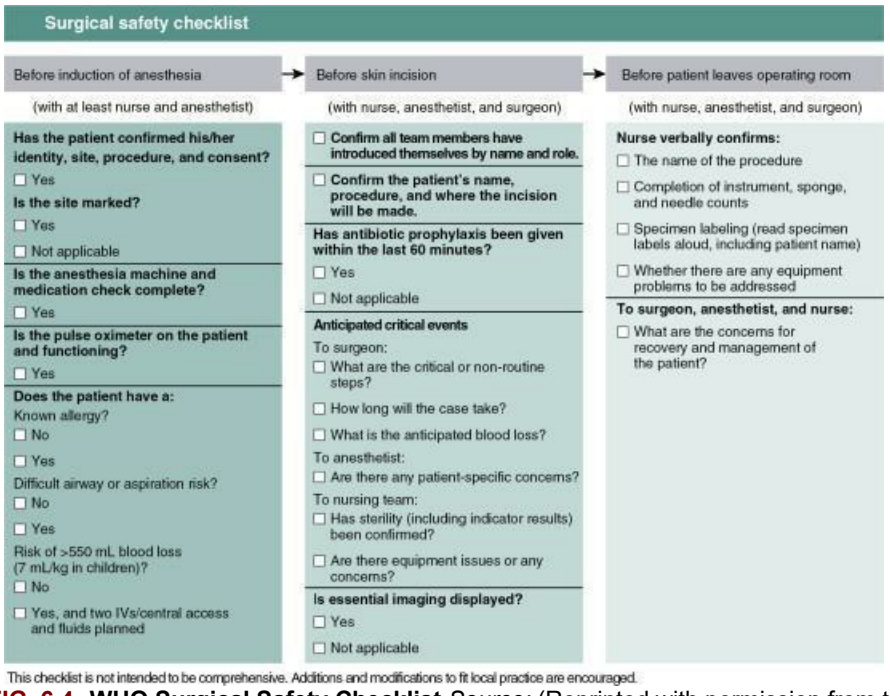
authority gradient, a term used to describe the psychological distance between a worker and a supervisor.[32] A less hierarchical environment promotes effective communication that is complete, clear, concise, and timely. **Situational awareness** refers to actively and openly monitoring changes in a patient's clinical status or a busy work environment. This enables collective adaptation to emerging situations by generating a shared mental model and aligning team members toward the same goal. Programs such as Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS), developed by the Department of Defense, utilize standardized communication behaviors such as briefings, debriefings, checklists, and critical language to create a culture that encourages all members of the team to speak up in the interest of patient safety.[33] Manufacturers such as Toyota have employed a process in which any worker can stop the manufacturing line by pulling the "Andon cord" to signal the need to immediately fix a problem and prevent an error.[34] Health care settings have begun to employ this "stop the line" strategy to encourage all health care workers—from ancillary staff, such as housekeeping and food services, to clinical staff, such as nurses and physicians—to alert the team to a patient safety concern before any harm is experienced by the patient.

The physician has traditionally been positioned at the pinnacle of the hierarchy, with the communication divide between physicians, nurses, and other staff being quite wide. While it remains necessary to have a leader of a team, the team will function more effectively if its members are not afraid to speak out and warn of a potential risk to the patient. The term flattening the hierarchy refers to creating an environment in which all members of the team feel safe in providing input, are valued for speaking up, and are not deprecated for doing so.[35] By permitting a free flow of information up and down the leadership chain, many potential adverse events can be thwarted.

Communication can be enhanced by use of structured conversations at critical junctures in care. Many health care systems use a tool called **SBAR** for communication during transitions of care and critical events.[36] SBAR stands for Situation, Background, Assessment, and Recommendation. The speaker first describes the current **situation** (*Mr. Saunders has developed a sudden onset of shortness of breath*). Additional details are then provided. The second component is the **background** pertinent to the current situation (*He has a history of COPD and CHF. Yesterday he underwent emergency surgery for a blood clot in his leg. He had bleeding resulting in his anticoagulant being held*). The key information needed to put the current situation into context is provided. This is followed by an **assessment** (*I am concerned that he has developed a pulmonary embolus. He may also be in congestive heart failure from all the fluid given during surgery*). The final component is the **recommendation** (*Please come assess the patient. I can call for a chest x-ray in the meantime*). This standard format allows for clear and concise information to be transmitted during what may be a stressful situation.

The surgical "time-out" is another example of structured communication. In 2008, the World Health Organization (WHO) published a free checklist (Fig. 6.4) with just 19 items to be reviewed at the preoperative, intraoperative, and postoperative stages of a surgical procedure to reduce the number of surgical complications occurring globally.[37] With over 234 million operations occurring annually around the world and an

estimated half-million deaths from these operations deemed to be preventable, the "Safe Surgery Saves Lives" multinational endeavor sought to improve both morbidity and mortality resulting from preventable human errors.[38] In the first major study looking at patient safety before and after implementation of the checklist, major complications were decreased on average by 36% and deaths declined by 47%.[39] The unexpectedly impressive results led some critics to argue that the results were too good to be true. However, a meta-analysis of studies employing the WHO checklist has confirmed those findings, showing a marked decrease in surgical complications (risk ratio, 0.59), particularly in studies in which compliance with the checklist was high.[40] It is not often that a free tool that takes less than 2 minutes to apply to a patient can save millions of lives. Yet there remains some reluctance among physicians and nurses regarding checklist implementation. In one study, despite the expectation of 100% utilization of the checklist, it was incompletely used in 60% of operations and not utilized at all in 10%.[41] This emphasizes the importance of changing both the individual and organizational culture to implement patient safety methodologies, even when the technology to do so is provided at no cost.



Surgical safety checklist

Before induction of anesthesia (with at least nurse and anesthetist)	Before skin incision (with nurse, anesthetist, and surgeon)	Before patient leaves operating room (with nurse, anesthetist, and surgeon)
Has the patient confirmed his/her identity, site, procedure, and consent? ☐ Yes **Is the site marked?** ☐ Yes ☐ Not applicable **Is the anesthesia machine and medication check complete?** ☐ Yes **Is the pulse oximeter on the patient and functioning?** ☐ Yes **Does the patient have a:** Known allergy? ☐ No ☐ Yes Difficult airway or aspiration risk? ☐ No ☐ Yes Risk of >550 mL blood loss (7 mL/kg in children)? ☐ No ☐ Yes, and two IVs/central access and fluids planned	☐ **Confirm all team members have introduced themselves by name and role.** ☐ **Confirm the patient's name, procedure, and where the incision will be made.** **Has antibiotic prophylaxis been given within the last 60 minutes?** ☐ Yes ☐ Not applicable **Anticipated critical events** To surgeon: ☐ What are the critical or non-routine steps? ☐ How long will the case take? ☐ What is the anticipated blood loss? To anesthetist: ☐ Are there any patient-specific concerns? To nursing team: ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns? **Is essential imaging displayed?** ☐ Yes ☐ Not applicable	**Nurse verbally confirms:** ☐ The name of the procedure ☐ Completion of instrument, sponge, and needle counts ☐ Specimen labeling (read specimen labels aloud, including patient name) ☐ Whether there are any equipment problems to be addressed **To surgeon, anesthetist, and nurse:** ☐ What are the concerns for recovery and management of the patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

• **FIG. 6.4** **WHO Surgical Safety Checklist** *Source:* (Reprinted with permission from the World Health Organization. http://apps.who.int/iris/bitstream/10665/44186/2/9789241598590_eng_Checklist.pdf.)

F. Health care-associated infections

A growing body of evidence demonstrates the risk of infection to patients in health care settings, primarily hospitals. These health care-associated infections (HAIs) contribute

to significant morbidity and mortality. Judging these to be mostly preventable, Medicare began withholding payments for HAIs in 2008. While any infection contracted in a health care setting is considered a HAI, the most common HAIs are surgical site infection, ventilator-associated pneumonia, central line–associated bloodstream infection, and catheter-associated urinary tract infection.

Risk factors contributing to HAIs include underlying complex medical problems, extremes of age, indwelling devices, surgical procedures, and antibiotic use. Several strategies and interventions have been designed to mitigate the risk and reduce the infections. A systemic culture of hand washing is the single best strategy to prevent infection. Development of evidence-based checklists and care bundles for indwelling devices has been shown to reduce HAIs. Care bundles typically consist of three to five evidence-based guidelines shown to have better outcomes when implemented collectively.[42] Strategies for preventing surgical site infections include adminstering appropriately timed preoperative antibiotics, maintaining normothermia, discontinuing prophylactic antibiotics within 24 hours, and completing proper preoperative hair removal with clippers. Bundles for ventilator-associated pneumonia prevention include efforts to avoid intubation in the first place or, upon intubation, elevation of the head of the bed, regular oral care, mimimization and interruption of sedation, and early ventilator weaning protocols. Prevention of catheter-associated urinary tract infection is enhanced by restrictive use of a catheter, insertion by trained personnel using a standard technique, and maintaining a closed system of collection that remains below the level of the bladder at all times.

G. Documentation errors

With the advent of electronic health records (EHRs), errors associated with illegibility have largely disappeared. Unfortunately, other documentation errors have become ubiquitous and can rapidly propagate throughout the EHR with far-reaching implications. The health record should serve as a platform for communication about the patient's history and condition; however, many current EHRs are better designed to support billing and regulatory needs than patient care. Errors of commission occur when incorrect or inaccurate information is entered into the record. Examples of these may be a typing or voice recognition error in which *hyper*tension is entered instead of *hypo*tension. Prepopulated notes or copy-and-paste functions can be time-saving tools; however, they may also result in entering incorrect information, such as documenting a normal extremity examination on a patient who has undergone amputation. Entering information in the wrong patient record also commonly occurs. Physician order entry into an EHR has reduced errors; however, overreliance on tools such as medication dose options has contributed to errors. EHRs build in alerts that appear during the order entry process to warn physicians and other health care professionals of potential drug interactions or incorrect dosing. However, excessive warnings can lead to alert fatigue, prompting them to be ignored. Unapproved abbreviations and typographic errors remain a problem in the electronic records similar to the paper chart. Errors of omission result from the failure to enter pertinent information. These may include

failure to enter allergies into the proper field to enable automated safety monitoring of medication orders, failure to document significant findings such as a heart murmur, or failure to document adequate clinical reasoning to justify a procedure. Finally, the ability to import extensive data from other sections of the EHR, such as laboratory results or medication lists, into patient notes creates chart bloat. This is when a daily progress note becomes several "pages" long and does not convey a sense of the patient's condition or pertinent information—the very features a medical record is intended to convey.

H. Patient identification errors

The Joint Commission requires using at least two patient identifiers directly associated with an individual patient when providing care, treatment, or services. Institutions are responsible for determining the specific identifiers, but those commonly used include patient name, date of birth, medical record number, address, photo, or phone number. Using two identifiers mitigates the likelihood of errors and improves overall safety. The growing issue of medical identity theft has created an additional source of error. When a false identity is used, the EHR may become populated with erroneous medications, past medical history, problem lists, and procedure notes. In addition to the financial implications of such fraud, inaccurate health data can result in delays in diagnosis and treatment, leading to serious consequences for all those involved.

I. Device-related errors

The explosion of medical technology has created an entirely new source of errors related to technology. Manufacturing errors include issues related to poor design, mechanical weakness, and software programming failures. User errors include incorrect device assembly, failure to follow instructions, and improper connections between components. Deference to and overreliance on technology also leads to errors such as failing to fully assess a patient, to recognize a change in patient status, and to manually verify medication, concentration, and dose.

Case study 2

A 72-year-old veteran with memory loss, diabetes, and hypertension is admitted to his local Department of Veterans Affairs (VA) facility after he develops difficulty breathing, tongue swelling, and facial numbness. He is diagnosed with angiotensin-converting enzyme (ACE) inhibitor angioedema. You stabilize the patient and monitor him in the intensive care unit before discharging him 48 hours later. Upon discharge, you update the patient's record to indicate that he has an allergy to ACE inhibitors, and you prescribe a new antihypertensive medication from a different drug class.

A month later, the patient presents again to the emergency department with signs of angioedema. Upon review, it is determined that the patient started taking his ACE inhibitor again. The patient is stabilized and admitted for observation, and the internist on call speaks to the patient's wife regarding how this occurred a second time.

The internist discovers that the patient has a local, non-VA primary care physician. After his hospital discharge a month earlier, the patient did well until he ran out of his medications. His wife, who is the patient's primary caregiver, called his local doctor to obtain refills. However, the other physician did not have access to the VA records and was unaware that the patient was recently hospitalized. The local physician refilled all of the patient's previous medications—including the ACE inhibitor, which had been discontinued.

1. How common is it for patients to move among health care systems?
2. What can be done to prevent this type of error from occurring in the future?

IV. Factors contributing to error

Multiple factors can contribute to errors in health care. Reason's Swiss cheese model of organizational accidents emphasizes that the "root causes" allowing an error to occur should be investigated and identified.[13] Using this as a foundation, Charles Vincent developed a framework for classifying factors affecting clinical practice. Contributory factors influencing safety are divided into seven broad categories: patient factors, task factors, individual factors, team factors, work environment, organizational and management factors, and institutional context.[43,44]

A. Patient, task, and individual factors

Patient factors such as personality, language, culture, and illness complexity have a direct impact on communication and bias. While the patient's condition has the most direct impact on care, individual patient factors, including language, cultural expectations, and psychological factors, may impact the way in which the patient interacts with physicians and other health care professionals. Clinician knowledge, skills, experience, and other individual factors affect clinical practice and outcomes, especially in stressful conditions requiring high levels of skill. Fatigue, stress, or lack of familiarity with procedures can negatively impact the ability of a physician or health care professional to safely perform procedures and subsequently impair the ability to deal with complications. Availability and use of clear protocols and the accessibility of accurate test results are examples of task factors. For example, institutions with protocols whereby a laboratory technician immediately contacts the physician or nurse with abnormal results associated with increased morbidity and mortality are much more likely to address these abnormalities compared to institutions that simply report such results in the EHR without any notification procedures.

B. Workplace, team, organizational, and institutional factors

Workplace factors (staffing, physical environment, light, heat, and interruptions) contribute to the physician's ability to carry out a task without being distracted. Heavy workloads without administrative support create a stressful environment that makes communication difficult, limits time at the bedside with patients, and increases the likelihood of an error. High-performance teams acknowledge that all members of the team, from environmental engineering personnel to leadership executives, are critical team members. Each person is a member of multiple teams contributing to patient care. The respect, mutual support, and communication skills between team members directly impact the patient and the care provided. Poor communication is most likely to contribute to poor teamwork and medical errors, but poor supervision or the unwillingness of less experienced team members to ask for assistance also have deleterious consequences. Organizational factors impact care through policies and

processes related to leadership, education, supervision, and availability of equipment or supplies. Senior management can engage standards and goals to support an organizational culture of safety that is valued above purely financial metrics. External regulatory agencies, the medicolegal environment, and financial constraints affect the institutional context.

C. Factors related to health professionals

While we can readily evaluate systems and processes for opportunities to improve safety, there remain human components to errors that are more difficult to evaluate and address. The study of this human component and how individuals make decisions is termed **cognitive science**. Classifying these errors into the categories of inadequate medical knowledge, incomplete data collection, and poor decision making can help identify areas for future improvement (Table 6.3).[45]

TABLE 6.3

Examples of Cognitive Contributions to Errors

Category	Type	Example
Faulty Knowledge	Knowledge base inadequate or defective	Clinicians not aware of the disease called Fournier gangrene
	Diagnostic skills inadequate or defective	Missed diagnosis due to misread electrocardiogram
	Therapeutic skills inadequate or defective	Patient suffers adverse event because of not being warned of potential side effects
Faulty Data Gathering	Ineffective, incomplete, or faulty workup, history, or physical examination	Failure to consult the patient's old medical records, leading to delayed diagnosis of drug-related lupus
	Faulty test or procedure techniques	Reversal of electrocardiogram leads prompts wrong diagnosis of myocardial infarction
	Failure to perform indicated screening	Missed colon cancer due to failure to obtain colonoscopy
Faulty Synthesis: Information Processing or Verification	Faulty context generation	Missed perforated ulcer in a patient presenting with chest pain and laboratory evidence of myocardial infarction
	Failure to order or follow up on appropriate test	No further imaging after a chest radiograph first reveals a small nodule
	Failed heuristics or "rules of thumb"	Diagnosis of bronchitis in a patient later found to have a pulmonary embolism
	Faulty interpretation of a test result	Missed diagnosis of *Clostridioides difficile* in a patient with a negative stool culture

In addition to the caregiver needing a solid foundation of medical knowledge, the process by which he or she interprets this information and makes a decision about urgency and severity is equally important. Every patient is unique, requiring decisions

that consider that uniqueness. When patients present to the emergency department, they are assessed or triaged based on a constellation of questions, their initial appearance, and just a few key pieces of information. To make judgments, physicians and other health care professionals use a set of constructs known as heuristics and biases. A **heuristic** is a pattern, or "rule of thumb," used to approach a problem. A **bias** is a tendency to think one way or have a gut feeling about a situation, and it originates in one's unconscious. Both can be helpful or harmful in certain circumstances.

Intuition is a key skill, especially when time is of the essence, for recognizing when a patient is critically ill or predicting what complication may occur. Individuals gain intuition through pattern recognition. Increased exposures create memories of how certain diseases progress in most patients. When similar patients or problems are encountered in the future, the physician or other health care professional subconsciously begins to match the old experiences with the new and apply what has been seen in the past to the present situation. On a positive note, these biases and heuristics allow physicians and other health care professionals to quickly make decisions. While largely effective, this can also cause failure through use of an incorrect decision tree. **Premature closure** may cause a physician and other health care professionals to discount information about the patient that does not fit the expected pattern or to persist in treating along a standardized pathway, even when a patient is not responding, because similar patients in the past did improve. Cognitive scientists have identified a number of biases that guide how physicians and other health care professionals make decisions. Understanding and recognizing these influences on daily decision making mitigates the potential for bias to result in patient harm.

Common biases impacting physicians and other health care professionals include:

1. *Availability bias:* Overestimating the probability of something that is relatively easy to recall. Judging the likeliness of an event by how readily it is recalled, not by careful assessment of all data.
2. *Confirmation bias:* Selective gathering and interpretation of evidence confirming a diagnosis while ignoring contradictory information. Tendency to seek out information that affirms one's initial choice and discount information that is contradictory.
3. *Omission bias:* Reluctance to take action out of fear of being held responsible for the outcome.
4. *Commission bias:* Tendency toward action rather than inaction.
5. *Hindsight bias:* Once a correct outcome is known, believing one accurately predicted the outcome, reducing the ability to learn from the past.
6. *Regret:* Overestimating the probability of a diagnosis with possible severe consequences because of anticipated regret if the diagnosis were to be missed.
7. *Recency bias:* It is easier to access recent information than older information, even if the older information is more relevant to the situation.
8. *Anchoring bias:* Making a decision based on initial starting points or impressions and failing to change despite further information.
9. *Aggregate bias:* Believing a given scenario is unusual or atypical, leading one to

ignore guidelines.

10. *Search-satisfying error:* Discontinuing a search for an answer once one comes across a reasonable finding.
11. *Sunk cost effect bias:* So much has been invested in a decision that one feels compelled to persist with it.

Human errors can also occur because of competing demands. Undoubtedly, patients expect that physicians and other health care professionals arrive at work each day awake, alert, and focused on their needs. Yet the realities of human life mean physicians and other health care professionals may be stressed, ill, fatigued, and less focused than desired. The need to provide 24-hour care and make rapid, critical decisions increases the stakes of such physical and emotional factors. In response to such concerns, the Accreditation Council for Graduate Medical Education has restricted work hours for resident physicians and trainees. First instituted in 2003, resident duty hour restrictions have undergone a series of changes based on research and outcomes to strike a balance between the competing forces of continuity of patient care, education, and patient safety.[46] Practicing physicians are expected to self-assess, weighing the risk of their own fatigue that makes them vulnerable to error against the risk of transitioning care to different physicians who may not know the patient.

Other high-stakes industries, such as the aviation industry, have legislated work and wellness policies, but health care has not done so for a number of reasons. Due to specialized individual skill sets, there may not always be another physician or system redundancy to whom a fatigued physician can transition the care of a particular patient. For example, consider a newborn infant with a severe congenital birth defect who rapidly becomes unstable and will only survive with an emergency operation. If the institution has only one pediatric surgeon trained to correct the defect but that surgeon has just finished operating for nearly 30 hours without rest, the risks of transferring a patient to a different hospital or to a less specialized caregiver must be weighed against delaying care or the provision of care by a fatigued physician at risk of making a human error.

As described previously, systems-based approaches to decreasing risk, such as structured forms of communication and standardized pathways for patient care, can be very effective, but individuals occasionally circumvent these processes. When physicians and other health care professionals repeatedly use a shortcut that deviates from a protocol, accept lower standards due to time or resource constraints, or conform to a different level of expectation, a new normal is created. Such recurrent deviation from standards and policy without repercussion is referred to as **normalization of deviance**. For example, a patient monitor sounds an alarm 10 times in an hour, and the nurse notes each time it is a false alert. The 11th time the alarm sounds, it is likely silenced without the nurse looking at the screen. This normalization of deviance could put the patient at grave risk if the 11th alarm was detecting an arrhythmia. The nurse has fallen prey to bias. A more appropriate response would be to investigate the cause of the repeated false alarms, reviewing monitor settings or adjusting the patient leads. Similarly, some physicians and other health care professionals do not contribute to an

environment of open communication and may be dismissive of the input of other team members; the lack of confronting such behaviors is a normalization of deviance. Adverse events arising from normalization of deviance are inevitable unless the institutional culture values addressing problems in real time. It is incumbent upon all team members to question deviance and support one another in adhering to vetted protocols. While this can be particularly challenging for trainees, due to fear of reprisal or concern about feeling incompetent, it is an important skill to master.

One technique to facilitate this conversation is described as the AAA (Ask, Advocate, Assert) method. The method relies on escalation of safety concerns to the team in a clear, respectful way. The first step is to ask clarifying questions. For example, a learner may ask, "Why do we give this drug if the patient has a listed allergy?" If the concern was not adequately addressed, the next step would be to advocate for a certain action: "I see that the patient has a documented allergy in the EHR. I don't think we should prescribe this medication." Finally, if there was an insufficient response, the next step would be to assert an action: "We should not prescribe this drug, and we need to involve the attending physician."

Although it is clear that many system and human factors contribute to medical errors, seeking systems-based solutions does not abdicate individuals from personal duty. Both individuals and institutions need to be held responsible for safety. In his description of a "Just Culture," James Reason distinguishes between inadvertent human error and egregious disregard of safety.[13] In a **Just Culture**, every employee advocates for an environment in which safety concerns can be assessed in a nonpunitive manner with willingness to address underlying causes. Individuals who provide unacceptable or negligent care resulting in harm should be held responsible for their actions. However, institutions embracing a Just Culture will thoroughly evaluate the circumstances and mitigating factors surrounding the event with an eye toward improvement before blaming individuals.[47]

V. Communicating with patients after adverse events due to medical errors

Medical errors can be devastating for the affected patients, families, caregivers, and organizations, but each of these stakeholders has a very different perspective. While patients often experience physical trauma after a medical error, the emotional trauma for the patients and family members can be decreased through respectful, empathetic communication from the physician and other health care professionals.[48] Patients and their families are typically fearful of further harm and need information about the injury and future health care consequences. Patients experiencing open communication and support from physicians and other health care professionals are more likely to continue the patient-clinician relationship after a medical error.[49] Alternatively, patients and families are more likely to pursue litigation if they feel the clinician was not caring and compassionate.[49] Failure to disclose a medical error to a patient and his or her family results in frustration, anger, and suspicion that erodes the patient-physician relationship and hinders further medical care. This leaves the patient not only injured from the adverse event but potentially secondarily injured from avoidance of further treatment. Patients want to be assured that their physicians and other health care professionals are truly sorry for the error and want to understand how they will ensure that other patients will not experience a similar outcome. In addition, patients may be forced to pursue litigation to deal with the financial impact of an injury.

Physicians and other health care professionals experience a significant amount of guilt in response to medical errors, but the majority have little experience with open disclosure of errors. Without the opportunity to disclose the error and reestablish an honest therapeutic relationship, physicians and other health care professionals may develop deleterious methods of coping or even choose to leave medicine after being involved in a medical error. Despite common fears of professional repercussions, experiences from the University of Michigan Health System and Veterans Affairs suggest that malpractice claims may be reduced through early disclosure.[50-52] A lack of transparency between patients and physicians erodes the therapeutic relationship, leading to dissatisfaction for both patients and physicians.[50] Both patients and physicians require resources to deal with the emotional stress precipitated by medical errors.

When a patient has been harmed, health care professionals, in consultation with the health system's department of quality, should approach the situation with transparency and provide honest communication to patients and families. Full disclosure of a medical error includes (1) an explanation of why the error occurred; (2) an apology; (3) an explanation of how the impact on the patient's health will be minimized, including an explanation of anticipated future care; and (4) a discussion regarding actions that will be taken to minimize the chance for future occurrence of similar injury to other patients.[53,54] The patient should receive a straightforward account of how the error occurred without placing blame or making accusations. The physician and other

members of the care team should acknowledge and take responsibility for their roles in the error when appropriate. It is impossible to predict how all patients will respond to full disclosure and apology following a medical error that results in significant harm. Patients report feeling a mixture of emotions, including sorrow, anxiety, depression, and frustration at the prospect that the error was preventable, but they are more likely to accept an apology when it is offered with expressions of remorse, sincerity, and a willingness to discuss the next steps in treatment.[53] While these conversations will be uncomfortable for those involved and perhaps difficult to hear, it is essential that clinicians remain attentive, listen actively, and demonstrate understanding, concern, and empathy for the patient's self-interests. These actions will help achieve the goal of rebuilding confidence in physicians and other health care professionals and begin the healing process. Many patients will be grateful for the transparent and honest nature of full disclosure accompanied by a sincere apology. Many patients appreciate the opportunity to voice their concerns and feel empowered by offering solutions to prevent the error recurrence.

Open error disclosure is an essential component of improving patient safety through organizational learning while simultaneously supporting the healing process. Communication with the patient and his or her family should be open and occur regularly following error disclosure. The initial disclosure may be overwhelming for patients but will inevitably prompt additional questions after they have had time to process the information. Many institutions have patient-clinician liaisons who provide a consistent relationship and communication schedule between the family, physicians, other health care professionals, and the organization. Most importantly, physicians and other health care professionals should continue to provide treatment and avoid withdrawing from the patient due to embarrassment or guilt.

VI. Second victims

Physicians and other health care professionals are nearly universally impacted by involvement in a medical error, even if they were not primarily responsible, making them the **second victims** of an adverse event or medical error. The emotional effect from adverse events impacts the entire organization and requires skillful management with compassion and empathy. An organization that effectively supports second victims will facilitate honest discussion with physicians and other health care professionals as they describe their involvement in adverse events. Shame, humiliation, and fear of punishment often isolate clinicians after they are involved in a poor outcome, especially if they are viewed by their colleagues as being primarily responsible for the error. Due to embarrassment, fear of punitive action, and concerns of loss of professional respect, physicians and other health care professionals frequently withdraw after an error occurs.[55,56] Traditional medical culture that emphasizes "error-free practice" tends to create an environment that precludes open discussion of errors and organizational learning.[57] Organizational support of frontline clinicians through formal procedures to support second victims involved in the adverse event is essential.[58,59] Institutional openness, discussion of error, and training in disclosure can help physicians and other health care professionals navigate difficult situations. Support services, including psychological counseling and peer support, are important in providing clinicians with effective coping strategies and cautions against maladaptive mechanisms.

VII. Reporting systems—mandatory versus voluntary

Error reporting systems are an important part of improving health care practice, enabling learning from errors and near misses. Such systems may be either voluntary or mandatory, and each approach has a distinct set of advantages and disadvantages. **Voluntary reporting systems** often receive error reports from clinicians who are directly involved in the event, as opposed to **mandatory reporting systems**, which typically receive error reports from a designated person who often is not directly involved in the error. When a report is generated from a person who has only second-hand knowledge of an event, important details necessary for an event analysis may be omitted.[60] Voluntary reporting systems are ubiquitous across health care systems and are commonly implemented using a web-based secure data collection process. Mandatory reporting systems include both federal and state efforts. The US Food and Drug Administration (FDA) medical device error reporting system requires hospitals and surgical facilities to submit reports to the FDA of suspected medical device–related deaths or serious injuries. Additionally, as of 2014, 26 states plus the District of Columbia have mandatory reporting systems for events that lead to a patient death or serious injury.

Reporting systems are most effective when they are perceived as designed to facilitate the improvement of patient safety. Voluntary systems are often perceived as more credible, and physicians and other health care professionals often place a higher level of trust in how submitted information will be used for learning and prevention of recurrence. This is in contrast to many mandatory reporting systems, which often generate a sense among practitioners that blame is likely to be assigned when an event is submitted. Reporting is typically mandatory for serious events (Box 6.1), including death, retained foreign object after surgery, radiation overdose, or transfusion error.[61,62] Initially these events were coined **never events**, implying that shocking, largely preventable actions such as wrong-site surgery or retained sponges should never occur. The National Quality Forum has expanded this Serious Reportable Events list to include serious and usually (but not always) preventable events divided into six categories: surgical or invasive procedure product or device, patient protection, care management, environmental, and radiologic, and potential criminal. According to Joint Commission standards, a **sentinel event** is one that reaches a patient and results in death, permanent harm, or severe temporary harm.[63] These events are deemed sentinel because they signal the need for immediate investigation and system improvement to protect the patient and prevent further harm. Although The Joint Commission does not require reporting of sentinel events, reporting is strongly encouraged to provide expertise during review of the event and contribute to a transparent safety culture.

• BOX 6.1

The National Quality Forum's Health Care Serious Reportable

Events (2011 Revision)

Surgical or invasive procedure events

- Surgery or other invasive procedure performed on the wrong site
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient

Product or device events

- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for functions other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting

Patient protection events

- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- Patient death or serious injury associated with patient elopement (disappearance)
- Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a health care setting

Care management events

- Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious injury associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Patient death or serious injury associated with a fall while being cared for in a health care setting

- Any stage 3, stage 4, and unstageable pressure ulcers acquired after admission/presentation to a health care setting
- Artificial insemination with the wrong donor sperm or wrong egg
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

Environmental events

- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a health care setting
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances
- Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting
- Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting

Radiologic events

- Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area

Potential criminal events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting

ASA, American Society of Anesthesiologists; *MRI,* magnetic resonance imaging.

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The success of reporting systems is almost entirely dependent on the ability of the system to facilitate process improvement and error identification. Since 2008 the federal government, through the Centers for Medicare & Medicaid Services, has stopped paying for the extra costs associated with a growing list of serious preventable errors, and other payers have adopted similar payment policies. In coming years, both

physician and hospital payments will be linked to quality and safety metrics established by the Centers for Medicare & Medicaid Services and other payers. Many errors have been identified and corrected as a result of reporting systems, including errors that originate outside of the direct care environment, such as medical device problems and drug manufacturing errors.

VIII. Assessment of risk and mitigation of medical errors

The prevention of medical errors and adverse events can be approached with a variety of strategies. One important concept is that of anticipating and mitigating risk. Active management of risk occurs in a continuous cycle beginning with assessment of risk, system evaluation, management or mitigation of the identified risks, and then assessment of the impact of the interventions (Fig. 6.5). Assessment of risk begins with an objective evaluation that considers the probability that an event will occur, as well as the potential impact of a given event. The approach to prevention of a rare but catastrophic event (e.g., a large earthquake or performing surgery on the wrong patient) is often different from the approach to managing a common but less devastating error (e.g., not following up on routine laboratory tests or administering a medication orally instead of intravenously).



• **FIG. 6.5** **The Cycle of Assessing and Managing Risk of Medical Errors.**

In assessing risk, it is important to consider the many factors that influence our health systems. These include the work environment, team and individual factors, and characteristics specific to a given patient. A systematic approach to risk assessment and mitigation enables the development of specific strategies, which may include the adoption of policies or protocols, the addition of training requirements, and the implementation of checklists or customized electronic reminder systems. To be effective, however, these strategies should be informed by a thorough understanding of the system to which they are being applied and the specific risk(s) they are designed to

alter.[17]

IX. Evaluation of near misses and errors

There is a body of scientific literature for analysis of both human and system errors. Several tools and techniques can be used to aid understanding of errors and development of solutions. The IOM report *Patient Safety: Achieving a New Standard for Care* describes aspects of event analysis, and many resources have been developed to facilitate the evaluation process.[64]

A key point in the evaluation of near misses and errors that cannot be overstated is the intent to identify solutions to problems rather than to assign blame to particular individuals. Although human factors play an important role in adverse events, they are rarely the only factor. There is an important distinction between ensuring adherence to protocols and standards versus making negative statements about an individual involved in a given situation. Blame can quickly erode trust and teamwork.

A. Error analysis tools

This section provides a brief overview of common error analysis tools. Inherent in all of these tools is a foundation of sound and robust science. Use of the tools is best accomplished by convening an interprofessional team of frontline staff, with expert facilitators and supported by leadership in a culture and system of safety.

1. Root cause analysis/event analysis

The overall goal of an event analysis is to understand the underlying causes that led to a particular event. Once commonly referred to as **root cause analysis**, most experts in the field now refer to these activities as **event analysis** (EA) in recognition that many events have more than one underlying cause. Although human factors contribute to most errors, the goal in an EA is to identify the system factors leading to the error so that appropriate solutions can be developed and implemented. An important tool in an EA is the iterative "5 Whys" technique. In this method, one keeps asking "Why" a particular action occurred until arriving at the underlying system issue(s) that contributed to the error. Table 6.4 outlines the key steps of an EA.[65]

TABLE 6.4

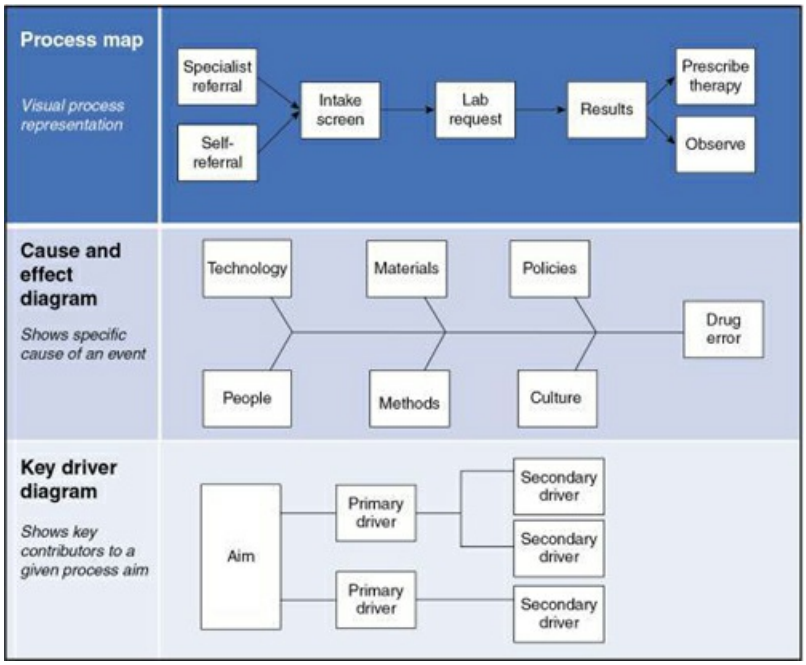
The Steps of an Event Analysis

Step 1: Awareness of the Event	All health care workers must be empowered to recognize and report an event or a near miss. Additionally, systems should be implemented to enable routine analysis of significant events.
Step 2: Information Gathering	Collect as much factual information about the event as possible. Sources should include the medical record and interviews with staff involved, and site visit of the incident.
Step 3: Facilitated	An effective team meeting will include a detailed discussion of the event, respecting the opinions of all present and avoiding the assignment of blame.

Team Meeting	
Step 4: Analyze the Event	Answer these four fundamental questions: • What happened? • Why did it happen? (Use "5 Whys" process.) • What have we learned from this event? • What should we change moving forward?
Step 5: Implement a Change	Depending on the event analysis, it may be decided that no action is needed. However, often there are gaps in processes identified that are amenable to change. These changes should be implemented by a designated person and their implementation monitored.
Step 6: Write it Up	Develop a comprehensive written record of the event analysis and ensure that the proper procedure was followed.
Step 7: Report Out	In order to ensure that others can benefit from the knowledge gained, a formal report should be generated and shared.

Adapted from NHS Education for Scotland and the National Patient Safety Agency. Significant event analysis: guidance for primary care teams. NHS Scotland. https://www.nes.scot.nhs.uk/media/346578/sea_-_full_guide_-_2011.pdf. Published 2011.

Tools commonly used in an event analysis include process mapping, a cause-and-effect diagram (also called a fishbone or Ishikawa diagram), and key driver diagrams (Fig. 6.6). Each facilitates an understanding of the various factors that contributed to a given event. A **process map** is a visual representation of a process showing how a sequence of events leads to a given outcome. Created on paper, electronically, or even using sticky notes, a process map can be used to identify the current state of a process—a key step in selecting changes or identifying areas for improvements. A process map can be used to demonstrate where in the process a system failure occurred. A **cause-and-effect diagram** shows the specific causes of an event, often categorized into groups such as people, processes, equipment, and environmental factors. A cause-and-effect diagram is powerful because it can reveal key relationships between a number of variables impacting a process. Finally, a **key driver diagram** shows the relationship between the aim of a process, the primary drivers that contribute to the aim, and secondary drivers that are necessary for the primary drivers.



• **FIG. 6.6** **Examples of a Process Map, a Cause-and-Effect Diagram, and a Key Driver Diagram.**

2. Failure mode and effects analysis

This error analysis and prevention tool developed by the US military in the 1940s also uses a process or flow map but identifies the potential sources of system failure, the likelihood of failure, and the relative impact of failure on the system before an adverse event actually occurs. Failure mode and effects analysis uses a step-by-step approach to understand and describe all possible design, manufacturing, implementation, or use failures of a given product or service. This technique is particularly useful to prevent failures in the design of a new process. Once sources of potential failure are identified, corrective actions and redesign and mitigation strategies can be developed and implemented for improvement or even before starting a new process.

3. Barrier analysis

This tool identifies the safeguards that could be implemented or instituted to protect vulnerable objects (patients) from harm. The barriers can be categorized in several ways: (1) physical, such as locked doors to medication rooms or limits on intravenous pump machines; (2) administrative policy and procedures, such as two-nurse review before administration of insulin; and (3) individual and team-based human actions, such as standard communication tools for change of shift. Using the analogy of the Swiss cheese model, barrier analysis seeks to add more slices of cheese or make the holes in each slice smaller.

4. Common cause analysis

This tool analyzes the cause of error across multiple events over a specific time period.

This process allows for greater understanding of trends and themes of errors in a particular system. By viewing errors across the system, leaders are able to better prioritize and implement improvements with the greatest overall impact on patient safety. A Pareto chart, in which individual factors are displayed in descending order as bars and the cumulative total is represented by an overarching line, can be a useful tool to visualize the type and frequency of errors in a system.

5. Morbidity, mortality, and improvement conferences

Morbidity and mortality (M&M) conferences have been a long-standing venue in which to objectively discuss and learn from adverse events. Born from early efforts to examine surgical errors, these conferences are now an important venue across all specialties to discuss improvement opportunities in a confidential manner protected by peer-review legal protections. Many institutions have renamed these meetings morbidity, mortality, and improvement (MM&I) conferences to emphasize a focus on creating system-level improvements. Interprofessional individuals have been integrated into these conferences, significantly enhancing the ability to consider system-level issues. The Accreditation Council for Graduate Medical Education now requires for accreditation that programs conduct MM&I conferences. Hosting standardized recurring meetings in which clinicians share their experiences with an eye toward system performance provides important evidence of an institutional culture of safety and improvement.[66]

X. Patient safety improvement strategies

Only after the "how" and "why" of an adverse event are understood can systems and processes to prevent recurrence be created. This chapter introduces the foundational concepts of patient safety and quality improvement. Chapter 7 provides more detail on these principles. Two of the most common methodologies for prevention of errors include standardization and constraint. In standardization, the expectation of how a process is normally expected to occur is clearly defined, and all team members are expected to meet the requirements without exception. In creating standards, care is taken to simplify processes, use technology or equipment to minimize human error, and reduce the probability of cognitive errors. Standards should be created by those closest to their use, flexible enough for wide applicability, and easily understood for training and implementation. Examples of successful application of standards to health care include The Joint Commission's "Do Not Use" List (Table 6.2) and the WHO Surgical Safety Checklist (Fig. 6.4).[23,37] At a local level, many institutions develop **clinical pathways** or protocols to standardize the care of patients with specific disease processes, allowing all team members to care for a patient using evidence-based guidelines, resulting in consistent care.

While requiring some loss of autonomous decision making, the use of such protocols has been shown to improve outcomes, reduce complications, and even lower the cost of care. In the 1980s, Toyota's manufacturing process was so streamlined and standardized that people came from around the world to observe their techniques. Their system of simplification with repetition became known as **Lean**, and soon industries far and wide were applying Lean to their own processes.[67] The health care industry shortly followed suit and began applying these same concepts to patient care in efforts to prevent harm, improve throughput, and enhance value.

Patient safety can also be improved through **constraint**, the creation of limitations in a system. Known in other industries as a "force function," a constraint requires a person to slow down at a critical juncture and complete certain steps or goals to proceed with the intended action. For example, if a hospital decided to employ the WHO Surgical Safety Checklist prior to every invasive procedure, the constraint might be set up that the nurse cannot provide the equipment for beginning the procedure until the checklist is completed. Another common example is the requirement that two medical professionals confirm blood type, crossmatch, and the patient's identification prior to transfusing blood. Policies utilizing constraints are intended to stimulate situational awareness, a recognition that an event with increased potential for harm is about to occur and all focus should be on the prevention of such harm.

Constraint can also occur through external forces, including governmental and regulatory agencies. An analysis of adverse events related to medical device failures was conducted by the FDA from 1985 to 1989. The FDA determined that nearly half of all recalls related to these devices occurred due to poor product design, inclusive of software errors. As a result, Congress empowered the FDA through the Safe Medical Devices Act of 1990 to create and enforce manufacturing processes and standards for

medical devices aimed at improving patient safety.[68]

XI. Changing the future of patient safety

In addition to culture change, perhaps the greatest opportunity for improving patient safety lies in advances in technology. The use of handheld computers (e.g., smartphones) has fundamentally changed the way humans interact with each other. These same technologies are already beginning to alter and enhance the way clinicians interact with patients. Interoperable EHRs can improve the accuracy and availability of information, leading to improved diagnosis and treatment through broad access to records and results from diverse medical settings. Warnings and alerts embedded in electronic systems can minimize human error by calling attention to potential drug interactions. Protocols created through standardization can be embedded in order entry platforms to guide the novice caregiver through the orders needed for a particular care pathway.[69] Digital technology can also create new types of errors and risks; however, the promise for improvement of these devices overshadows their flaws.

A range of devices from bar codes on patient identification bands to "smart" insulin pumps that evaluate blood glucose to determine appropriate dosing without human interaction all have the potential to protect patients from harm. Consideration of the interface of the instrument with the patient and with the physician or other health care professional is critical to inform the efforts of engineers in the design and redesign of medical devices from the perspective of safety. For example, many patients have been harmed by the accidental connection of enteral feeding solutions to an intravenous line. It is not uncommon for a critically ill patient to have six or more intravenous lines with associated pumps that may be adjacent to a feeding pump, all clamped to the same pole. Envisioning this scenario makes it easier to understand how tubing could be connected to the incorrect delivery line. Historically, all of these devices used connectors of the same size and shape—a setup for error. In 2013, the International Organization for Standardization engineered a new design and standard for enteral devices.[70] Once this is fully implemented, enteral and intravenous connections will no longer be compatible, virtually eliminating the potential for erroneous administration. It is through these and similar technologies that health care will become safer.

Perhaps the greatest impact on patient safety will come from changes in the education of physicians and other health care professionals and the culture of medical delivery. Traditional medical education has emphasized the medical knowledge necessary for patient care with a paucity of training in how to ensure safe delivery of care. Recognition of the importance of systems-based care, interprofessionalism, leadership, and communication in the prevention of medical errors has led to incorporation of these topics into medical school and residency curriculums to varying degrees. This textbook is an effort to provide the reader with these core concepts in recognition of the need to fundamentally change the way professionals are trained by melding core scientific knowledge with health systems science.

In 2012, Eastern Virginia Medical School became the first to require for graduation the completion of the Institute for Healthcare Improvement Open School Basic Certificate program on quality, patient safety, and related delivery skills, and scores of medical

schools have since followed suit.[71] The Institute for Healthcare Improvement Open School program is available without fee to medical students, residents, and faculty and lays the foundation for improved delivery of safe patient care. More extensive curricular change can be found in other medical schools where education in patient safety is fully integrated into the coursework alongside medical knowledge.[72,73] By teaching these skills at the onset of medical education as integral to patient care, the culture of safety can be changed for the better. Through these efforts, it is hoped that all health care professionals enter practice understanding their essential role in creating a patient-centered and team-based approach to patient safety.

XII. Chapter summary

Faced with overwhelming evidence that our health care system is causing harm, significant effort is underway to make it safer. These measures include recognition that most errors occur largely due to system errors, though human error was historically the focus of blame. Efforts must be made at the individual, local, and even international levels to create and implement tools for evaluating and preventing episodes of patient harm. Research utilizing reporting systems and enhanced technology has the potential to mitigate errors on a larger scale in the future. Through acknowledgment of human fallibility, routine error assessment, and standardization in communication, a culture of vigilance can supplement current prevention efforts and improve the safety of our health care systems. Providing the right care for every patient at the right time requires that all members of the health care team understand errors and error prevention while being committed to creating solutions to improve patient care.

Exercise

Patient safety has risen to the forefront of public attention as the health care system struggles with how to provide safe, efficient, and effective patient care. Have you or a family member been impacted by medical error? If so, how did this impact the patient and your family? How has this impacted you as a clinician?

Describe an experience in which you witnessed a medical error or near miss. Ask yourself how the system contributed to the error, even if it seems an individual is to blame. How did the physicians, other health care professionals, or system respond to the event? Did you witness an impact on the clinicians involved in the case? How could a similar error be prevented in the future?

Questions for further thought

1. Describe the difference between an error and an adverse event.
2. Describe the difference between a latent error and an active error, and how they potentially interact in leading to an adverse event.
3. How does the operating room environment increase the risk for errors, and what interventions can be put in place to mitigate that risk?
4. How can medical education have an impact on reducing cognitive errors that can ultimately lead to patient harm?

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Brennan TA, Leape LL, Laird NM. et al. *Incidence of adverse events and negligence in hospitalized patients* results of the Harvard Medical Practice Study N Engl J Med 1991;324: 370-376.

The Harvard Medical Practice Study was designed to study the incidence of injuries resulting from medical management, negligence, and malpractice. More than 30,000 charts were reviewed from a large, randomized sample of medical patients discharged from New York hospitals in 1984. The study revealed a high incidence of adverse events and negligence, with adverse events occurring in 3.7% of all hospitalizations and 27% of these adverse events due to negligence.

Kohn LT, Corrigan JM, Donaldson MS. Committee on Quality Health Care in America, Institute of Medicine. To Err Is Human Building a Safer Health System 2000; National Academies Press Washington, DC.

Issued in 1999 by the Institute of Medicine (since renamed the National Academy of Medicine), this landmark report cited the high frequency and costs of medical errors and provided impetus for the growth of the patient safety movement by bringing patient safety issues to the forefront of public concern. Based on multiple studies, it concluded that between 44,000 and 98,000 people die each year as the result of medical errors. The report described the epidemiology of errors and concluded that the majority of errors in medicine are attributable to faulty systems. The report called for a comprehensive approach to improved systems of care by physicians, health care professionals, consumers, payers, governmental agencies, and accreditation bodies.

Lazare A. *Apology in medical practice* an emerging clinical skill JAMA 11, 2006;296: 1401-1404.

The author describes that an effective apology is the logical next step after disclosure of a medical error. He suggests that apologizing for a medical error can promote healing and strengthen relationships between clinicians and patients. An apology should include an acknowledgment of the offense, an explanation, an expression of remorse, and reparation. The author offers 10 mechanisms through which apologies promote healing.

Reason J. *Human error* models and management BMJ 2000;320: 768-770.

The author describes the concepts of human error and explains that human error can be viewed in either a persons approach or a systems approach. He

then describes the Swiss cheese model of system failure, which recognizes that error is inevitable and that every step in a process (such as health care delivery) has the potential for failure, with each layer of the system serving as a defensive layer to identify and catch the error before harm reaches the patient. High-reliability organizations focus on transitioning from a persons approach to a systems approach.

Wachter RM, Pronovost JP. *Balancing "no blame" with accountability in patient safety* N Engl J Med 2009;361: 1401-1406.

The authors in this commentary explore the relationship between blame and accountability, and why enforcement of standards for physicians tends to be weak, and propose a balance that can promote a safety culture and safe patient care. In this perspective, the authors, who are two patient safety leaders, describe noncompliance with hand washing as a pointed example of a physician behavior that can be dealt with by holding people accountable for failure to adhere to a safety standard.

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Quality improvement

Paul F. Weber, MD, RPh, MBA, Anne Tomolo, MD, MPH, Mamta K. Singh, MD, MS

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In this chapter

This chapter defines quality improvement (QI) in health care and the relationship of quality to health care value (Chapter 5) and to patient safety (Chapter 6). It summarizes the importance of measuring quality for the purpose of public reporting as well as for improving health care quality. It defines types of quality measures and data sources and their associated limitations. It describes the most commonly used QI methods in health care (Model for Improvement, Plan-Do-Study-Act, Lean, and Six Sigma). Examples of the most common challenges in health care quality (clinical decision support, standardization, equipment redesign and forcing functions, frontline engagement of clinical microsystem teams, leadership, and change management) are described with examples of successful interventions to address each challenge. Lastly, the chapter summarizes the relationship between QI and scholarship.

Learning Objectives

1. Distinguish quality improvement in health care from value, patient safety, high-reliability organizations, and human factors engineering.
2. Summarize the types and limitations of quality measures and data sources.
3. Explain the quality improvement methods used most frequently in health care (Model for Improvement, Plan-Do-Study-Act, Lean, and Six Sigma).

4. Describe several common quality challenges in health care and successful interventions employed to address each challenge.
5. Contrast quality improvement scholarship with traditional research.

I. Quality improvement in health care

A. Definition

Quality improvement (QI) in health care is defined as the combined and unceasing efforts of everyone (health care professionals, patients, their families, researchers, payers, planners, and educators) to make changes that will lead to better patient outcomes (health), better system performance (care), and better professional development (learning). Taken this way, QI encompasses all of the changes made to improve health and health care delivery. As such, QI should be interwoven into the daily activities of all health care professionals, as each professional really has two jobs when he or she comes to work every day: to do his or her work and to improve his or her work.[1] For some, the most useful QI definition comes from the Agency for Healthcare Research and Quality (AHRQ): systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups.[2] It must be remembered that while all improvement involves change, not all change produces measurable improvement.

B. Relationship to value and patient safety

Patients expect quality health care, and therefore they typically assume care is safe. Quality and safety are not synonymous, however. In addition, any discussion of quality care necessitates a discussion of cost and value. Chapter 5 provides a detailed discussion of value in health care, including the links between quality and safety. It defines health care value as the quality of care divided by the total cost of care. Quality can be defined as the sum of patient outcomes, safety, and service, or as including six dimensions: care that is safe, timely, effective, efficient, equitable, and patient centered (STEEEP).[3] Chapter 5 discusses the well-documented dissonance between US health care spending and many measures of quality. Thus health care professionals must recognize early in their training that QI efforts should focus on safety, distributive justice, and resource utilization in addition to costs.

Chapter 5 also suggests five actions that health care professionals can and should take to provide high-value care:

1. Understand the benefits, harms, and relative costs of interventions.
2. Decrease or eliminate the use of interventions that provide no benefit, may be harmful, or both.
3. Choose interventions and care settings that maximize benefits, minimize harms, and reduce costs.
4. Customize care plans with patients that incorporate patients' values and address their concerns.
5. Identify system-level opportunities to improve outcomes, minimize harms, and

reduce health care waste.

If a service is overused (such as daily complete blood count testing in stable inpatients or advanced imaging in acute low back pain), a QI approach would provide a useful and necessary framework to reduce waste. By contrast, if a service is deemed to be of value (such as use of a series of specific steps shown to decrease risk for central line–associated bloodstream infections), the focus of the QI effort is likely to be change management, implementation, and support, in addition to cost reduction.

In addition to the deeper discussion of health care value in Chapter 5, several other chapters relate directly to QI. Several chapters discuss the US health care system at large and review the structure and processes of health care systems in more detail. Chapter 6 is dedicated to patient safety. This chapter focuses on the use of QI interventions in health care improvement up to the health care organization level, including an introduction to high-reliability organizations (HROs) that emphasize learning and culture, acknowledge risks, and support standardization in order to continually improve. Many QI methodologies were appropriated from other industries (such as Lean from Toyota and Six Sigma from Motorola) and applied to health care. Other methodologies and tools for improving quality, such as systems engineering, are beyond the scope of this chapter.

Case study 1

HRO Health System just acquired a neighboring acute care hospital with a general medical practice that had been part of a pilot accountable care organization. During this process, HRO noted that the acquired institution failed to meet multiple clinical care quality measures such as percentage of patients with blood pressure at goal. Among its top priorities, the new leadership team will initiate efforts to transform the hospital to a high-reliability organization in alignment with the rest of its member institutions within HRO Health System.

1. Consider your role in this transition, whether you are a leader of HRO Health System, at the newly acquired acute care hospital, or with the general medical practice. What could be your role if you are a medical (health professions) student on a clerkship rotation or a resident at this health system?
2. How are quality and high-reliability organizations connected?
3. What five principles are integral to high-reliability organizations?
4. What are the five characteristic ways of thinking at a high-reliability organization?
5. What are the relevance of culture and learning at high-reliability organizations?

C. Relationship to high-reliability organizations

HROs are defined by the AHRQ's Patient Safety Network as organizations that operate in complex, high-hazard domains for extended periods without serious accidents or catastrophic failures. Chapter 6 provides more detail on HROs and their role in improving patient safety and therefore improving health care quality. This concept is

relevant and attractive for health care due to the complexity of its operations and the risk of significant and even potentially catastrophic consequences when failures occur. Importantly, high reliability does not exclusively mean effective standardization of all health care processes. Furthermore, standardization, while necessary, is insufficient for achieving resilient and reliable organizations. The principles of high reliability seek to achieve a condition of persistent mindfulness within an organization. HROs cultivate resilience by relentlessly prioritizing quality and safety. In addition, HRO personnel are empowered to make real-time operational adjustments to maintain safe operations.

HROs work to create environments in which potential problems are anticipated, detected early, and addressed via rapid response to prevent catastrophic consequences. This organizational mindset is supported by five characteristic ways of thinking: (1) preoccupation with failure; (2) reluctance to simplify explanations for operations, successes, and failures; (3) sensitivity to operations (situation awareness); (4) deference to frontline expertise; and (5) commitment to resilience.[4]

To complement HRO initiatives, The Joint Commission suggests that hospitals and health care organizations work to develop a leadership commitment to zero-harm goals, establish a positive safety and quality culture, and institute a robust process improvement culture before they can begin to mature as HROs.[5] As organizations on their journey to becoming HROs achieve a culture supporting early acknowledgement of unsafe situations by any employee, they incorporate disciplines such as human factors engineering to make improvements.

D. Relationship to human factors engineering

Technology and equipment are rapidly and exponentially being integrated into health care delivery, including electronic health records (EHRs), point-of-care devices, and smart device applications (apps). It is imperative that the human element be fully considered for these technologies to reach their promise and improve health, making human factors engineering an essential consideration to optimize design, functionality, and outcomes. Human factors engineering is the discipline of applying what is known about human capabilities and limitations to the design of products, processes, systems, and work environments. It can be applied to the design of systems having a human interface, including but not limited to hardware and software. Its application to system design can improve ease of use, system performance and reliability, and user satisfaction while reducing operational errors, operator stress, training requirements, user fatigue, and product liability. Furthermore, human factors engineering is distinctive in being the only discipline that relates humans to technology.[6] Systems that recognize and incorporate human factors from design to clinical application are more likely to enable improved health care quality (outcomes, safety, and service) for patients. One such framework is human-centered design.

E. Human-centered design

With recognition and support globally, human-centered design has received the rigor of

a standard sanctioned by the International Organization for Standardization (ISO) with a formal listing as ISO 9241-210:2010 (Ergonomics of human-system interaction—Part 210: Human-centered design for interactive systems).[7] Per this ISO standard, human-centered design

> is an approach to interactive systems development that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors/ergonomics... and contextual framing.[7]

As a result, human-centered design develops solutions to problems by involving the human perspective at every step of the problem-solving process.[8]

II. Quality measurement

A. Measuring quality

Earlier chapters have highlighted many gaps in health care, including the six dimensions of quality (STEEEP) mentioned earlier. Gaps in health care can be recognized, measured, or both at multiple levels: a frontline care delivery team (clinical microsystem), a hospital or clinic (mesosystem), a health care system (macrosystem), a region, or even a nation. Existing gaps in health care quality may be unrecognized, recognized or "seen" but not measured, measured and used internally for local health care improvement efforts, measured and published as health care improvement or health services research, or measured and publicly reported.

Not everything in health care can be measured, so it is important to prioritize which gaps must be reduced so one can decide what should be measured. Meaningful data are needed to stimulate change, and measurement is needed to know if improvement has occurred. Measurement moves health care from opinion-driven to data-driven decision making. It is the key to dispelling deeply ingrained assumptions and generalizations as well. Any discussion of QI must therefore include an explanation of quality measures. In general, quality is measured for the following reasons[9]:

- *Measuring quality enables teams to identify what works and what does not work in health care (through health care improvement efforts, research, or both).* Measuring health care quality is essential not only to evaluate the performance of the health system and the care experience, but also to drive necessary improvement where the delivery of care falls short of expectation or desired outcomes. There are reasons other than QI to measure quality.
- *Measuring quality helps consumers (patients and their families) make informed choices about their care.* Health care decisions are complex, and patients face a variety of choices. Measuring and reporting the quality of health care can help patients get the information they need in order to make decisions about where and when to seek health care.
- *Measuring quality influences payment by holding health plans and providers accountable for providing high-quality health care.* Tying accreditation, certification, public reporting, and financial incentives (or penalties) to the quality of health care can encourage health plans, physicians, and other health care professionals to deliver the best care possible.
- *Measuring quality promotes a culture of safety by preventing overuse, underuse, and misuse of health care.* Overuse and misuse of health care services (procedures, tests, and medications) can lead to preventable complications and death. Measuring health care quality helps to ensure that patients receive the right care at the right time, the first time, every time.
- *Measuring disparities in health care delivery and outcomes maintains focus on all dimensions of quality.* Racial and ethnic minorities routinely face more barriers to

care and receive poorer quality care. Measuring health care quality can help us understand the effectiveness of care that diverse populations receive, which can help policymakers target improvements and hold physicians and health care professionals accountable.

B. Types of quality measures

Within the last 2 decades, measurement of health care quality has come to embody an emerging principle of "while some is good, more is not necessarily better and may be harmful." Clearly measurement is important for the United States to know its current health care performance, know how it performs in relationship to other countries, and establish goals for future performance. However, measurement and reporting can expend tremendous time and resources. There are nuances to interpreting quality measures, making interpretation difficult for health care professionals as well as lay individuals. For example, a brief review of hospital mortality rates by practice leaders in a specific hospital may not consider inclusion of variables such as risk adjustment (i.e., how sick the patients were to begin with) and expected mortality (preventable death). For some measures, it may not be clear whether it is good to be high, low, or somewhere in between (e.g., cesarean section rates). The proliferation of measures also has created a signal-to-noise problem. What does the United States need to focus on to have the greatest impact on patient care and well-being?

As described in previous chapters, Avedis Donabedian (widely regarded as the father of health care quality measurement) took up this topic nearly a half-century ago and provided a framework for understanding how we might measure and understand quality in health care: structure, process, and outcome.[10]

1. Structural

Structural measures are often accessible and "concrete" measures. Examples include nurse-to-patient ratios in the intensive care unit (ICU), numbers of advanced practice providers attaining certain credentials, and the number of monitored beds in a facility. Structural measures are used when it is known that care settings meeting certain standards are more likely to provide higher-quality care; they are easier to capture and most revealing when deficiencies are found.[11] Their major limitation is that the relationship between structures and outcomes is often not well established. Furthermore, just because a specific infrastructure exists, that does not mean that the system actually uses the capability. Thus it may not be clear if a structural measure truly results in better patient health such as for EHRs.

2. Process

Process measures are typically assessments of activities carried out by health care professionals to deliver services. Examples include the percentage of patients with symptomatic or asymptomatic left ventricular (LV) dysfunction (LV ejection fraction <40%) who are placed on angiotensin-converting enzyme inhibitors, the percentage of patients receiving prompt antibiotics after recognition of sepsis, and the percentage of 2-

year-olds in a primary care population receiving vaccinations aligned with national practice guidelines. Good process measures should always be backed by evidence that reliably links the process measured with improved outcomes. Process measures also have limitations, in part because evidence-based process measures are not available for many areas of care. Process measures tend to focus on preventive care and management of acute or chronic disease, but are difficult to identify for areas such as teamwork and organizational culture. They may not capture the true quality of care delivered by an individual provider, as different health care professionals may contribute to varying degrees to the care that is being measured.[12]

3. Outcome measures

Outcome measures are generally defined as the health state of a patient resulting from health care. It is helpful to consider two types of clinical outcome measures: intermediate outcome measures and long-term outcome measures. Intermediate outcome measures reflect changes in physiology that lead to longer-term health outcomes. Examples of intermediate outcomes include blood pressure, body mass index, and laboratory tests such as hemoglobin A_{1c} or low-density lipoprotein cholesterol. Long-term outcome examples include quality of life, occurrence of types of unwanted events that can cause morbidity (e.g., a heart attack or stroke), and mortality. Long-term outcome measures are those measures that patients are most willing to pay for (i.e., perceive as most valuable or relevant). They are the measures that health care professionals and teams most want to improve. While Donabedian supported outcomes measures as the ultimate validation of the effectiveness and quality of medical care, they may not be practical in cases in which the outcome is rare, when failures are evident only years after a procedure or other health care intervention, and when outcomes are subject to sample-size considerations. Outcome measures are also subject to a variety of influences, not always easily captured and not always obviously related to the systems or processes of care, such as the 30-day readmission rate.[9] For this reason, process measures (linked by evidence to good clinical outcomes) are often used instead as "proxies" for health outcomes.

4. Balancing

Balancing (or counterbalance) measures highlight the impact of a system change from a different perspective. As stated in Chapter 2, the components of a complex system are interdependent. Balancing measures help identify how an intervention may unintentionally affect other aspects of the system. For instance, if a clinic tries to improve the number of foot examinations of their diabetic patients by measuring foot examination documentation (process measure), the balancing measure would be to check how this extra documentation is impacting patient wait times during clinic visits. One major advantage of balancing measures is that they require a clear sense of the interdependencies within the process and anticipate the collateral impact of a given change on another part of the system.

Table 7.1 provides examples of structural, process, outcome, and balancing measures

that hospitals might use in an effort to limit one unwanted health care event: hospital-acquired blood infections after intravenous lines are placed in large (or central) veins (central line–associated bloodstream infections).

TABLE 7.1

Examples of Structure, Process, Outcome, and Balancing Measures to Help Decrease CLABSIs in an ICU

Measure Type	Focus of Assessment	Criterion	Goal
Structural	Expertise in CL placement	Percentage of ICU physicians and other health care professionals participating in simulation-based training and annual competency assessment	100% of ICU physicians and other health care professionals participate
Process	Use of CL bundle (series of steps performed for each CL placed)	Percentage compliance with all elements of the bundle for ICU patients with a CL	At least 95% compliance with all bundle elements
Outcome	Incidence of CLABSI	Number of CLABSIs per 1000 catheter days in ICU patients	Zero CLABSIs
Balancing	Time required to complete CL placement bundle	Staff time needed to successfully prepare for and complete all CL bundle steps	Daily variation in time required to complete bundle within an acceptable range

CL, Central line; *CLABSI*, central line–associated bloodstream infection; *ICU*, intensive care unit.

5. Patient experience

More recently, patient experience (previously satisfaction) measures have been developed and used to give feedback to health care professionals and systems on patients' experiences of their care, including the interpersonal aspects of care. These measures may assess many other aspects of care, including the clarity and accessibility of information from physicians and other health care professionals, whether teams provide patients with test results, and how quickly patients are able to get appointments for urgently needed care. Patients with better care experiences are often more engaged in their care, more committed to treatment plans, and more receptive to medical advice.[9]

C. Sources of data

Data are at the core of any QI initiative because they are needed to define the extent of the problem and to assess the impact of improvement. Just as there are a variety of QI methodologies, there are many types and sources of data that can be utilized in a QI effort. Data may range from large databases with national and international scope to back-of-the-envelope counts. The big categories of data sources include administrative data, abstracted data, and surveillance data, as well as data from direct observation, surveys, EHRs, and registries.

1. Administrative data

Perhaps the most well-known example of administrative data is the Medicare Provider Analysis and Review (MedPAR) file, which contains data from claims for services provided to beneficiaries admitted to Medicare-certified inpatient hospitals and skilled nursing facilities. It contains details on demographics as well as diagnoses, procedures, and discharge dispositions, including deaths and readmissions. These data are analyzed and repackaged in numerous public websites comparing and grading facilities and used in formulas for value-based purchasing and other federal programs linking performance to reimbursement. MedPAR also provides a rich source for data for research purposes. While the MedPAR data are often 3 or more years old, hospitals typically have internal access to these data within weeks after patients are discharged from the hospital. The data are not real time but can guide efforts aimed at improving hospital-based clinical outcomes. Researchers can query specific diagnoses (e.g., sepsis, stroke, pneumonia) to determine outcomes such as mortality, length of stay, resource utilization, and discharge status (e.g., home, nursing home, hospice) or extract codes classified as "complications" (e.g., iatrogenic pneumothorax or accidental puncture) to conduct further evaluations.

2. Abstracted data

Data abstracted from patient records can provide more clinical detail than administrative data based on claims. While coding and claims data allow for analysis related to outcomes (such as mortality, readmissions, and cost) and even regional or national trends, or both, with regard to variations, they do not provide detail on clinical practice (such as compliance with evidence-based standards of care). For example, the use of beta blockers during both acute and long-term management of heart attack reduces mortality, yet reports have indicated that they are only prescribed appropriately in a minority of cases. Chart abstraction is needed to determine whether eligible patients received the recommended treatment or it was withheld for an acceptable reason (presuming that this is documented in the chart). Determining compliance with recommended practice in this manner is time and labor intensive and is therefore reserved for more prevalent conditions associated with morbidity and mortality (e.g., heart attack, heart failure, stroke, pneumonia, sepsis) for which endorsed best practices are available.

3. Registries

Many organizations and professional societies have developed registries focused on specific populations (e.g., trauma, cancer, stroke) or procedures (e.g., cardiac surgery, all surgical care, cardiopulmonary resuscitation). Data are abstracted into a standard tool, submitted to a central clearinghouse, and subsequently analyzed. The advantage of registry data over claims data is the detailed clinical information often available in registries, including functional status after an event such as stroke or joint replacement surgery. As with data abstraction and direct observation, the disadvantage of registry data is the labor-intensive process to build and maintain the registry. In addition, many

registries come with significant fees. In the future, use of registries may be facilitated and made more efficient as EHRs and other clinical databases are able to transmit data to registries electronically.

4. Surveillance data

Surveillance data are collected and analyzed in order to understand the health of a population and do not focus on individual patients or clinical encounters. The most common surveillance efforts in hospitals are related to surveillance for hospital-acquired infections. The collection of these data is independent of the clinical care and the decision making of the physician or other health care professional of record. Instead, system reports of patient populations (e.g., patients with central lines or urinary catheters hospitalized within a specific time period) and test results (e.g., positive blood or urine cultures) are collected and analyzed based on criteria developed by an oversight body (such as the Centers for Disease Control and Prevention).

5. Surveys

The most common surveys used to collect data for health care measurement focus on patient experience. While there are many ways to survey patients, the standardized tool mandated for hospitalized patients is the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. Surveys can also be used for other purposes as varied as measuring employee engagement or safety culture. A major challenge with all survey data is ensuring an adequate response rate.

6. Electronic health records

EHRs have great potential to provide quality data at the level of individual patients, all patients for a given physician or other health care professional, and all patients in a system across the continuum of care. There are many challenges in using EHRs for meaningful quality reporting, including difficulty in extracting information in a free text form, invalid reports resulting from incomplete input of needed data, and lack of compatibility of EHRs with other data systems used in gathering and analyzing quality data.

7. Directly observed data

While most quality data are gathered from patient records, administrative codes, and test results, some behaviors are best collected via direct observation. Hand hygiene compliance is one such measure. Washing hands is generally accepted as a low-cost, low-risk intervention that can help reduce transmission of infections to patients. While proxy measures such as soap usage may suggest the level of hand hygiene, the most legitimate way of measuring hand hygiene compliance among health care workers is to directly observe whether or not they wash their hands. Similar to abstracted data, direct observation is labor intensive, and the challenge is ensuring that there are an adequate number of observations to make data meaningful.

III. Quality reporting

A. Perspectives of different stakeholders

As previously stated, health care quality is measured to help patients and their families make informed choices about their care, to influence payment by holding health plans and professionals accountable for providing high-value care, to ensure patient safety, to decrease disparities in care delivery and clinical outcomes, and to help identify effective interventions to improve health and health care. It is therefore not surprising (and is important to pause and consider) how and why different stakeholders in the health care system might rank the importance of various quality measures. Measurement is critical, but the interpretation, context, and impact of measures require a broad understanding of health care system complexities. In general, patients and families care most about clinical outcomes such as mortality (life and death), morbidity (functional status, pain, or other limitations), and overall quality of life. Employers would agree but are more focused on the costs of employee care than the employees themselves.[11] These rankings are not necessarily static over time. With an increased focus on costs of care and the impact of costs on society broadly, as well as increased out-of-pocket costs by patients,[12] stakeholders may share more similar rankings over time.

B. Examples of publicly reported measures

There are thousands of endorsed health care quality measures in the United States. These can be searched through the AHRQ National Quality Measures Clearinghouse[13] using many search filters or categories, including measure type (structure, process, outcome, balance, and patient experience), patient demographics (age and gender), care setting, organization that endorsed the measures, health care professional role (e.g., nurses, clergy, pharmacists, and physicians), data source (EHRs, public health data, and billing data), and the six dimensions of quality (STEEEP). It is helpful to learn about several of the most commonly used publicly reported measures.

Many quality measures are developed and disseminated at a national level by the federal government and its partners. The Centers for Medicare & Medicaid Services (CMS) core measures[14] are developed by a collaborative that includes health insurers, CMS leaders, and the National Quality Forum, a not-for-profit, nonpartisan health care improvement organization. Core measures seek to aid in promotion of evidence-based measurement for QI, consumer decision making, and value-based payment. The CMS partnered with the AHRQ to develop the HCAHPS described earlier.[15] Patients and health care organizations can benchmark quality at the state[16] or hospital[17] level. Commonly used patient safety measures include the National Patient Safety Goals from The Joint Commission[18] and the AHRQ's Patient Safety Indicators.[19]

Although many quality measures focused initially on hospital care, the number of measures for the outpatient setting (such as Minnesota Community Measurement[20]),

transitions of care across settings, and a wider range of health conditions is increasing. For example, in recent years there has been an increased focus on outpatient safety, health care disparities, and measures for geriatric and pediatric patients. Several private benchmarking organizations also provide quality measures to the public, including Vizient, The Leapfrog Group, and Healthgrades.

C. The future of quality measurement and reporting

Many challenges remain in the quest to appropriately, feasibly, and reliably measure the quality of health care. The Affordable Care Act requires (as outlined in the National Quality Strategy) performance in six priority domains of quality: patient experience and engagement, population and community health, safety, care coordination, cost, and efficiency.[21] Efforts to improve quality measurement must include a transition to using more broad-based, meaningful, and patient-centered care over an episode of care rather than dependence on the use of setting-specific, narrow "biopsies" or snapshots of process measures, such as use of aspirin at the time of hospital discharge for heart attack patients. Efforts must also include identification of important measures, retirement of measures that have been consistently achieved, combining measures in a portfolio that addresses multiple stakeholder needs, and adoption of these measures across public and private payment systems.[22]

Experts have suggested a number of steps needed to raise the bar to improve health outcomes. These steps would ideally include using clinical measures focused on care (rather than more limited information based on billing data) that are harmonized (same measures with the same definitions used elsewhere in the system), and measuring outcomes for all patients (rather than for small segments of patients receiving selected care) all of the time (i.e., efficient data collection via the EHR versus labor-intensive data abstraction).[23]

IV. Quality improvement methods

Many QI methodologies are currently utilized in health care, and they have more similarities than differences. Some have advantages in their simplicity (e.g., Plan-Do-Study-Act [PDSA]), while others tap into experience from other industries (e.g., Toyota Lean model). Some health care organizations choose to declare allegiance to a single methodology (e.g., Six Sigma), while many others will have a more blended or context-specific approach. Some health care delivery problems require more precision (e.g., preventing wrong-site surgery or ensuring that newborn babies go home with the correct parent), necessitating choice of one method (such as Six Sigma, which seeks to eliminate errors or "defects") over another. While it is common to have a core group of experts, some level of training and familiarity with these principles in leaders and frontline teams is critical for successful use of these methods. Many use the term *method* to refer to the higher-level view of the entire QI philosophy or approach and use the term *tool* to refer to specific (smaller-scale) approaches to one small part of a larger QI initiative or project. In order to close gaps and improve care delivery with any methodology, the improvement team members must clearly define the gap they seek to close and the measures (data) needed to determine whether they have succeeded.

A. Model for improvement

The Model for Improvement (MFI) is the most commonly used QI approach in health care and was popularized by the Institute for Healthcare Improvement as a framework to guide improvement efforts.[24] This framework is meant to work in concert with any QI methodology that an organization may be using and involves two parts. Before applying the MFI, it is essential to assemble a team that includes key stakeholders and ensure leadership support of the QI effort. Together the team members will explore the system failure that requires improvement. Use of fundamental improvement tools such as process maps, frontline staff interviews, and cause-and-effect diagrams enables the team to thoroughly analyze the current state and serves as the foundation for improvement.

After the team has a shared understanding of the current process, the team members answer three critical questions from the MFI (in any order) before testing change ideas using QI methods[25]:

1. What are we trying to accomplish?
2. How will we know that the change is an improvement?
3. What changes can we make that will result in an improvement?

As a Chinese proverb states, "The beginning of wisdom is to call things by their proper name." Question 1 requires the team to define the problem and the aim of the improvement exercise. The aim should be measurable, time specific, and clear in scope and population impacted. A commonly used acronym for goal setting is to use the

SMART (Specific, Measurable, Attainable, Relevant, and Time-bound) framework. It is critical to clearly define the scope of the project to ensure that the target goal is truly attainable with the available time and resources. Question 2 identifies the appropriate measures to track success. As previously stated, all improvement involves change but not all change will lead to improvement. Defining measures (with baseline and target) and tracking progress in time are critical to determine whether change results in improvement. Finally, question 3 identifies key changes that will be tested. These ideas can come from various sources, including frontline workers, experiences of others, and publications.

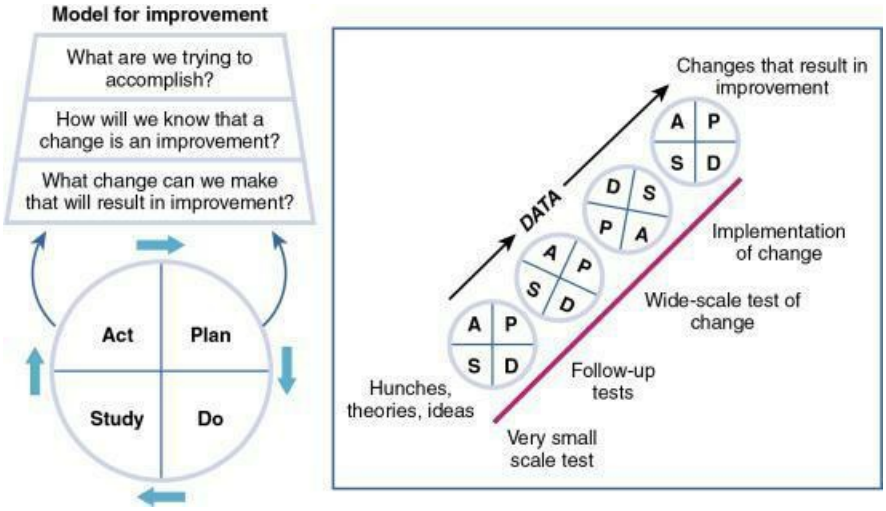
As mentioned earlier, a critical element of any successful QI effort is getting the right people (key stakeholders) on the improvement team. Teams vary in size and composition but generally need to have a diversity of roles and disciplines represented. For example, if a team seeks to decrease wait time in a clinic, membership should include representation from nurses, receptionists, schedulers, information technology, facilities, and perhaps even ancillary services such as laboratory or radiology (depending on the structure and function of the clinic) as well as physicians. Team composition does not need to be unnecessarily complicated, and it is crucial that, once appointed, all team members find their participation to be valuable to the aim.

In summary, selecting the right team, ensuring leadership support, clearly defining the problem/aim, establishing quantifiable measures, and selecting ideas for change are all crucial prerequisites before any change can be implemented. Once the team is ready to implement a change idea, then one of the QI methodologies is used to test it in a methodical manner. The most commonly used testing tool in the MFI is PDSA.

B. Plan-do-study-act

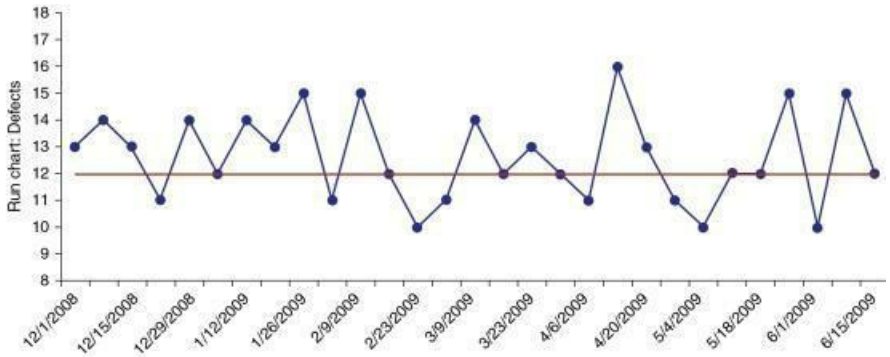
After planning is complete, the QI project is ready to start performing tests of change.[26] PDSA cycles provide the simplest structure for iterative development of change, either as a stand-alone method or as a part of wider QI approaches such as MFI.[27] The Plan phase of PDSA defines the specifics of the change intervention (who, what, where, and when) and plans the data collection. Most of this will likely already have been covered during the planning steps described previously in the MFI. If PDSA is utilized as a stand-alone tool, the elements related to defining aim, assembling the right team, defining measures of success, and outlining change interventions occur in the Plan phase. The test of change begins during the Do phase. The fundamental principle of the PDSA cycle is to rapidly test small-scale pilot(s). It is critical to document obstacles so they can be addressed in subsequent cycles.

During the Study phase, the team analyzes the results using predetermined process, outcomes, and balancing metrics. In the Act phase, the QI team adapts intervention(s) based on results of the Study phase and incorporates the findings into a planning cycle to test the next or revised change based on what was previously learned (Fig. 7.1).[28]



• **FIG. 7.1** **Model for Improvement and PDSA Cycle.** *Source:* (Reprinted with permission from Langley GJ, Moen RD, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. 2nd ed. Hoboken, NJ: John Wiley & Sons; 2009.)

The number of PDSA cycles needed varies based on the complexity of the initiative. Run charts, which plot measures on the y-axis against time on the x-axis (Fig. 7.2), provide an easy way of tracking progress over time and the impact of each cycle on the target measure. Through this data-driven iterative process, decisions can be made about which of the originally proposed changes actually result in improvement, will get implemented on a larger scale, and will ultimately become the new way of doing work.



• **FIG. 7.2** **Run Chart.** *Source:* (Used with permission of Mayo Foundation for Medical Education and Research; all rights reserved.)

C. Lean

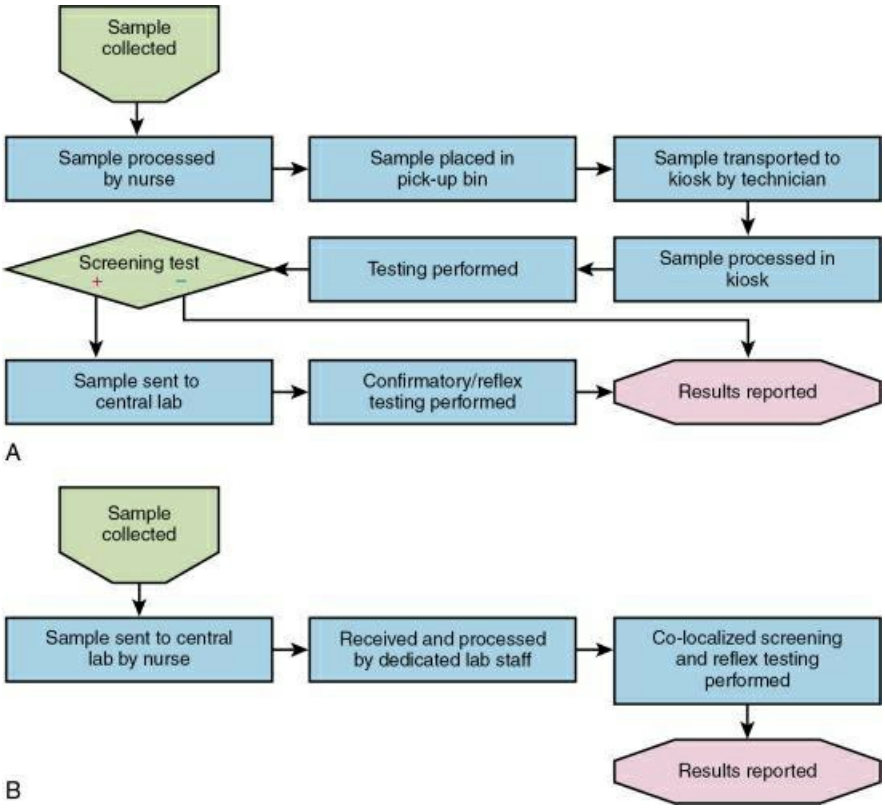
Principles of the Toyota Production System (TPS) have been applied to other industries, including health care, in the form of Lean methodology. Taiichi Ohno, a Toyota Motor Corporation engineer, is credited with creating TPS, which is based on maximizing efficiency by eliminating waste ("muda" in Japanese). Waste, or non–value-added activities, from a business perspective does not add to the financial margin or customer

experience and therefore needs to be eliminated. Seven different types of health care waste have been identified[29]:

1. Waste of overproduction (largest waste)
2. Waste of inventory or stock at hand
3. Waste of rework (e.g., assembly mistakes)
4. Waste of movement (e.g., poor work area ergonomics)
5. Waste associated with waiting (e.g., patients waiting to be seen for appointments)
6. Waste of processing (e.g., outdated policies and procedures)
7. Waste of transport or handling

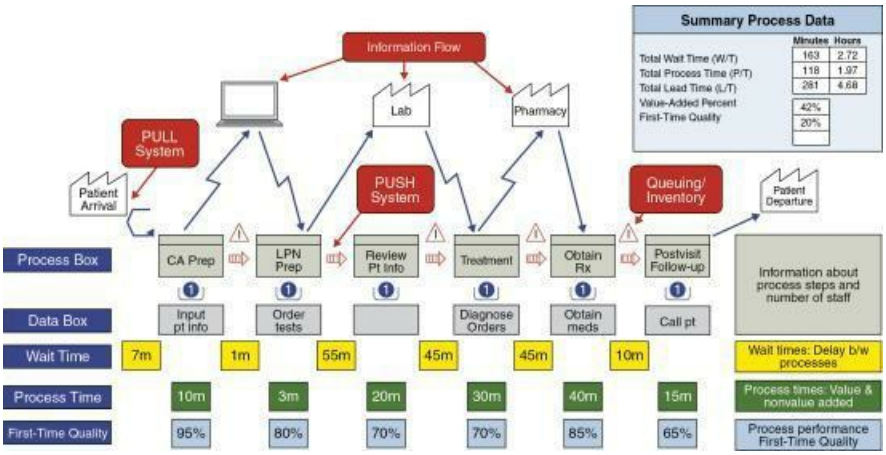
Lean tools aim to eliminate every form of waste and simplify and maximize value by putting the right processes in place. The first step in improvement is to identify all the steps in the existing process or "current state." This is best accomplished by bringing a cross section of workers, from the service chief to frontline staff, together to develop a common understanding of each existing process step (process mapping). Since most professionals are focused on their task, it is often eye-opening to review the full picture together. This highlights the importance of ensuring that each step in the process is represented by someone on the team who routinely does the work. The team then seeks to improve performance by removing all steps that do not create value.

Fig. 7.3 illustrates two process maps, one representing an existing laboratory process (Fig. 7.3A) and the other representing the process after it has been streamlined using Lean methodology (Fig. 7.3B). It demonstrates how wasted steps can be reduced to improve efficiency and timeliness in processing laboratory specimens.[30]



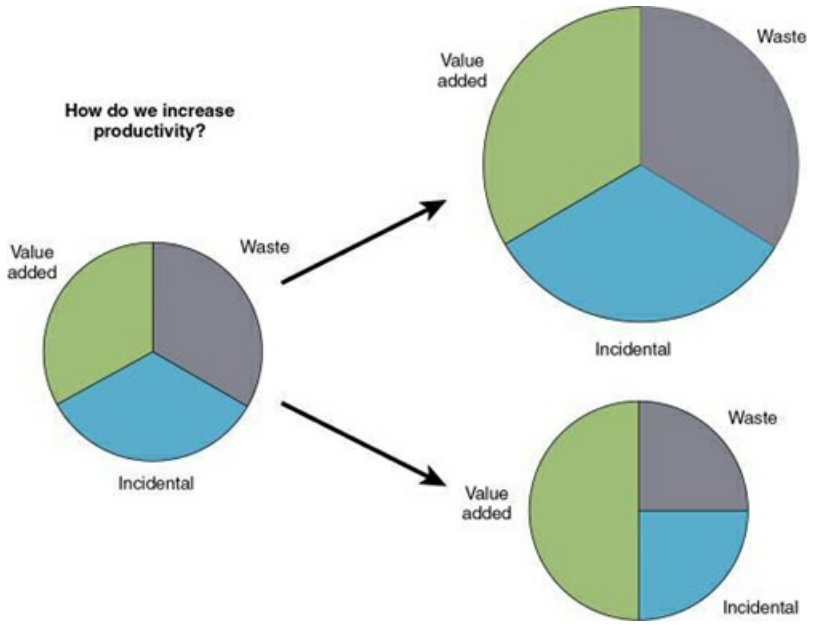
• FIG. 7.3 Laboratory Process Flow Before and After Lean Intervention. The top diagram (A) shows the steps in processing lab specimens before Lean methodology was used to streamline the process; the bottom diagram (B) shows the final process after the improvements were made. *Source:* (Used with permission of Mayo Foundation for Medical Education and Research; all rights reserved.)

Value stream mapping is a more complex Lean tool (Fig. 7.4). This detailed process map includes estimates of time taken for each step and the quality of the work done at each step. Value is always determined from the perspective of the customer (typically the patients in health care). Lean tools such as value stream mapping are often used to decrease turnaround time for services (e.g., laboratory testing or imaging) or to improve throughput through a busy area, as depicted in Fig. 7.4, which shows steps in a clinic or emergency department flow.



• **FIG. 7.4** **Value Stream Mapping.** This value stream map depicts steps in a clinic or emergency department check-in process. *Source:* (Used with permission of Mayo Foundation for Medical Education and Research; all rights reserved.)

When clinical teams seek to improve their productivity (e.g., increase the number of completed surgical procedures in a given day), they often initially plan to build more structure, such as operating rooms, to increase their output. Lean teaches that work is either value-added work (i.e., something that patients will pay for, such as having an ultrasound performed), incidental work (such as billing and coding by physicians), or waste. If there is significant existing waste in the process to start, building more structure will magnify the waste, whereas Lean tools might provide more capacity by eliminating waste, as is shown in Fig. 7.5.



• **FIG. 7.5** **Increasing Productivity With Lean.** Note that if waste is not removed from the process, then the waste is magnified when more resources are added to expand the process. *Source:* (Used with permission of Mayo Foundation for Medical Education and Research; all rights reserved.)

For example, Park Nicollet Medical Center in Minnesota eliminated the need for patient wait rooms in its new ambulatory clinic by redesigning workflow. Instead of scheduling patients in "batches" (e.g., five patients assigned to five rooms at one time), patients were instead checked in using the concept of continuous flow.

Another key concept in Lean methodology relates to standardization and eliminating inappropriate variation in practice. As mentioned in previous chapters, health care professionals must balance eliminating variation and individualizing care for patients. Health care can never be 100% standardized, but by eliminating variation that does not add value (thus standardizing the roughly 80% of common situations), the system creates capacity for tailoring the situation for the remaining work. At Park Nicollet, orthopedic surgeons were shown case carts with all the instruments and supplies they had ordered for total hip and total knee replacement surgery, each with a price tag attached. The surgeons were unaware of the variability in use of instruments and supplies for the same procedures and the cost impact. Through discussion, there was a 60% reduction in the number of instruments. The exercise was expanded to general surgery, and the net effect reported was 40,000 fewer items per month that needed to be sterilized.

D. Six sigma

Like Lean, Six Sigma originated in the manufacturing industry. It was developed by the Motorola Corporation in the mid-1980s. While both methodologies focus on eliminating waste, Lean emphasizes removal of all unnecessary and wasteful steps, whereas Six Sigma eliminates variation by minimizing defects in a process. A defect is defined as any instance when a product or outcome is not within acceptable standards. Examples can include harmful events such as wrong-site surgery or wasteful events such as wrongly labeled laboratory specimens. "Sigma" is a statistical unit that compares how many standard deviations a process is performing when compared to perfection. The level of sigma performance (a scale of 1 through 6) correlates with the defects per million opportunities (DPMO), which in turn allows calculation of the defect or error-free rate (Table 7.2). The DPMO is essentially the observed defect rate extrapolated to every 1,000,000 opportunities. When a process is functioning at Six Sigma level, there are 3.4 DPMO, yielding an error-free rate of 99.99966% (i.e., virtually error free). While an error-free rate of 99% may seem excellent—it is the often-quoted rate for airline performance in returning lost luggage—it is considered inadequate simply given the high number of opportunities. While it may not be feasible to achieve Six Sigma in every process, some health care "defects" (such as sending a newborn infant home with the wrong parents or wrong-site surgery) require a methodology that seeks to get as close to error free as possible. This methodology challenges preconceived notions regarding what is impossible in improvement.

TABLE 7.2

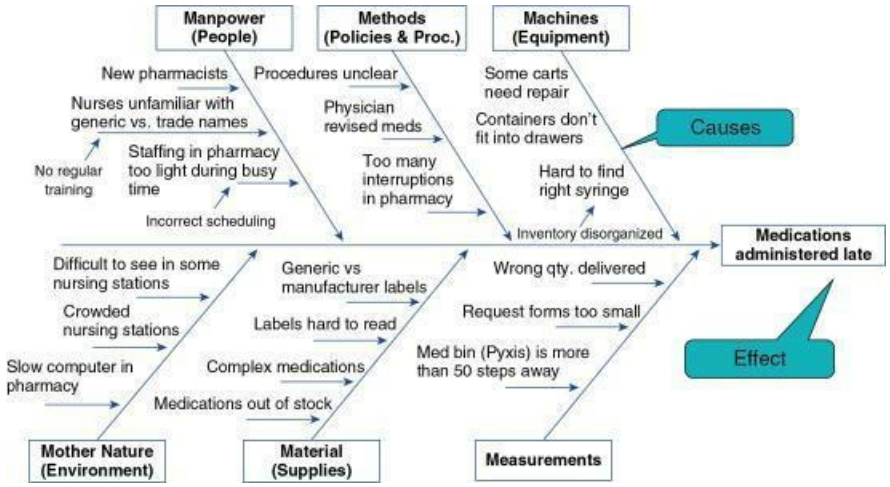
Sigma Levels

Sigma Level	Defects per Million	Yield
1	690,000	31%
2	308,000	69.20%
3	66,800	93.320%
4	6210	99.3790%
5	230	99.9770%
6	3.4	99.99966%

Six Sigma performance is achieved through systematic steps to help identify and address root causes. The five steps are Define, Measure, Analyze, Improve, and Control (DMAIC). In the Define step, the improvement team creates a project charter, which describes the scope, purpose, goals, and stakeholders for the project. It is important that all members of the QI team agree on these details of the project before moving forward. The Measure step is the second step, when the team develops a plan for data collection, including details related to the target defects, and collects baseline data on how the process is performing. Some health care organizations using a hybrid approach to QI methodologies use DMAIC to plan, execute, and communicate their QI work.

Health care professionals tend to jump to solutions before ensuring that all team members have accurate information about what is actually occurring before improvements are designed and implemented. In addition to drawing a process flow as shown in Fig. 7.3, other QI tools are available to help accomplish this step. Examples include:

- Drawing a cause-and-effect (fishbone) diagram (Fig. 7.6) to help narrow down root causes by collecting contributing factors in broad categories such as people, equipment, environment, and supplies
- Conducting time and motion studies (direct observation of a task, recording the time it takes to complete the task, such as nursing time spent to complete documentation during a shift)
- Completing a SWOT (Strengths-Weaknesses-Opportunities-Threats) analysis



• **FIG. 7.6 Fishbone Diagram or Cause-and-Effect Diagram.** This diagram represents potential different reasons for late administration of medications. *Source:* (Used with permission of Mayo Foundation for Medical Education and Research; all rights reserved.)

In the Analyze step of DMAIC, the baseline performance is analyzed using statistical and other QI tools to ascertain the reasons for the defects. Use of specific QI tools (such as the "5 Whys"[31]) helps ensure that the team adequately understands what is contributing to the defects (quality gap). Many health care professionals on QI teams are quick to suggest solutions before the quality gap has been adequately defined, the baseline (preintervention) performance has been measured, and the team has sufficiently considered the key factors or reasons for the gap. Those new to QI may find it helpful to consider a response to the question, "If you have 1 hour to save the world, how would you spend that hour?" Some have attributed this answer to Albert Einstein: "I would spend 55 minutes defining the problem and then 5 minutes solving it."[32]

After analyzing the baseline performance (i.e., data), the team develops creative solutions or interventions that are implemented in the Improve step. During this fourth step, postintervention data are collected (often at multiple points) to identify which interventions are most effective.

In the fifth and final step (the Control step), processes are developed to ensure that successful interventions are adopted as new standards and that reverting to old processes is impossible. Mechanisms to monitor compliance with new processes are also developed in this step.

E. Lean six sigma

The Lean and Six Sigma strategies have been combined into a methodology known as Lean Six Sigma. Joint implementation may overcome weaknesses of either system when implemented alone. Lean offers standard solutions to common problems by focusing on the value stream and the customer but is seen as weak on organizational infrastructure and analytic tools. Six Sigma includes a strong emphasis on defining defects using QI tools but is often perceived as too complex.[33] Combining the two approaches provides a framework for evaluating workflows to ensure efficiency and value (Lean) and a focus

on measuring and eliminating errors (Six Sigma).[34] In combination, these approaches foster an environment that focuses on measurement and rapid continuous improvement.

There is belief that Lean, Six Sigma, Lean Six Sigma, and PDSA are vehicles to sustain high-quality health care, but whether widespread adoption of these methodologies in health care will be effective is an open question. Systematic reviews of PDSA,[27] Lean, Six Sigma,[35] and Lean Six Sigma all report a lack of rigorous evaluation in health care. Furthermore, there is clearly a lack of adherence to the principles of the QI methodologies, such as PDSA applications reported without any iterative cycles of change and Six Sigma studies reported without error rate calculations of sigma levels. It is therefore difficult to ascertain whether a particular method is effective in health care.

In summary, no one QI method has proven superior to others in the health care setting, and no one method is ideal for all situations. Using a QI methodology ensures a standardized and rigorous approach to closing gaps without missing a crucial step. The underlying principles of analysis, measurement, and review are consistent across all methodologies, and the disciplined application of all steps is far more important than the choice of the specific method (Table 7.3).

TABLE 7.3

Summary of Specific Quality Improvement Approaches

Methodology	Model for Improvement	Lean	Six Sigma
Origin	*The Improvement Guide*[a]	Toyota Production System	Motorola
Focus	Structured planning and testing of solutions to accelerate improvement	Eliminate waste across service lines to improve quality, workflow, and value	Statistical-based problem solving and improvement
Primary Target	Piloting small tests of change	Workflow	Large problems and variation
Approach	Setting aims Establishing measures Selecting a change: • Plan • Do • Study • Act	• Value • Value stream • Flow • Pull • Perfection	• Define • Measure • Analyze • Improve • Control
Primary Result	Improvements through small tests of change	Reduced flow times	Uniform process output

[a]Langley GJ, Moen RD, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.* 2nd ed. Hoboken, NJ: John Wiley & Sons; 2009.

V. Common quality issues and successful interventions

As described, successful QI interventions clearly define the problem (quality gap), measure baseline and postintervention performance, establish the existing and desired processes, implement QI methods and tools in a disciplined manner, and use iterative testing of small-scale change. The change ideas that lead to desired outcomes are often combined into a finalized protocol or proven set of recommendations and readied for widespread dissemination. Unfortunately, widespread expansion of a quality initiative frequently does not yield the desired outcomes, often leading to disappointment, cynicism, and continued suboptimal care. This can occur because success often hinges on adoption and behavior change by frontline providers, who may view the change as "one more thing to do" or the "flavor of the month." Simply providing the methods and telling people to do something does not assure that it will get done. In order to maximize the chance of successful implementation of any initiative, it is important to leverage the system that supports humans in doing their best work (i.e., making it difficult to do the wrong thing). Several such strategies are highlighted in this section.

A. Clinical decision support

A clinical decision support (CDS) system links patient data with stored knowledge in a database and provides suggestions to physicians and other health care professionals to improve the care they deliver.[36] Given the volume and complexity of clinical information, CDS systems leverage the power of the EHR to link that knowledge to an individual patient problem and inform physicians and other health care professionals in real time how to translate that knowledge into patient care. CDS can take the form of medication order support (e.g., prompting adjustment for diminished renal function) and order sets that incorporate recommended practices (e.g., pneumonia or sepsis care, reminders to discontinue catheters or monitors, or critical laboratory notifications). On occasion, CDS systems can result in alert fatigue and even cause harm by delaying treatment. One potential cause for delay is the use of the hard stop to avoid harmful consequences (e.g., drug-drug interaction in medication prescribing software). A seemingly well-intended alert can interrupt care, and efforts to bypass alerts for legitimate and unanticipated circumstances can cause direct patient harm. Similarly, alert fatigue can arise from a high number of clinically insignificant alerts that consume time and cause mental distraction. Increasing the specificity of alerts by employing mechanisms to prevent unnecessary notifications (such as ensuring a patient is on enteral nutrition before suggesting an intravenous-to-oral medication change) can help decrease clinically insignificant alerts. See Chapter 10 for more details on CDS systems.

B. Standardization: Protocols and order sets

Traditional approaches to diagnosing and treating patients have relied upon physicians

making decisions based on their education and training and the application of clinical knowledge. One consequence of this individualized approach has been wide variation in care, some of which may be acceptable based on patient-specific or system factors but sometimes does not meet the definition of quality care. One way to address unacceptable variations in care is through the use of protocols and order sets. For certain conditions, best practices can be built into algorithms or protocols that drive the frontline providers to deliver those processes as long as clinical criteria are met. Embedding these best practices into the EHR so the standard choices are ordered by the physician or other health care professional via order entry is done by use of order sets. Protocols can be very specific (e.g., hypoglycemia protocol that directs the nurse to administer the precise dosage of dextrose for blood sugar <50 mg/dL) or more comprehensive, as has been done in recent efforts related to care redesign.[37]

C. Equipment redesign and forcing functions

Overreliance on memory and dependence on education (and reeducation) of staff is not an effective QI strategy. All too often, especially when things get busy, staff juggling multiple priorities will miss critical steps, make errors, and risk causing harm to patients. One example of this has been staff accidently connecting enteral tube feeds to intravenous catheters. Instructing staff to "be more careful" is less effective than using catheters with connectors that are incompatible with the incorrect receiver. This is an example of equipment redesign that makes it impossible for a human to erroneously make an incorrect connection. One example of a forcing function is to make it impossible for a clinician to complete order entry on a patient until he or she addresses critical elements such as code status and prophylaxis to prevent deep venous thrombosis (blood clot). As discussed earlier, forcing functions in the EHR can have unintended consequences and need to be utilized with caution.

D. Frontline engagement and team-based care

Any QI effort requiring behavior change by frontline providers requires an understanding of factors associated with successful behavior change. Too many great ideas fail to take hold because the individuals most impacted do not see the value or (worse) believe the change to be detrimental to safety, quality, or efficiency. Input from frontline staff in every aspect of care redesign is vital to fostering ownership. Additionally, ensuring that staff receive adequate feedback once an initiative is underway helps ensure follow-through and hardwiring of the new practice. Audit with feedback is one strategy used in the belief that health care professionals are prompted to modify their practice when their performance is inconsistent with a desired target.[38] While it can be effective, the effectiveness seems to depend on baseline performance and how the feedback is provided. For example, feedback is more likely to be effective if it is delivered by a supervisor or trusted colleague, provided multiple times, delivered in both verbal and written form, and includes an explicit target and action plan. The challenge in every QI project is not simply developing a good intervention but ensuring

its successful execution. That is where frontline engagement and teamwork become vital.

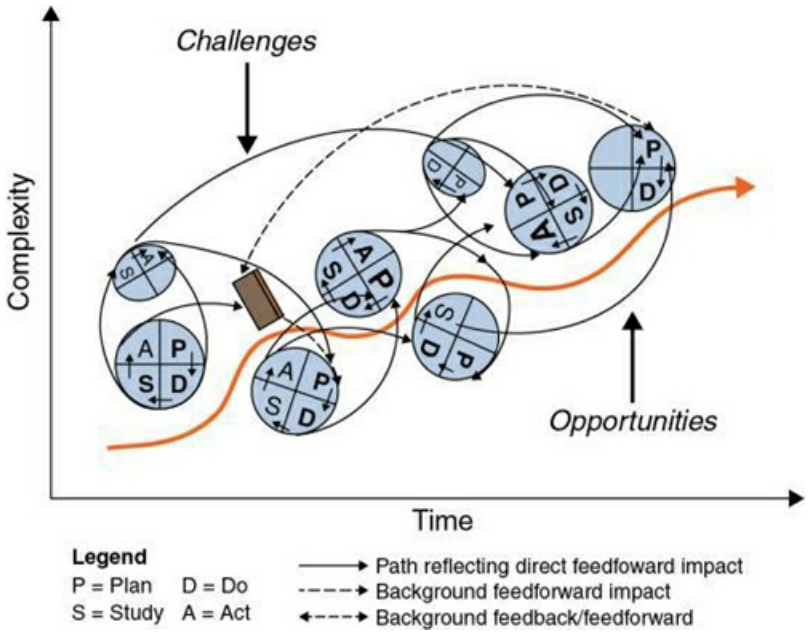
E. Leadership and board accountability

Quality and safety as organizational priorities must start from the top, and for most hospitals the top is a board of trustees. Ensuring that leadership is working tirelessly to improve outcomes and remove barriers for frontline staff to do their best work is a key responsibility of the board. This notion was popularized when included as a key element of the Institute for Healthcare Improvement's 5 Million Lives Campaign. This campaign aimed to reduce patient harm in hospitals, and included full engagement of the governing leadership in quality and safety as the sole nonclinical intervention. This intervention was commonly known as "Getting Boards on Board."[39] In a previous era, hospital boards were primarily responsible for the organization's financial status and reputation. From a more modern view, boards (in partnership with executive leaders) set system-level expectations and accountability for safety and quality. This core responsibility is translated into action by setting specific aims to reduce harm and improve quality, reviewing data and hearing stories that put a human face to data, fostering an environment of transparency, and ensuring continuous learning and support of patients, families, and staff. Finally, the board holds the executive team accountable for achieving clear QI goals.

F. Change management

Virtually all QI efforts involve making a change at some scale. People have varying responses to change, from innovators and early adopters to laggards (the last to adopt an innovation). In addition to frontline engagement, a key element of successful QI efforts includes the early identification of champions. A champion is typically an early adopter who embraces the challenges and is knowledgeable of the alignment with the organization's strategic goals. Much of the change needed involves changing behavior, highlighting the importance of connecting to motivation, making the right thing easy to do, offering reward and recognition in a meaningful way (which is not always financial), and fostering an environment of engagement by all.

The variety of attitudes and actions that take place when system- or process-level change is proposed has implications for the implementation and adoption of innovations and interventions. As a result, the application of the PDSA cycle does not follow the completed cycles proceeding up a ramp of improvement, as depicted in Fig. 7.1. This representation is useful for demonstrating a path for successful improvement through the connection of learning from successive cycles; however, its use in practice may not be linear. The limitations of the ramp of the neatly mapped-out PDSA cycles may become apparent through application to health system improvement initiatives with incomplete cycles, roadblocks, and failed cycles, as seen Fig. 7.7.[40] Despite these experiences, the rapid cycle learning that occurs using the MFI provides a framework for successful improvement, although the graphic depiction of the cycles may vary.



• **FIG. 7.7** **Revised Conceptual Model of Rapid Cycle Change.** *Source:* (Reprinted with permission from Tomolo AM, Lawrence RH, Aron DC. A case study of translating ACGME practice-based learning and improvement requirements into reality: systems quality improvement projects as the key component to a comprehensive curriculum. *Qual Saf Health* Care. 2009;18[3]:217-224.)

VI. Quality improvement scholarship

Until recently, QI reporting in the literature was challenging because it lacked formal publishing guidelines. Authors tried to publish their iterative, dynamic, context-dependent improvement projects into traditional research frameworks ranging from case reports to randomized controlled trials (RCTs).[41] Given the differences between QI and research, these reporting frameworks fell short of capturing the improvement efforts. This tension between QI work (improving processes of care) and advances in scientific knowledge (improving clinical evidence) was highlighted in an editorial by Don Berwick in 2008 in which he discussed the limitations of the oft-glorified RCT to address all-needed learning.[42] He explained why the traditional RCT model cannot be directly applied to many health care improvement attempts. Most system improvements (such as rapid response teams for deteriorating hospitalized patients) are complex and have many components, requiring social change. The effectiveness of systems (and therefore of system improvements) relies in part on leadership, changing environments, organizational history, and many other factors. As QI uses this explanatory approach that encourages broader evaluations of the context and lessons learned, it is critical to recognize and report this context. QI work that is not shared in a systematic way can limit the learning from and spread of the work, and lead to redundancy as professionals repeatedly reinvent the wheel.

Reports of scholarly health care improvement work became standardized in 2008 with the initial publication of Standards for QUality Improvement Reporting Excellence (SQUIRE)[43] guidelines, which were revised (as SQUIRE 2.0) in 2015.[44] The guidelines provide a framework for reporting new knowledge about improving health care and are intended for reports that describe system-level work to improve the quality, safety, and value of health care. They detail methods to establish that an observed outcome is due to the planned intervention. (More information about SQUIRE guidelines can be found at http://www.squire-statement.org.) Many health care improvement teams also use these guidelines to help plan, execute, and report their projects. An in-depth discussion of the opportunities to improve the rigor of health care improvement scholarship is beyond the scope of this chapter, but several common themes are included here.

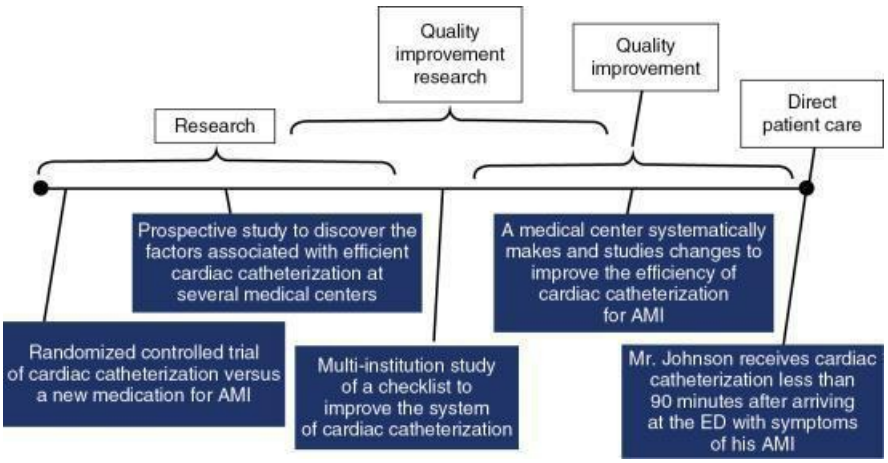
There are frequent inconsistencies in the description of and adherence to QI methodologies in the literature (when compared to how they are actually used in practice). For example, a systematic review of the application of the PDSA method found that many studies utilizing and reporting PDSA fail to include key features of the methodology (such as iterative cycles, prediction-based test of change, small-scale testing, use of data over time, and documentation).[27] This is not a problem with the tool, per se, but with its use.

QI and other health care improvement teams are not effective at telling their stories. The SQUIRE 2.0 guidelines highlight several important ways in which QI can and should be different from traditional research, including context. In addition, the intervention may and likely will change throughout the study in response to feedback,

continuous data analysis, and interaction with the context. The SQUIRE 2.0 guidelines emphasize the importance of facilitating this change in order to advance the science and know what works, rather than remaining focused on a fixed intervention that does or does not work.

Health care professionals are not good at understanding the stories QI teams have to tell. There are many issues in interpreting evidence from a QI study, including whether the intended interventions actually occurred, data quality was assessed, follow-up was sufficiently long to allow for a drift in clinical behavior, and all patient-important outcomes were considered.

Finally, at the heart of any QI reporting is the recognition of the sometimes-subtle differences and frequent overlap between clinical research and QI activities. An instrument to distinguish between the two is reported in the literature, which highlights differences and allows for professionals to decide how to proceed with their institutional review boards prior to conducting such projects.[45] As many activities fall in between, Fig. 7.8 illustrates the relationship between QI activities and the continuum of patient care and scientific inquiry.[45]



• FIG. 7.8 The Continuum of Patient Care, Quality Improvement, and Research. Examples are provided relating to patient care, quality improvement, and research for acute myocardial infarction (AIM). *ED*, Emergency department. *Source:* (Reprinted with permission from Ogrinc G, Nelson WA, Adams SM, O'Hara AE. An instrument to differentiate between clinical research and quality improvement. *IRB*. 2013;35[5]:1-8.)

VII. Chapter summary

QI in health care includes any effort (small or large scale) to improve health care delivery, outcomes, or both. QI is part of the health care value equation (defined as quality of care divided by cost over time) and includes patient safety. Quality is measured in order to improve care, help consumers make choices, and influence payment of health care professionals and organizations in ways that will improve care.

There are several types of quality measures, including structural, process, outcome, balancing, and patient experience measures. Each has its strengths and weaknesses, and a combination is required to ensure comprehensive quality care. Measures are taken from many data sources, each with its strengths and weaknesses, including administrative data, abstracted data from patient records, registries, surveillance data on populations of patients, survey data, EHR data, and directly observed and recorded data.

Each stakeholder group in health care varies in how it ranks the importance of quality measure types. Many measures are publicly reported and can be obtained at the national, state, or local (i.e., by hospital) level. Many necessary changes are anticipated in how quality measures are developed, adopted, and used in the future.

The MFI and PDSA are two commonly used QI methods in health care. Other commonly used QI methods (Lean and Six Sigma) originated in the manufacturing industry and have been applied to health care problems. Use of one method over another varies frequently by institution, by the quality gap each QI team is seeking to close, or both.

Successful QI interventions for common health care problems have included CDS systems, protocols and order sets, equipment redesign and forcing functions, frontline engagement and team-based care, leadership and board accountability, and change management.

There are distinct differences between traditional scientific research and QI scholarship. Use of the SQUIRE 2.0 guidelines, the current benchmark for publishing QI interventions, both to plan and to disseminate projects can help teams improve the rigor of QI scholarship.

Exercise

Quality improvement (QI) has become a key function of health care professionals and the health system. QI projects also are a required component of graduate medical education. There are often several QI initiatives that are planned, are ongoing, or have been completed.

Consider the ones that have been completed. Identify those that were sustained, and those that were abandoned. Talk to those persons involved. Ask questions that may identify why a QI initiative did or did not have enduring effects. Consider how those factors should impact any planned quality initiatives.

Case study 2

The Keystone Study looked at 103 ICUs in Michigan and aimed to reduce the median and mean rates of catheter-related bloodstream infections utilizing a central line bundle with the following components: hand washing, using full-barrier precautions during central line insertion, cleaning the site with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters. The ICU department also used a daily goal sheet to improve clinician-to-clinician communication, implemented interventions to reduce the incidence of ventilator-associated pneumonia, and attempted to improve unit-level safety culture. Those involved in this study also engaged local champions, encouraged partnering with local hospital-based infection control practitioners, delivered extensive education, revamped central line kits, proposed "emergency stops," engaged in daily rounds discussion, and involved C-suite–level leadership (chief executives or officers).

While this project was successful, you could conclude that the use of this checklist in any ICU could lead to the same results. Furthermore, the methodology of the study reveals a bundle of interventions beyond the ones stated earlier. The authors themselves note that they "did not evaluate the relative effectiveness of the separate components of the intervention."

1. What questions should you ask to identify why the project was successful and how the success may be replicated in other settings?
2. Can you identify the key challenges of this study and devise ways to make it more likely that useful conclusions will emerge?

Questions for further thought

1. Why is it important to measure health care quality, and how might the measurement results be useful to different stakeholders (patients, payers, institutional leaders, and public health officials)?
2. What characterizes a high-reliability organization?
3. What are the five types of quality measures and their strengths and limitations?
4. Which QI method—a PDSA cycle, Lean, or Six Sigma—would be most appropriately applied to improving patient experience during the activities comprising a doctor's appointment (related to time spent waiting to see the physician, having laboratory tests drawn, and filling a prescription)? Which method might be better to identify and reduce errors within the same processes?
5. What are some things that can be done in terms of facilitating technology, system processes, or leadership qualities to enable quality and safety improvement efforts to succeed?

Annotated bibliography

Batalden P, Davidoff F. *What is "quality improvement" and how can it transform healthcare* Qual Saf Health Care 1, 2007;16: 2-3.

The authors highlight the domains of interest in quality improvement, selected tools, methods used to close specific quality gaps, and the knowledge systems involved in health care improvement.

Committee on Quality Health Care in America. Institute of Medicine. Crossing the Quality Chasm A New Health System for the 21st Century Available at http://www.nationalacademies.org/hmd/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx March 1, 2001; Accessed June 7, 2019.

This white paper classifies the types of quality gaps (dimensions of quality) that health systems must target in their health improvement efforts and lays out the road map for how to improve US health care quality.

Donabedian A. *The quality of care* how should it be assessed JAMA 12, 1988;260: 1743-1748.

This sentinel article summarizes the initial national discussion on measuring health care quality.

Glasgow JM, Scott-Caziewell J, Kaboli P. *Guiding inpatient quality improvement* a systematic review of Lean and Six Sigma Jt Comm J Qual Patient Saf 12, 2010;36: 533-540.

This systematic review summarizes what is known about the effectiveness of Lean and Six Sigma in health care, as well as the limitations of the existing literature.

Taylor M, McNicholas C, Nicolay C, Darzi A, Bell D, Reed J. *Systematic review of the application of the plan-do-study-act method to improve quality in healthcare* BMJ Qual Saf 2014;23: 290-298.

This systematic review summarizes what is known about the effectiveness of Plan-Do-Study-Act cycles in health care, as well as the limitations of the existing literature.

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Principles of teamwork and team science

Jason Higginson, MD, MA, Linda Hofler, PhD, RN, NEA-BC, Maya M. Hammoud, MD, MBA

CHAPTER OUTLINE

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In this chapter

Health care is undergoing a revolution, moving from a lone-provider model to one that embraces the recognition that the system of care is the essential element to the health of patients. The goals of the Triple Aim, improving quality, outcomes, and costs of health care delivery for patients and populations, and

the Quadruple Aim, which also includes team member well-being, require teamwork and an understanding of team science. Teams working toward a common goal can improve health outcomes for individuals and communities. An understanding of teams, their structures, and their critical elements will enable health professions students to fully engage in this critical component of the future of health care. This chapter outlines for health professions students the basic framework by which teams are formed, educated, and trained. This understanding of teams will be reinforced by a discussion of how interprofessional collaboration is the cornerstone of future health professions education. Focusing on both the theory and practice of team science will equip students with the necessary knowledge to be effective members and leaders of teams.

Learning Objectives

1. Describe the importance of teams to patient safety and patient-centered care.
2. Identify who comprises a team and the hallmarks of effective teams.
3. Explain the relationship between teams and interprofessional practice.
4. Describe the components of collaboration required to create effective teams.

I. Introduction—teams as a critical aspect of health systems science

In any human endeavor where complexity and multiple variables coexist with significant consequences for failure, risk is mitigated when teamwork and team performance are emphasized. The focus of this chapter is on teams, teamwork, team science, and interprofessional collaborative practice and their relationship to health care and health systems science (HSS). Effective teams and team membership are crucial elements to success in any undertaking that involves more than one individual. High-reliability organizations (HROs) operate in complex, hazardous environments, making few mistakes over long periods of time. HROs are increasingly becoming a focus in HSS because of the recognition that they represent a model approach to improving several core domains of HSS. A key aspect of HROs is a focus on teams.[1,2]

As noted in Chapter 1, the goals of HSS are improving understanding and application of the principles, methods, and practice of improving quality, outcomes, and costs of health care delivery for patients and populations within systems of medical care. Teams are an integral component of HSS. Applying lessons on teams from HROs can inform those interested in HSS about the incorporation of teams and teamwork into health care environments. Notable HROs often studied for their incredible record of safety and attention to teamwork are aviation, naval nuclear propulsion, and civilian nuclear power generation. Case studies in these environments demonstrate that failures are rarely the result of the actions of a single individual but are often the result of collective systems failures.[2,3] The root cause of these failures is often the result of elements of poor team performance, such as communication failure, poor interpersonal interaction, and lack of role clarity.

The landmark Institute of Medicine report *To Err Is Human: Building a Safer Health System* found that potentially 98,000 preventable deaths occurred in the United States annually due to medical error.[3] (Note: The Institute of Medicine was renamed the National Academy of Medicine in 2015.) One of the key recommendations from this report was the need to "establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management." Understanding the attributes and theory behind team science will better prepare health professions students to incorporate a team-centered focus into their career and will lead to significant improvement in achieving the goals of the Triple Aim—health for all individuals (population health), an ideal experience for all patients as they interface with the system (including quality and satisfaction), and a reduction in the per capita cost of health care—as well as the Quadruple Aim, which includes the wellness of physicians and other health care professionals.[2,4]

II. The promise of interprofessional practice

The individual expert model prevalent today in health care must be transformed to a model that crosses disciplines, generations, professions, and groups—to a more team-based collaborative partnership, which will produce STEEEP (safe, timely, effective, efficient, equitable, and patient-centered) care.[3]

Teams are now recognized as a crucial element of HSS. Health care delivery systems involve numerous interfaces and patient handoffs among many health care professionals for any given patient regardless of the context of care. For example, in a 3-day hospital stay, a patient may interact with as many as 30 different professionals, including physicians, nurses, x-ray and laboratory technicians, nutritional staff, and transport team members. Team collaboration is essential to ensure that the diverse group of professionals interacting with patients on a daily basis integrates their activities with the patient's best interest at the center of their actions. Collaborative teamwork in health care is commonly referred to as interprofessional practice. The promise of interprofessional practice is "when multiple health workers from different professional backgrounds work together with patients, families, caregivers, and communities to deliver the highest quality of care."[5]

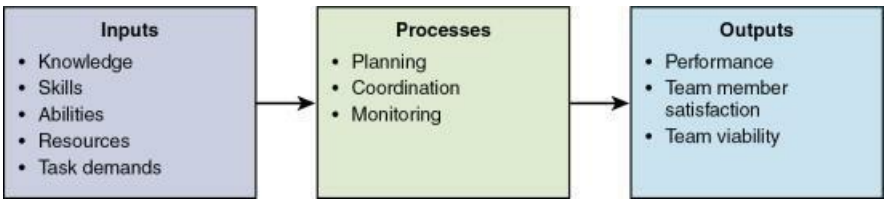
The growing complexity of health care mandates the need for team science education at all levels from health professions students to seasoned health care professionals as it provides the basis for overhauling the health care system and improving health outcomes. The US health care system is the most costly in the world, accounting for 17.9%[6] of the gross domestic product, with estimates that this percentage will grow to 19.4% by 2027[7] yet with comparatively poorer outcomes. A plethora of publications over the last 3 decades have called for significant changes in health care systems due to the recognition that the United States is not achieving the best health outcomes for individuals or whole populations, yet the United States spends an exorbitant amount for poor-quality health care.[8]

A. Defining teams

What defines a team? Over the last half-century, much work in the social sciences has been focused on defining what makes a team and what elements contribute to effective team performance. The National Academy of Sciences in 2015 released *Enhancing the Effectiveness of Team Science,* which aimed to summarize the state of this varied literature.[9] It identified the widely accepted definition of a team as *two or more individuals brought together by an organization who are working or interacting (face-to-face or virtually) on one or more institutionally important common goals or tasks and are assigned different roles and responsibilities while embedded in an encompassing organizational system with linkages to the broader system or task environment.*

Why are teams defined in this way? The prevailing heuristic that leads to this conclusion on the definition of a team is the input-process-output model developed by

McGrath.[10] By studying groups of individuals working together, it becomes clear that input factors such as individual personalities and identities, individual skill, team task definition, and team structure and size alter the functioning of the team. Processes such as how teams are assembled and composed and the rules that govern interaction modulate many of the inputs and result in the team's ultimate output effectiveness (Fig. 8.1).



• FIG. 8.1 Input-Process-Output Framework. *Source:* (Reprinted with permission from Fernandez R, Kozlowski S, Shapiro M, Salas E. Toward a definition of teamwork in emergency medicine. *Acad Emerg Med*. 2008;15[11]:1104-1112.)

B. High-performing teams

Team effectiveness is defined by evaluating whether a team achieves its goals. References about effective teams in the medical literature frequently derive conclusions and parallels from studies of teams that function in fields other than health care. Given the unique nature of health care, it is important to note that these parallels should be reviewed with caution. The study of teams in health care is an area open to continued investigation as health care contains nuances that may alter the prevailing operational theories of team performance. Nonetheless, many common elements have been identified as characteristics of high-performing teams.[9]

First, teams with a shared understanding of their goal have been demonstrated to be significantly more effective than those without a universal understanding of their goal. If all team members understand the output they are trying to achieve, it is more likely that efforts will be directed toward that goal. Second, clear definitions as to team members' roles (i.e., role clarity) are another essential element in team effectiveness. By focusing on role clarity, teams are able to efficiently deploy the various skills that exist and reduce duplication of efforts to achieve defined goals. Third, team cohesion and low levels of conflict are critical to effective team performance. Teams must be cohesive and limit friction among members to ensure that effort by all will be utilized for goal achievement. When friction and disunity take hold, effort is often wasted or team members limit their participation. Building team cohesion results in trust among team members, facilitates task engagement, and builds team citizenship, all of which result in improved effectiveness. As an example, the elements of team effectiveness related to patient safety and quality improvement are displayed in Table 8.1.

TABLE 8.1

Overview of Teamwork Aspects Relevant to Quality and Patient Safety

Aspect of Teamwork	Examples of Safety-Relevant Characteristics
Quality of collaboration	Mutual respect Trust
Shared mental models	Strength of shared goals Shared perception of a situation Shared understanding of team structure, team task, team roles, etc.
Coordination	Adaptive coordination (e.g., dynamic task allocation when new members join the team; shift between explicit and implicit forms of coordination; increased information exchange and planning in critical situations)
Communication	Openness of communication Quality of communication (e.g., shared frames of reference) Specific communication practices (e.g., team briefing)
Leadership	Leadership style (value contributions from staff, encourage participation in decision making, etc.) Adaptive leadership behavior (e.g., increased explicit leadership behavior in critical situations)

Used with permission from Manser T. Teamwork and patient safety in dynamic domains of healthcare: a review of the literature. *Acta Anaesthesiol Scand.* 2009;53(2):143-151.

C. Leading teams

The effectiveness of a team is a function of both its assembly and subsequent leadership.[11] Leadership is not the focus of this chapter and is dealt with in more depth in Chapter 9. Reflection on observed styles of leadership by health professions students can help draw the link between observed team performance and leadership performance. Leading requires a diverse array of talents, including vision, strategy, resource allocation, operational tactics, professionalism, inspiration, integrity, emotional intelligence, and mission-mindedness, to name but a few of the necessary qualities. Over the last century, many theories regarding effective leadership have been explored and developed, often in fields other than health care. However, understanding the various leadership models that have emerged can inform the growing health care leader as to potential approaches to leadership.[12]

The reality of considering various leadership models is that in most contexts, some elements from each will be necessary. Each leader and team will be unique and require different techniques to achieve team goals. Leadership of a team can be approached in a myriad of ways, and no one approach or person will be suited to every situation. However, what is generally accepted is that effective leaders foster an environment in which mutual respect and support develop, a common vision and goal for the team is established, communication is appropriate, and conflict is managed within the team.

The science defining what constitutes effective leadership is difficult to evaluate as leadership is difficult to define and measure. Regardless of the strategies employed, leading a team requires a balance of coaching and directive approaches. Knowing team dynamics, understanding the change process, and bringing the best out of individuals

contribute to effective team functioning. Making the study of leadership an aim in health professions education will allow students to think more deeply about leadership, hone and practice leadership skills, and reflect on their strengths and weaknesses.

D. Constructing teams

As much as the leader influences the effectiveness of a team, the team members are equally important. Selecting team personnel is an important process, and individual members must possess the knowledge, skills, and attitudes to accomplish the defined goal. However, team membership is not always a completely volitional process. Often team members are drawn from the already assembled workforce. Outlining the essential attributes required of the team prior to team assembly is a critical step in developing a successful team. Thought should be employed in explicitly defining what the goal will be and what tasks will need to be accomplished and by whom. Clear expectations as to the requisite knowledge, skills, and attitudes should be applied to team-member selection. Identifying who will be empowered to perform the various tasks needed to achieve the goal will inform decisions as to membership needs. In most circumstances where teams are drawn from already established work pools, it is incumbent that leaders take into account the various knowledge, skills, and attitudes of those individuals assigned to the team and ascribe roles that are commensurate with the talents available.

Choosing the appropriate team size is equally important to membership as it relates to effectiveness. Team size influences communication patterns as well as the ability to meet, to assign work, and to redirect activity toward goal achievement. After the team is assembled, some thought should be employed to define the operational rules of the team: when and how communication and meetings will occur, how decisions will be reached, and who possesses decision rights. Understanding team growth and dynamics will allow a leader to anticipate and respond to the challenges faced while leading a team.

E. Stages of team development

Health care professionals, and more specifically health professions students, are frequently joining new teams as part of their everyday experience. Teams constantly change and progress through well-recognized stages. Reflection on the stages of team development can provide insight for health professions students as they examine the teams they join. Students may note that their experiences on highly effective teams are a reflection of a team that is mature in team development. This may contrast with dysfunctional teams that are low performing and have yet to build trust and team cohesion.

There are four well-established stages of team development:

- **Stage 1: Forming**—exploration and building trust
- **Stage 2: Storming**—attitude changes, competitiveness, tension, disunity
- **Stage 3: Norming**—satisfaction, respect development, decision making

- **Stage 4: Performing**—high level of interaction, performance increased and optimized, confidence within the team[1]

In stage 1, team members are identified, group goals are set, and the members begin to understand the capabilities of the various team members. Once the team is formed, stage 2 begins, and roles and responsibilities are delineated. Patterns of communication are established. This can be one of the more difficult phases to progress through, as there are numerous points where tension and disunity can develop. It is important to note that leadership is essential in this phase to ensure that open communication, despite conflict or tension, becomes the norm. This will help to maintain those valuable to the team as team members and prevent transitions of the disgruntled to the sidelines. It must be noted that this does not mean harmony and consensus must reign but that collegiality in the face of disagreement must become the norm.

Stage 3 begins when team trust is established. This allows for effort toward achieving the team's goals to begin. During this stage, team members come to understand that they can rely on one another's abilities and can disagree openly with maintenance of mutual respect. Finally, the last stage is that of a mature team in which a shared common goal has been established, trust is a norm, and productive work is performed with efficiency.

Not all teams mature through these stages. However, growth through these stages will result in teams that exhibit backup behavior in which team members compensate for each other, manage conflict within the team, regularly provide feedback, and self-correct.[1] The definition of an effective team is a goal-driven group of individuals with a common shared mental model for success. They exhibit mutual aid and trust and are able to achieve the team's desired end state.

III. Teams and collaboration

Zwarenstein and colleagues have reviewed the existing literature relevant to interprofessional collaboration and noted measurable changes in patient outcomes when structured processes for interaction and collaboration were initiated.[13] Their findings highlight a key question in evaluating teamwork: Is organized collaboration teamwork? Often in the literature, the concepts of teams, teamwork, and collaboration are used synonymously.[14]

For the most part, this is a reasonable approach, but it is important to note that the commitment to a common goal may not be as strong or made as explicit in a collaborative setting as it is with a clearly defined team. Recall that the definition of a team makes explicit that the group objective is a common goal, whereas in collaboration some goals may overlap but individuals may not share the same priority. In HSS, there is an overarching goal for collaborative efforts: health for all individuals, an ideal experience, and achieving both at the lowest possible cost. Given this context, studies citing outcomes for interprofessional collaboration in health care are relevant to evaluating team performance. Zwarenstein and colleagues noted in their review of the collaborative practice literature that there is a relatively low sample size of studies.[13] Many interventions have yet to be replicated, but the evidence that exists suggests collaboration does improve outcomes.

IV. Evaluating teams and teamwork

Specifically demonstrating the connection between teamwork and actual patient outcomes or successful goal achievement, as noted, remains challenging.[12] The reason for this difficulty is that evaluation of teamwork requires quantification of complex behaviors that do not, in and of themselves, directly correlate to the desired outcome[15]; however, the utilization of a validated and reliable scoring tool can provide valuable feedback to a team and redirect the efforts of teams. Numerous tools are available. The key consideration in tool selection is determining if the selected tool is applicable to the team environment it will be used to evaluate.[16]

The main domains generally evaluated by the available tools examine one or more of four aspects of teamwork, team training, or both: attitude, comprehension, behavior, and process. As discussed earlier, a high-functioning team has a shared vision for success, and this can readily be measured by assessing the attitudes and understanding of team members in relation to team goals. There is a growing literature demonstrating that awareness of goals does alter patient outcomes. A good example comes from infection control research demonstrating that knowledge of hygiene goals such as hand washing will increase rates of hand washing and decrease nosocomial infections. The behavioral assessment tools available usually measure communication and coordination between team members. While these are clearly important elements of teamwork, the available literature is not as robust regarding the measured effect on health outcomes. The literature that does exist in this area is often from the procedural specialties and does demonstrate improved performance with better communication from team members. However, it is likely safe to assume, and there is growing evidence to support the notion, that higher levels of communication and coordination are desirable in all areas and will improve outcomes and increase value in health care. Finally, process assessments measure rates at which teams complete or utilize a prescribed process. Again, these have been demonstrated in procedural specialties such as surgery, anesthesia, and intensive care to improve coordination of efforts, increase role clarity, and enhance care delivery.

Regardless of the noted difficulty in measuring team performance, it is generally acknowledged that evaluating the function of teams is an important aspect of improved patient safety and quality of care. The number of tools available to health system leaders increases every day, and they are available and applicable in ever more numerous environments in which health care teams operate.

V. Understanding health systems, systems thinking, and teams

Systems thinking is a crucial element of any HSS endeavor, as described in Chapter 2. Systems thinking allows recognition, understanding, and synthesis of the complex interdependencies and relationships within a functional system such as health care. The components of a system are the constantly changing workings of a multilayered organization. The ability to recognize patterns and repetitions of daily interactions and how they work together in accomplishing a specific purpose is essential to maximizing the outcome of those interactions.[17] Systems thinking allows the formation of linkages among disparate areas of activity in health care to advance the overarching goal of HSS: improving outcomes, patient experience, and value in health care. Competency in HSS requires that health professions students understand how patient care relates to the health system as a whole and how to use the system to improve the quality, experience, and value of patient care (the Triple Aim) and team-member well-being (the Quadruple Aim).[4] Health professions students are therefore expected to demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care.[18]

A. Teamwork and the national landscape

Teamwork and teams are now widely regarded by national organizations as a critical element of the national approach to quality and patient safety. Various agencies are defining how teamwork relates to their diverse activities, including regulation and policy, education, clinical practice standards, professional networks, and community outreach.

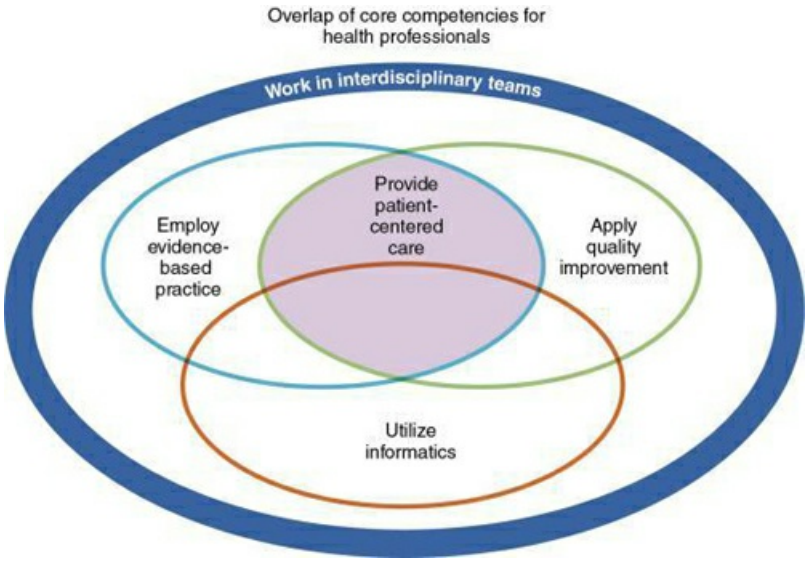
The Health Resources and Services Administration (HRSA), an agency of the US Department of Health and Human Services, is the primary federal agency charged with improving health and achieving health equity through access to quality services and a skilled health care workforce. HRSA directs its efforts by coordinating the efforts of 90-plus programs and more than 3000 grantees. One way HRSA has demonstrated the contribution of teams and systems thinking in patient safety and health outcomes is with its Patient Safety and Clinical Pharmacy Services Collaborative (PSPC).

The PSPC reported in May 2013 the results of a team-based initiative that included 344 teams of community health care providers, representing more than 885 organizations of community-based health care providers across 48 states, the District of Columbia, Puerto Rico, and the Virgin Islands.[19] Team members represented community health centers, hospitals, and schools of pharmacy, nursing, and medicine. The PSPC teamwork initiative decreased adverse drug events that caused harm to patients, with an average improvement of 40% between 2009 and 2010 for a high-risk patient population. Numerous different approaches to similar problems were observed,

reflecting different local needs. Success was achieved by allowing organizations participating in the initiative the ability to identify their own needs, their own delivery system, and key processes that needed attention. Another key finding was the importance of widening the definition of the team and including patients in the solutions. Patient needs and expectations were drivers of many of the team-based innovations.

B. Interprofessional collaborative practice and competencies: Improving health care through relationships

A critical turning point in health over the last couple of decades was the release of *Health Professions Education: A Bridge to Quality* by the Institute of Medicine,[20] which identified the core competencies needed for health care professionals of the future (Fig. 8.2). The report emphasized that health care professionals should be educated to deliver patient-centered care as members of teams, emphasizing evidence-based practice, quality improvement approaches, and informatics.



• **FIG. 8.2 Health Professions Core Competencies.** *Source:* (Reprinted with permission from Greiner A, Knebel E. *Health Professions Education: A Bridge to Quality*. Washington, DC: National Academies Press; 2003.)

The World Health Organization also prepared a framework and definition for interprofessional education and collaborative practice that is widely accepted:

> Interprofessional education occurs when students from two or more professions learn about, from, and with each other to enable effective collaboration and improve health outcomes. Once students understand how to work

> interprofessionally, they are ready to enter the workplace as a member of the collaborative practice team. This is a key step in moving health systems from fragmentation to a position of strength.[5]

This recognition that interprofessional education represented a critical aspect of the future of health care led to the formation in 2009 of the Interprofessional Education Collaborative (IPEC) by six US education associations of health professions to promote and encourage constituent efforts that would advance substantive interprofessional learning experiences to help prepare future health care professionals for enhanced team-based care and improved population health outcomes.[21] The IPEC organizations represent allopathic and osteopathic medicine, dentistry, nursing, pharmacy, and public health. IPEC created core competencies for interprofessional collaborative practice to guide curricula development across health professions schools. Examination of the IPEC core competencies can enhance understanding of the essential elements that will help an interprofessional team be successful.

IPEC core competencies for interprofessional collaborative practice include four domains. The first domain centers on changing the manner in which formation of professional identity is approached. The underlying philosophical principle guiding this is the recognition that health care is an ethical pursuit. Situating the learner's ethical obligations around his or her role as a member of a health care team would advance interconnectedness among health professions. Previously, professional identity formed in ways that fostered silos and separation of the various health professions, each with a separate perception of practitioners' ethical obligations. IPEC advances the notion that emphasizing the common ethical imperative of collaborative practice and patient-centeredness will be critical in development of an interprofessional ethos in health care education, practice, and teams.

The second domain focuses on ensuring that health professions students understand and can articulate their roles and responsibilities and how these relate to the roles and responsibilities of others on the health care team. Diversity of capabilities is identified as the underpinning of functional teams. Furthermore, the ability to evaluate and understand the capabilities of team members fosters an environment of trust and support. Inaccurate understanding of role scope and capabilities can lead to friction and poor team performance due to mismatched expectations and abilities.

The third domain focuses on communication among health care professionals. It has long been known that communication is an essential element of teamwork. It is now becoming clear that communication among interprofessional teams is an essential element needed in health professions education. Communication patterns and abilities set the mode and manner of team interactions. Poor patterns that are heavy in nonshared jargon disrupt teamwork. Clear communication with a shared lexicon and mutually agreed-upon patterns and methods improves team functioning.

The fourth and last IPEC domain is teams and teamwork. Forming and functioning as a team is a complex task. Education for health care professionals needs to focus on the elements of team performance shown to improve effectiveness. There is an imperative that health care move to a paradigm with shared accountability for the outcomes of the

patients being cared for by the health care system. Shared accountability can be seen as setting a common team goal by which all team members understand they have a role to play in the eventual outcome. For this notion to take root, shared problem solving, shared decision making, relinquishment of professional sovereignty with acceptance of group dynamics, and acceptance of shared expertise are vital.

For the competencies contained in these four domains to become an integral part of health care teams, they must become part of the everyday environment in health care. This will begin to be the case when students of all the health care disciplines learn together routinely, practice as teams, and gain clinical skills in a team-focused environment. Institutions will need to make this a priority and develop faculty capable of leading the transition to team-based care. Students will need to be evaluated and mentored not only in the knowledge, skills, and attitudes necessary for their chosen career specialties, but also in their performance as members of a team.

VI. Team training

A. Educating teams—theory

While teams are part of everyday experience, forming and maintaining effective teams is not routinely taught. Understanding the methods and theories by which people learn is an essential aspect of developing teams and teamwork. It is only part of the job to understand the competencies necessary for effective teams to operate. It is equally important to understand how those competencies are transmitted to health professions students and practitioners. Furthermore, as discussed earlier, health care is only now realizing the need for health professions students to learn together before they can work together as a team.

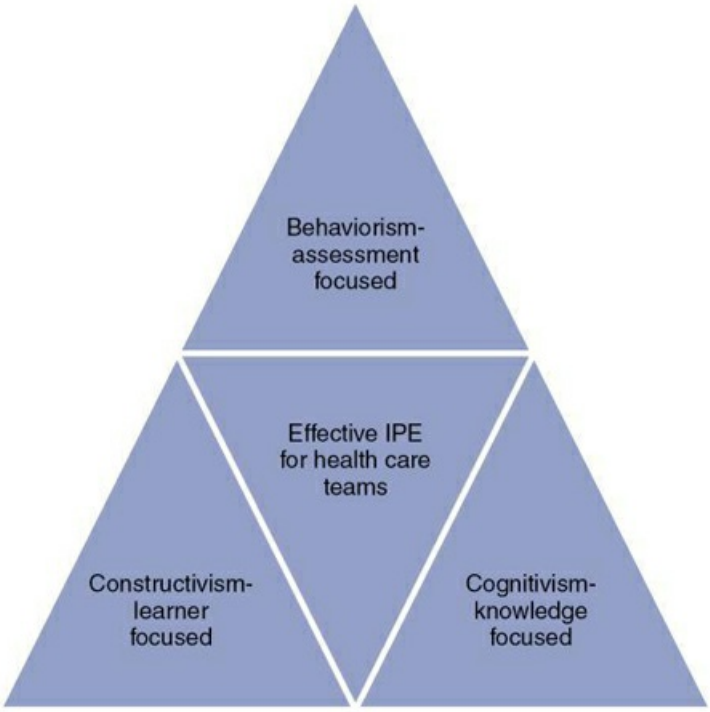
Theories about learning are plentiful, and the details are beyond the scope of this chapter. However, it is important to note the basics of these theories, which inform how education on teams may be enhanced. There are broad categories of learning theory that need to be considered when thinking about interprofessional education: behaviorist theory focuses on the outcomes of learning or behaviors, cognitivist theory emphasizes the role of internal thought, and constructivist theory focuses on the person who is learning.[22,23]

Behaviorists posit that learning occurs through trial and error and experientially. Furthermore, all learning results in outcomes that can be measured. Thus interprofessional education models that take a behaviorist approach often focus on what can be measured at the end of the education process and find methods to ensure that desired behaviors are learned. The learning may be reinforced by rewarding the desired behaviors. Using a behaviorist model can result in learners who exhibit significant behavioral change due to the inherent capacity of students to focus on what they know will be rewarded. However, some argue that this ignores an important element of education: thoughtfulness about why actions are being taken. Behaviorist models can at times fail to reinforce reflection by students as to why they are doing what they are doing and the consequences of such learned behavior.

Cognitivist and constructivist theories, which address the process of learning and the learner, aim to establish higher-order skills that build patterns of problem solving and insight. These theories form the foundation for commonly used experiential learning models such as problem-based learning or inquiry-based learning. The tenets of these educational theories are reflected in the key assumptions of adult learning theory. These tenets state that adults are self-directed and independent, tap into previous experience to inform current learning, value learning that has a direct impact on their daily experience and problems, and respond to internal motivation above external motivation. Proponents of cognitivist/constructivist theory feel that students in these models will change their behavior because they have an awareness of the reasons behind the need for a given pattern of action.

It is likely that some coupling of all the various educational models will be necessary

to develop best practices for education on teams to impact patient safety and quality in health care (Fig. 8.3). It will be equally important to be able to ensure that behaviors change through reward and feedback while simultaneously ensuring that students are equipped with the higher-order problem-solving abilities necessary to meet challenges that are not easily identified.



• **FIG. 8.3** **Learning Theory and Effective Interprofessional Education (IPE).**

B. Educating teams—practice (models for medical team training)

As discussed previously, recognition that teams are the base unit that will improve health care and achieve national patient safety objectives derives from work on teamwork in other industries. The easiest example to cite, and the archetype most often followed for medical team training, is that of commercial aviation. The flight industry has a fatal mishap rate of 0.2 lives lost per every 1 million miles of travel. This represents a sixfold decrease in fatalities since the 1970s and is a remarkable achievement given that air travel has seen increasing volume over that same time period.[24] Aviation adopted the team training model known as Crew Resource Management (CRM). CRM was a response by the aviation industry to an alarming number of fatal accidents that occurred in the late 1970s and early 1980s. The aim of CRM was to change the aviation industry culture from an individualistic pilot-centric culture to one that embraced the team concept of safety. No longer did all direction and corrective monitoring sit with one individual, the pilot; rather, the entire team was

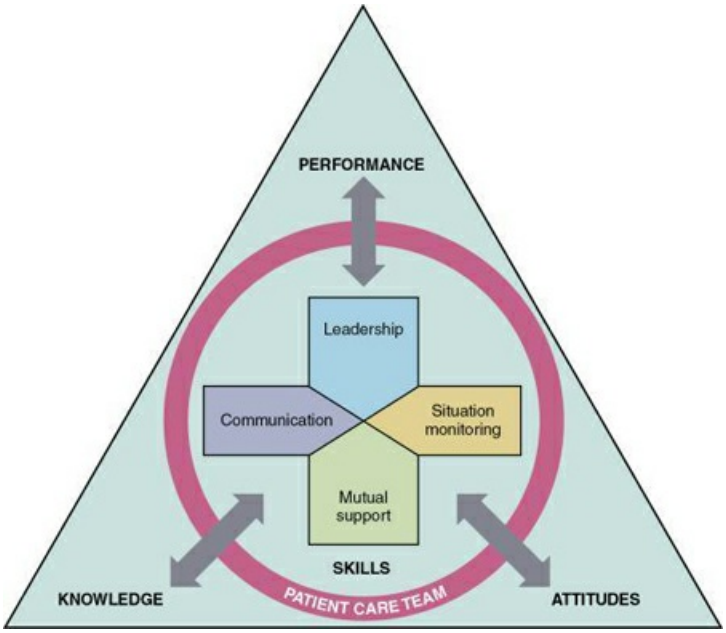
responsible for the safe operation of the aircraft. This was not an easy transition, and formation of a team ethos did not occur by decree. An active process was necessary to change the industry standard; CRM became that standard. A similar shift is ongoing in health care.

Prior to the CRM movement, a pilot was solely evaluated on the technical skills of flying; performance as a team member was not evaluated. CRM utilized full team simulation to evaluate team performance—in particular, situational awareness, metacognition of team members (i.e., "do team members have insight into their thought patterns?"), shared mental models, and efficiency of resource management. These are all the hallmarks of functional teams. Another aspect of CRM is that it progresses through three phases. Phase one is indoctrination and awareness, characterized by development of a shared vision for safe operations of an aircraft, shared vocabulary, and shared expectations for interpersonal interaction and decision making. CRM also reframes outdated leadership expectations and focuses on standard operating procedures. Phase one is accomplished through didactic lectures, group discussion, analysis of cases, and role-playing training/simulation exercises. Often CRM is modulated in response to surveys from crews as to areas of perceived need or poor performance.

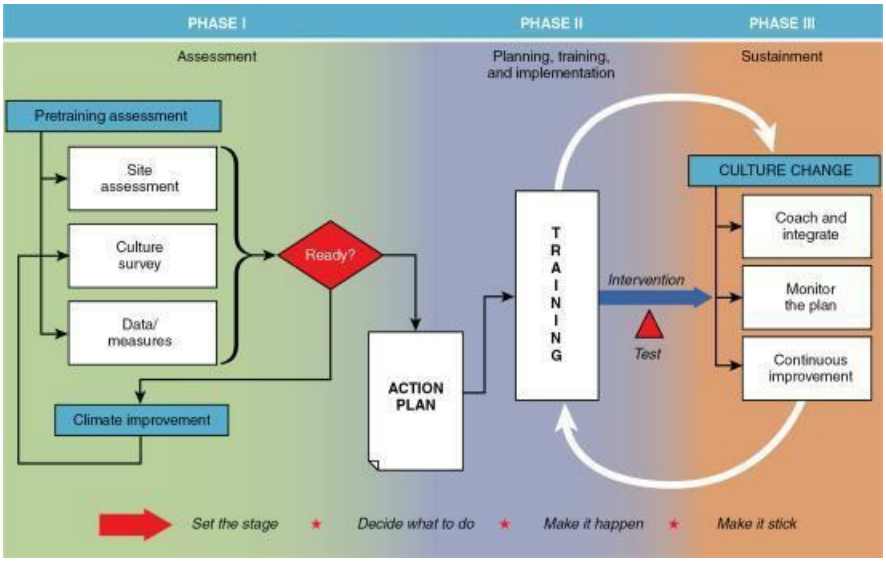
Phase two is characterized by recurrent training. No matter how well executed the indoctrination is, ongoing reinforcement and practice are key to successful CRM training. Furthermore, team needs may change over time, and assessment and redirection are often needed to maintain team skills and focus.

Phase three is continuous reinforcement characterized by focusing on CRM concepts outside of the training environment. This is often accomplished by making the CRM concepts part of mishap reporting and standard performance evaluations. Applying the concepts this way sends the message that CRM is an important aspect of everyday operations.

The success of CRM in aviation has seen its adaptation to health care in the form of medical team training. The most common team training method discussed in health care is Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS). TeamSTEPPS is derived from collaboration among the Department of Defense Patient Safety Program, TRICARE Management Activity, and the Agency for Healthcare Research and Quality and was rolled out in 2006.[25] TeamSTEPPS focuses on many of the areas discussed in this chapter that lead to teams becoming high functioning. It has the broadest application of the various programs that exist because it is not based on any one health care discipline but targets team concepts in general. As illustrated in Fig. 8.4, the four main areas of focus are leadership, situation monitoring, mutual support, and communication. TeamSTEPPS is taught via a mixture of didactic lectures, discussions, and simulation events. Much like CRM, it is a multistep process from initial training to sustainment (Fig. 8.5).



• **FIG. 8.4** **TeamSTEPPS Instructional Framework.** *Source:* (From King H, Battles J, Baker D, Alonso A. TeamSTEPPS™: team strategies and tools to enhance performance and patient safety. In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches [Vol. 4: Technology and Medication Safety].* Rockville, MD: Agency for Healthcare Research and Quality; 2008. http://www.ncbi.nlm.nih.gov/books/NBK43770/. Accessed July 15, 2019.)



• **FIG. 8.5** **TeamSTEPPS Resources Implementation: A Culture Shift Toward Safety.** *Source:* (From King H, Battles J, Baker D, Alonso A. TeamSTEPPS™: team strategies and tools to enhance performance and patient safety. In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches [Vol. 4: Technology and Medication Safety].* Rockville, MD: Agency for Healthcare Research and Quality; 2008. http://www.ncbi.nlm.nih.gov/books/NBK43770/. Accessed July 15, 2019.)

Numerous other programs are available for team training. Some of these are

specifically focused and include Anesthesia Crisis Resource Management, which brings CRM concepts to anesthesia, and Team-Oriented Medical Simulation, which focuses on the entire operating room.

VII. Chapter summary

Study of HSS, the third science, is increasingly recognized as equal in importance to learning the clinical and basic sciences. All three areas of expertise have equal applicability to health care's ultimate goal of delivering high-quality care as safely as possible. Outlined in this chapter are the critical pieces to forming and maintaining high-performing teams and the role teams play in interprofessional collaborative practice. Health care is evolving with the goal of improving patient care, experience, and value. These goals form the framework for HSS, and teamwork and team science are the critical connection between plans and execution in any health care setting. Attention to the aspects of teams, team functions, leadership, education, and training will be essential to achieving mastery of HSS and advancing the goals of high-quality and high-value patient care.

Questions for further thought

1. What is the definition of a team?
2. What are the qualities present on an effective team?
3. What are the four defined stages of team formation?
4. Why are teams critical to health systems science?

Case study 1

You are an orthopedic surgeon. The discharge of your patients is frequently delayed due to late or incomplete discharge orders from the medical team, or both. This delay in the timeliness of the discharge process results in patient confusion regarding departure from the medical facility and causes increased patient frustration with a prolonged discharge process. In addition, the delay in discharge creates bottlenecks and delays in the pharmacy, delaying discharge medication retrieval and preventing or truncating nurse discharge teaching. Finally, as an added problem, the backup results in a lack of bed availability for new surgical patients on this unit.

1. Who are the members of your interprofessional health care team involved in this process?
2. What is your role?
3. What are the possible consequences of the poorly functioning team beyond those stated in this case study?
4. Where could this process be improved and by whom?
5. How could this health care team improve its effectiveness and provide a positive patient experience?

The interprofessional team in this situation is everyone involved in the care of the patients (doctors, nurses, and pharmacists) and the patients themselves. Breakdown in this discharge process can have significant ramifications for the patients. Medical errors can occur due to the patients not being fully informed as to discharge instructions and medication use. Patients could suffer significantly because of the likelihood of frustration mounting with a delayed and rushed discharge. Staff discord could mount as the ability to complete assigned tasks becomes more challenging due to wasted time waiting for orders to initiate tasks. The process of discharge requires multiple levels of communication and will require the formation of a team among all involved. First, the medical team can define and communicate the patient goals/factors that will result in discharge following admission or surgery. Predefining the goals and communicating them to other staff members on the team can allow for anticipation of possible discharges. Once discharge is anticipated, staff members can be proactive in requesting discharge orders once a patient meets predefined parameters, instead of waiting for the medical team to reevaluate the patient. Second, communication between the pharmacy and the physician/nursing team members can establish a mechanism to review the patient's medications and anticipate potential discharge orders prior to actual

discharge. This process can allow early ordering and teaching of medication information, reducing the rush on the day of discharge and likely improving communication. Decreasing wait time, increasing patient knowledge, and setting and meeting expectations through these processes have been demonstrated to reduce errors and increase patient satisfaction.

Case study 2

You are a solo family physician working in a rural area. You pride yourself on your dedication and commitment to maintaining your practice at the cutting edge of evidence-based medicine. You no longer admit patients to your local hospital because it has moved to a hospitalist model; you still follow their progress while admitted and see them in your office once discharged. Recently, you have noted wide variation in the management of your patients with regard to medication use and length of stay. You feel you could make some suggestions to the hospitalist team since you are current on the literature and in the unique position of seeing the variation that exists.

1. Is there a need for a team in this situation?
2. What should be the goal of the team?
3. How might a team help?
4. How should you approach forming a team with the hospitalists?
5. Who should lead this team?
6. What factors might decide this choice?

There is a need to form a team in this situation. The goals of HSS are to improve individual patient and population outcomes, better patient experiences, and increase the value of care. Your recognition of wide variation of practice among the hospitalists suggests there is likely an opportunity to improve both individual and population outcomes. A team approach to this problem could help align everyone's efforts, build consensus as to best practices, and alert people to alternative opinions within the group. This level of alignment can improve inpatient care by ensuring that practice is based on evidence and decreasing staff confusion through a common approach. Outpatient care will likewise benefit as the bond and communication to the inpatient area will likely improve through team interaction. Your approach to forming a team with the hospitalists will be critical to achieving success. How you frame the issue will determine interest levels and commitment. It is critical to not alienate the hospitalists through accusations, but to solicit help in solving a problem. In health care, forming teams often involves getting people to rally behind a shared common aspiration. You should frame this as intending to improve patient outcomes. In this situation, choosing a leader is critical. Often leaders are assigned by organizations. Here there is no mandate to form a team, and therefore no clear leader. Leadership will reside in whoever is passionate about the task at hand. You, having identified the problem and having concern for the outcome, are an obvious choice. However, your role as leader may change as the work progresses if others are interested or the work to be done is more on the inpatient side.

Case study 3

You are the medical director of a neonatal intensive care unit and a member of its quality council. After reviewing yearly quality data, it is discovered that the unit is performing very poorly in central line–related bloodstream infections. Everyone is dismayed and turns to you for guidance. You immediately recognize this as a major concern. You state up front that you are not sure how to solve the problem, but that addressing it is your top priority for the unit going forward. You immediately begin to alert everyone who works in the unit of the quality council's discovery, begin to solicit people interested in helping solve the problem, and elicit their opinions for possible solutions. After forming the team, you discover that a number of newly hired nurses do not know the unit policy for maintaining central lines. You are also informed that the pharmacy has recently changed vendors for total parenteral nutrition (TPN), and the new vendor's TPN bags require a work-around by the nurses to connect to the unit's IV tubing. During a team meeting, your charge nurse informs you that she has a friend who works in a nearby unit that had the same issue and now has not had an infection in over 500 days. That unit has a bundle of interventions they are confident led to their success.

1. What have you done well in this process?
2. What stage is this team currently in in team formation?
3. What is this team's way forward?

You have done a number of things well in leading this process. First, you were very responsive to the unit council's concerns regarding the infection problem, immediately raising the issue and soliciting help and solutions. Communication is a critical element of any successful team. Your communication resulted in numerous findings from the staff that may have direct bearing on fixing the problem. Furthermore, your communication with the team resulted in your charge nurse discovering another team with the same problem and a potential solution. That team is currently formed, has well-established communication and trust with many potential solutions in place, and is therefore entering the final stage of team development. The way forward for your team is to evaluate the information the team members have received, adapt that information to the local situation, communicate the plan to the unit, and enact the plan. The team has to manage the change process and ensure that points of tension and friction are promptly managed. Continual messaging of the overall goal is needed as well as keeping everyone well informed of intended changes. Establishing feedback mechanisms on the impact of the changes is also critical.

Case study 4

You are a busy family medicine physician with a full schedule of patients to see in your office every day. The office is staffed with a medical office assistant with Lean improvement training, a physician assistant, a registered nurse, and a registration/discharge associate.

There have been recent changes in the patient/family education documentation requirements from insurance payers for office visits aimed at improving patient safety. It is important for the practice to comply with the educational activity and documentation, both for patient safety and for payment for the medical care provided.

At least five patients a day have a visit type that would require the changed education and documentation. Meeting this requirement will involve a complete change in workflow, which could impact every patient seen by the practice.

1. Is there a need for a team to solve this situation?
2. Who should lead the team?
3. What are the consequence of inaction to you? To the patients? To the health care professionals? To the practice?
4. What would be the goal of the team?

You would first identify and communicate with the staff member with the most knowledge and competence to assess the impact of this change on the operations of the office. In assessing workflow to determine what kind of team to assemble to study the impact and plan the change, it will be important to determine who has decision rights to implement change, what the communication plan is, and who is going to lead the work group to determine what, if any, changes need to be made to the workflow. The consequences of inaction could be catastrophic both clinically, from a safety perspective for patients, and from a financial perspective in the business functions of the office.

The goal of the team would be to assess the impact, process map the current process, process map the proposed new process, and design a workflow to ensure that the goals of patient safety and business needs of the practice are met. Your role is to ensure that the team leader and the team members understand the goals, decision rights, and process for understanding and changing workflow, in addition to how the team will communicate with patients and fellow team members.

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Leadership in health care

Sara Jo Grethlein, MD, Brian Clyne, MD, MHL, Erin McKean, MD, MBA

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In this chapter

In considering how to best develop effective health care leaders, some fundamental questions arise. How is leadership best taught and learned? What leadership models or theories are most applicable to health care? How does health care leadership differ from management, and how do leadership and management intersect? Is health care leadership distinct from leadership in other industries? Are there distinguishing leadership competencies in a health care environment? What are the opportunities and pathways to health care leadership? This chapter addresses these and other questions as the multifaceted topic of leadership in health care is explored.

Learning Objectives

1. Understand the factors driving the leadership imperative in health care.
2. Describe key competencies related to health care leadership.
3. Describe pathways to formal leadership roles across multiple domains in health care.
4. Understand the concept of professional identity formation as it relates to leadership.

I. Introduction

The US health care system is undergoing disruptive change characterized by major shifts in the traditional models of care delivery, payment, and government regulation. Spiraling costs, inadequate access, inconsistent quality, increased competition, and the need for improved population health are just a few of the challenges facing modern health care. In response to these challenges and an increasingly complex system, the demand for effective leadership has never been higher. From the primary care physician leading a team in an office practice to the chief executive officer (CEO) tasked with managing a hospital system, leaders in many forms will shape the future success of the health care industry.

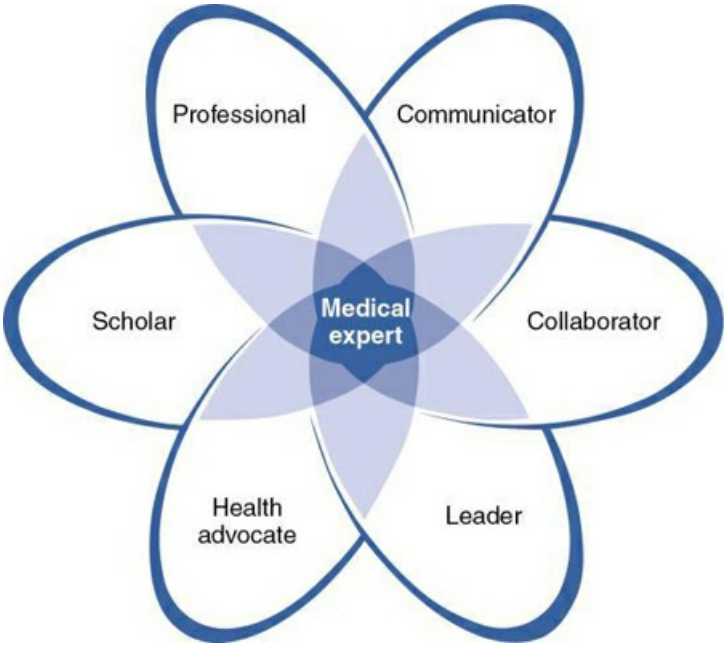
Many of these future leaders will be physicians and other health care professionals. According to a 2014 survey, 60% of hospitals plan to hire more physician leaders in the next 5 years.[1] Traditionally, physicians have ascended to leadership roles based on clinical skills, scholarly productivity, or research excellence. However, it is becoming clear that successful health care leadership demands intentional development of skills such as creative thinking, an ability to work across disciplines, operational skills, and an understanding of organizational culture—topics notably absent from most health care professional school curricula and residency training programs.

Despite a growing emphasis on preparing clinician leaders, some experts have speculated that deeply ingrained physician characteristics and the culture of medical training run counter to the forms of leadership now required. Consider the formative members of the leadership pipeline—health care professional school applicants—whose early lives are filled with achievement and leadership potential. If leadership is valued highly by the profession, essential for the future of health care, and vital for acceptance to our professional schools, how then does the health system end up with practicing physicians who require intensive retraining as leaders? Some have speculated that characteristics that have traditionally led to acceptance to medical school, such as competitiveness and independent-mindedness, may neutralize necessary leadership skills. For example, physicians typically value autonomy and are taught to act in the best interest of individual patients. Health care systems are traditionally hierarchical, rewarding individual achievements. This may not be the optimal foundation for leading change that requires collaboration, relational skills, emotional intelligence, and systems thinking. This might explain the recent proliferation of academies, courses, and degree programs designed to train (or intensively retrain) health care leaders.

II. The health care leadership imperative

To confront the many challenges facing the US health care system, experts and organizations have pointed out the critical need for effective leadership. Physicians and other professionals are being called upon to develop and demonstrate the capabilities to lead health care transformation.[2-4] The Institute of Medicine (renamed the National Academy of Medicine in 2015) has described the need to "develop leaders at all levels who can manage the organizational and systems changes necessary to improve health."[5] The Association of American Medical Colleges (AAMC) has called for "new roles for physician leaders" and a "focus on organizational leadership in a new era of health care."[6] The American Association of Colleges of Nursing, along with other health care organization collaborators, introduced the Clinical Nurse Leader role in 2003. Clinical practices, hospitals, and health care systems need strong, competent, and visionary leaders to navigate the changing landscape. Professional organizations (such as the American Medical Association and the American College of Healthcare Executives) provide education, leadership development, and options for collective action. Government agencies, such as health departments and the military, are also in need of health care leaders.

Medical education accreditation bodies are incorporating leadership competencies into their training and practice standards. For example, leadership has become an essential competency for medical students as described in the AAMC Core Entrustable Professional Activities for Entering Residency. Among the expected behaviors of medical school graduates is the ability to "provide leadership skills that enhance team functioning, the learning environment, and/or the health care delivery system."[7] In graduate medical education, the requirement to develop physician leaders is explicit. The Accreditation Council for Graduate Medical Education requires residents to demonstrate the ability to "work effectively as a member or leader of a health care team or other professional group."[8] In 2013, the American Association of Colleges of Nursing described entry-level competencies for all Clinical Nurse Leaders, including maintaining an outcomes focus, interprofessional communication skills, and the ability to apply improvement science and systems theory.[9] The Royal College of Physicians and Surgeons of Canada's CanMEDS Physician Competency Framework was modified in 2015 to include "Leader" as one of the essential roles of physicians (Fig. 9.1).[10] This change from "Manager" to "Leader" in the CanMEDS framework reflects the emphasis on clinicians working collaboratively and "[engaging] with others to contribute to a vision of a high-quality health care system and take responsibility for the delivery of excellent patient care through their activities as clinicians, administrators, scholars, or teachers."



• FIG. 9.1 CanMEDS Diagram Reflecting "Leader" as One of the Essential Roles of Physicians. *Source:* (Copyright © 2015 The Royal College of Physicians and Surgeons of Canada. http://www.royalcollege.ca/rcsite/canmeds/canmeds-framework-e. Reproduced with permission.)

Distinction is often made between managers and leaders, with the commonly held belief that "Managers do things right. Leaders do the right things."[11] In this dichotomy, managers are portrayed as orderly, predictable figures who focus on structure, planning, and execution. Leaders, by contrast, are the visionary catalysts focused on defining purpose and executing change. In health care, managers are needed to identify efficiencies and improve operational structures, especially in the clinical setting. Leaders must be skilled at seeing connections and future opportunities in a rapidly changing and competitive landscape. While the core functions of managers and leaders may be different, there is significant overlap in their requisite skill sets. Both roles are crucial to organizational success, and management skills make leaders more effective.

III. Who are health care leaders?

Traditional thinking in health care left leadership to administrators, often limiting physicians and nurses to patient management or departmental/unit service roles. Fast-forward to the current environment, where clinician leadership has been shown to improve patient outcomes, decrease clinical operational and capital expenditures, improve efficiency, and improve staff satisfaction and retention.[4,12] Barriers to physicians and other health care professionals engaging in leadership have included the lack of leadership training, the lack of a common language in quality and leadership, the assumption that physicians will resist change, the undervaluing of the cumulative effect of incremental changes, and a lack of institutional culture that empowers frontline clinicians and staff. Changes to a deeply ingrained culture often require moments of crisis. The value crisis in health care has provided an opportunity to change how the health system thinks about and designs leadership training in health care. Professional development to succeed in both formal, authority-based roles and informal, transformational leadership roles is necessary.

In the realm of formal administrative leadership, several collaboratives have emerged to represent groups of leaders. The Institute for Healthcare Improvement (IHI) Leadership Alliance[13] is a collaborative of health care leaders committed to the science of improvement and the **Triple Aim**: improving the experience of care, improving the health of populations, and reducing per capita costs of health care. Berwick and colleagues argued that "Leaders involved in health care must be actively and directly involved in catalyzing change needed to achieve the Triple Aim" because of contextual challenges in redesigning systems of care, rapid evolution of delivery innovations that outpace the development of national or state policies, the need for trusting relationships with the public, and bipartisan political gridlock that squelches authentic dialogue and progress.[14]

The IHI has proposed four mental models for health care delivery: (1) consideration of individuals and their families as partners in care; (2) a focus on value (defined as quality per cost); (3) service alignment with value-based payment systems (e.g., organizing care based on value rather than organizing care based on volume and the fee-for-service system); and (4) empowerment of all participants as improvers.[15] These models in turn demand high-impact leadership behaviors, including person-centeredness, frontline engagement, relentless focus, transparency (about results, progress, aims, and defects), and boundarylessness.

Person-centeredness requires considering the needs and values of patients, families, and communities, not single-mindedly focusing on disease statistics and dollars. Frontline engagement demands that leaders be present and transparent, sharing information and asking open questions while adapting to the needs of the team or organization. Relentless focus requires articulating a clear vision and aligning activities with priorities to achieve stated aims. Boundarylessness extends frontline engagement to include transparency, sharing lessons learned, and collaborating throughout a system or organization. These models and behaviors are thought to characterize true leaders in

both formal and informal positions within health care. Competencies demanded of leaders in health care are elaborated later in this chapter.

The National Center for Healthcare Leadership (NCHL),[16] a United States–based think tank of physicians, health care professionals, system administrators, suppliers, and academics, is a nonprofit organization focused on the development of health care leaders in the formal administrative setting in order to improve health care delivery and population health. The NCHL offers structured coaching, executive fellowships, and consulting services aimed at improving the leadership capabilities of executives and their teams, regardless of background or path to leadership. The NCHL has specific initiatives on women's leadership and diversity leadership, attempting to understand the gaps in formal leadership opportunities and preparation for these groups, as well as aiming to positively impact executive leadership diversity.

There is less literature and discussion about informal leadership in health care, though this does not reflect its relative importance. Nonadministrative leaders often are experts in their respective fields with great potential to influence processes and behaviors. By definition, leaders must have followers. Followers need not be direct reporters, and expert leaders of engaged followers very often are found outside of the executive suite. When these leaders are identified, empowered, and trained, they have the capacity to influence culture change and process improvement. Each day, there are countless examples of effective frontline leadership in health care. The system depends on individuals without formal titles to identify problems, take action, and initiate meaningful change. Mona Hanna-Attisha, MD, MPH, a pediatrician in Flint, Michigan, challenged state government officials with her research showing a spike in lead levels in children after alterations in the city's water supply.[17] Her persistence, coupled with courage and an intense patient-centered mindset, led to statewide changes and a national focus on health care disparities and environmental health. She embodied professionalism, outcomes focus, team management, effective communication, and navigation of the politics in microsystems and macrosystems.

Students and staff who are in entry-level positions often question why they are being given leadership training or being exposed to a leadership curriculum. In an ideal health care environment, any member of the team is empowered to demonstrate situational leadership. It is easy to underestimate the power of leading from within or influencing organizational behavior without holding a formal administrative role. As an example, a nursing student studying hospital-acquired infections became concerned that the computer keyboards on mobile workstations were the source of a recent *Clostridioides difficile* outbreak on the medical wards. Assuming responsibility for improving the system, the student gathered data and reframed the problem as both a patient safety issue and a financial concern for the hospital. He engaged key stakeholders in infection control and identified areas of best practice. He communicated his findings to the hospital leadership, appealing to them by sharing persuasive firsthand patient stories. Ultimately, he gained support for implementing a solution—a modification to the hand hygiene policy that includes cleaning of all computer keyboards.[18]

Another informal leadership example can be the exertion of influence by

organizations. One excellent example comes from the American Medical Student Association (AMSA). Concerned by examples of conflict of interest between the pharmaceutical industry and medical school faculty or staff and the lack of education around this issue, the AMSA began a PharmFree campaign in 2002 by gathering information about the relationships between institutions and the pharmaceutical industry. The organization hoped that by publicizing the identified potential conflicts of interest, they would encourage schools to limit gifts, advertising, and contact with sales representatives in order to minimize undue influence of commercial entities in medical decision making about therapeutic choices.[19] Through this program, in 2006, the students invited each school to submit its policies and curriculum for evaluation and then published an 11-point PharmFree Score Card. High-profile schools initially scored poorly, and the resultant publicity spurred change. In 2008 the AAMC and in 2009 the Institute of Medicine formally called for inclusion of conflict-of-interest education in the curriculum of medical schools. The AMSA has continued its leadership in this domain, publishing model curricula and updating the annual scorecard. The impact of this effort has expanded at many institutions, where student input is now incorporated into both curriculum and policy formulation.[20]

Case study 1

After graduating from a prestigious residency program where she had been chief resident, Dr. Hogan completed a competitive fellowship in infectious diseases. She quickly earned a reputation for clinical excellence, strong research skills, and dedication to bedside teaching. She became the youngest division director and fellowship director in the institution before her recent promotion to chief academic officer. Almost immediately, Dr. Hogan was overwhelmed with the complexity of the job and began questioning her decision to join the executive ranks of the hospital's administration. She had inherited a staff with low morale due to conflicts between two key members of the group. There were also major budget constraints, programs facing loss of accreditation, and physicians in need of professionalism remediation. From her day-to-day schedule to long-term strategic planning, Dr. Hogan decided to take on every issue personally. She was frustrated to learn that her talents as a clinician and teacher were less relevant as she dealt with finances, human resource policies, conflict, and change initiatives. Things reached a critical point when the board voted to acquire a network of local hospitals to enhance clinical revenue and reduce outside competition. Dr. Hogan was charged with leading the integration of all educational programs in the system, a monumental undertaking. She knew that to be successful and advance in her career, she would need a new set of skills. Dr. Hogan enrolled in a leadership training course at the local business school and, over time, she learned to be as effective in the boardroom as she had been at the bedside.

1. Are health care professionals like Dr. Hogan prepared for leadership roles?
2. What factors contribute to the demand for leadership skills among health care professionals?
3. Can leadership skills be learned? If so, how do health care professionals go about acquiring foundational leadership skills?
4. What are some common pathways to health care leadership?

IV. The importance of clinician leadership

The American Association for Physician Leadership (AAPL) was founded in the 1970s in order to develop physician managers. An AAPL white paper reported that only 5% of hospital leaders were physicians in 2014.[21] However, hospitals with physician executives are highly ranked and disproportionately outperform other hospitals in cancer care, management of digestive disorders, cardiology, and cardiac surgery. Physician-led hospitals also score higher in performance management and Lean management (i.e., management focused on continuous quality improvement). This improved performance may come from leaders with deep knowledge of the core business. In almost all industries, executive leadership of companies or systems comes from the core business function domain. For example, executives in the competitive soft drink industry tend to have strong marketing and strategy backgrounds, while auto industry executives tend to have strong backgrounds in operations, engineering, or product development. Again, this intimate knowledge of the industry may provide a greater ability to create a vision, address core values, focus on both process and outcomes, strategize, assess data in context, communicate and empathize with stakeholders, and engage frontline leaders to execute a plan.

A 2013 white paper by the McKinsey & Company consulting group[12] noted the critical importance of direct involvement of frontline clinicians and physician engagement. The authors estimated from their consulting experience in over 150 hospitals that if a system strives to achieve an overall 5% to 10% reduction in operational costs, nonclinical variable costs would need to be reduced 30% if clinical operations were left unchanged. This would be nearly impossible. In other words, improvement in health care value cannot be fully achieved without changes to the actual delivery of clinical care. To achieve changes in clinical care, the participants in care processes must be engaged, informed, and empowered.

V. Influential leadership theories

Cultures throughout history have celebrated leaders as heroic figures who possess special qualities. Emperors, generals, and business tycoons are depicted as having exceptional strength, courage, or brilliance resulting in positions of high status. As leadership became a topic of academic study in the early 20th century, the initial research focused on identifying the personality traits that distinguish these leaders from nonleaders. The "great man" theory and other trait theories of leadership suggested that charisma, self-confidence, intelligence, and extroversion made leaders different from everyone else. Subsequent research on behavioral theories sought to isolate the behavior patterns that distinguish leaders. Behaviorists focused on how leaders act and identified different leadership styles, including people oriented versus task oriented. Trait theory implied that leadership is innate and predisposed; behavioral theory suggested that people could learn to be leaders by understanding how to behave and interact with others.

The notion that leaders are made rather than born sparked decades of further research attempting to describe and quantify leadership on many dimensions, but it remains an elusive subject from the point of academic study. Ultimately, effective leadership likely requires the right combination of personality traits, modifiable behaviors, and context. Several modern leadership theories—transformational, situational, and servant—have dominated the physician leadership development movement and are further described here. Other leadership theories exist, such as transactional leadership, in which the leader alone sets goals along with rewards and penalties. Such hierarchical leadership roles are commonly seen in health care but lack alignment with behaviors known to empower patients and professionals to improve outcomes. For example, the 2014 Veterans Health Administration scandal in the United States regarding wait times shed light on transactional leadership styles in which impossible standards conflicted with professional obligations and available resources, leading to fear, falsification of records, and cover-ups.[22]

A. Transformational theory

Transformational leadership theory is focused on how leaders stimulate others to transcend their own self-interests to reach higher-order goals or visions. It involves building a commitment to organizational objectives and empowering others to accomplish those objectives.[23] Transformational leaders motivate others through raising awareness of idealized goals and through role modeling. The "four Is" of transformational leadership as described by Bass and Avolio are idealized influence, inspirational motivation, intellectual stimulation, and individualized consideration.[24] Quinn described transformational leadership functionally as being results centered, internally directed (acting on values and with integrity), other focused (committing to the collective good even at personal cost), and externally open (adapting to feedback and the environment, taking appropriate risk).[25]

In health care, transformational leadership could be demonstrated in guiding departmental leaders to work toward overall institutional success rather than focusing solely on their departmental goals. This could manifest as more prosperous units supporting less profitable ones, sharing resources, or approving priorities that place other groups' needs before their own for the betterment of the entire organization. Another illustration of transformational leadership could be fostering behaviors, policies, and processes that imbue a culture of diversity, equity, and inclusion. This would be values based, oriented toward gaining improved patient care results, focused on collective good, and adaptive to current societal and patient needs.

B. Situational theory

In situational leadership theory, effective leadership depends on selecting the right style contingent on the followers or context. Situational leaders shift among four behaviors depending on how willing and able followers are to complete a task: directing, coaching, supporting, or delegating.[26] In this model, the effectiveness of a leader is determined more by environmental factors, the characteristics of the followers, and the nature of the work at hand. Situational leadership requires attention to the needs of subordinates and the complexity of the task. In the clinical context, leading a team to resuscitate a critical patient might require a combination of delegating, directing, and coaching, all in a matter of minutes. For hospital executives, leading a merger between two institutions would require a different style than responding to a public relations crisis such as a highly publicized patient safety issue.

C. Servant theory

Servant leadership theory contends that a leader's influence derives from serving others. While it has some features similar to transformational leadership theory, servant leaders are primarily focused on the needs of followers rather than organizational objectives. Characteristic behaviors of servant leaders include listening, empathizing, accepting stewardship, and actively developing others' potential.[27] Countless examples of servant leadership exist in health care, where professionals use these behaviors to care for patients and bring out the best in others. Frontline clinicians and primary care physicians are often the archetype for servant leadership in health care—the image of a devoted clinician who delivers care directly to his or her patients and to the community. Others work to promote health equity and use their positions to advocate on behalf of those who cannot. Examples include public health leaders advocating for gun safety in order to prevent childhood injuries or clinicians working to curb the epidemic of deaths from opioid abuse through prevention (i.e., improved physician education) and treatment programs.

D. Emergent leadership

Leadership may be required of individuals without formal or structured roles. This may occur either in relation to a time of crisis or in response to chronic concern. In contrast to

traditional leaders who are elected or appointed, emergent leaders arise informally within groups. Characteristics of the emergent leader include situational awareness, confidence, flexibility, and the ability to inspire.

For example, consider a medical student who recognizes that high school students from underrepresented groups have limited opportunities to explore health care careers. She comprehends this as a structural issue and is aware of the need for a more diverse health workforce to mitigate against health inequities. She has experienced the value of longitudinal clinical mentorship in building skills, confidence, and interest in medicine, and wonders if a similar strategy could be used to diversify the medicine pipeline. Collaborating with classmates and organizing volunteers, she develops a new program to provide clinical exposure, advising, and education to local high school students interested in medicine. By aligning her program with growing initiatives for institutional diversity, she is able to secure funding and administrative support to create a sustainable pipeline model.

VI. Guiding principles of health care leadership

The response to the leadership imperative in health care has been an explosion of training programs, targeting all levels of experience across the full range of disciplines. Many academic medical centers, major universities, and professional and specialty societies now sponsor leadership training programs.[28,29] Some are comprehensive and ambitious, such as the United Kingdom's National Health Service, which established a Healthcare Leadership Model and a development program for all physicians and health care professionals.[30]

Although there is growing emphasis on leadership development, there is no clear consensus on what defines effective health care leadership, nor is there much evidence about best practices to guide training. As a result, programs emphasize a wide range of skills and vary in their methods.[31] Some heath care leadership programs stress quality improvement, while others emphasize technical competencies such as finance or strategic planning. Still others focus on clinical or academic development. The clinician leadership movement has evolved to the point where one can pursue very specific leadership training to enhance business acumen, communication skills, political sophistication, emotional intelligence, and many other targeted, core leadership skills.

Most contemporary leadership programs are organized by broad domains (e.g., direction setting, working with others) that are further classified into the specific knowledge or skills desired. Several published studies have sought to identify the most important competencies for health care leaders. One study that examined physician beliefs regarding leadership competencies determined that interpersonal and communication skills, professional ethics and responsibility, and continuous learning and improvement were the most important.[32] A study of physician leaders found that emotional intelligence and vision were among the fundamental competencies to being a successful physician leader.[33] Another study found that communication, ethics, and conflict resolution were the most highly rated competencies for health care leadership.[34] Stoller contended that having a service orientation, being collaborative and adaptable, being a change agent, having vision and initiative, and developing others are especially important for effective health care leadership.[35] The Stoller model overlaps with the Feagin Medical Leadership Model from the Duke Institute for Health Innovation, which describes patient-centeredness as the core of health care leadership, followed closely by teamwork, selfless service, integrity, emotional intelligence, and critical thinking.[36]

Interprofessional leadership programs and those designed specifically for nurses, pharmacists, and health care administrators emphasize the same content areas as those targeted toward physicians.[37,38] One example is the Woodruff Leadership Academy at Emory University, which is designed for health care professionals from many disciplines. The content includes seminars on strategic thinking, personal awareness, negotiation, and conflict management, all within a health care context.[39] Nursing-specific leadership programs incorporate leadership theory and change management, with particular emphasis on teamwork and professional ethics.[40,41]

The NCHL has created a copyrighted model of "competencies required for outstanding health care leadership for the future." The Healthcare Leadership Alliance Model is interprofessional and emphasizes core leadership and management competencies developed through psychometric analysis and a modified Delphi technique with experts from different areas of health care administration. In this model, competencies are organized into domains of transformation (achievement orientation, analytic thinking, community orientation, financial skills, information seeking, innovative thinking, and strategic orientation); people (human resources, interpersonal understanding, professionalism, relationship building, self-confidence, self-development, talent development, and team leadership); and execution (accountability, change leadership, collaboration, communication skills, impact and influence, information technology management, initiative, organizational awareness, performance measurement, process management/organizational design, and project management).[42] The United Kingdom's Healthcare Leadership Model includes nine dimensions (or domains), with detailed descriptions of leadership competencies within each dimension.[43] The Medical Leadership Competency Framework, also developed by the United Kingdom's National Health Service, is centered around "delivering the service" and describes domains of shared leadership, including setting direction, demonstrating certain personal qualities, working with others, managing services, and improving services.[44] Within each domain, there are four elements, and within those elements are four competencies each. The tool is progressive, noting three distinct phases of leadership growth anchored to relevant and timely learning phases: undergraduate, postgraduate, and continuing practice.

In 2011, Al-Touby proposed the Functional Results-Oriented Healthcare Leadership model.[45] This model is directed toward "attaining excellent patient outcomes" and postulates that leadership must serve the predefined task, the team, and the individuals within the team, having a constant focus on exceptional results. In many ways, this model emphasizing a central purpose of excellent patient outcomes is similar to the Toyota Production System (TPS) model. The TPS is a model for manufacturing that has been applied to service industries, utilizing Lean production. Lean production focuses on doing more with less. There is continuous effort to eliminate waste and leave only value-added steps in a process. "Waste" includes defects or errors, overproduction (unnecessary services given), wait (or wasted time), excess processing or movement, and not using talent. More importantly than Lean management alone, the TPS employs "A3 management," which emphasizes purpose (including the patient as the center of health care delivery), processes (continual pursuit of perfection and team-based problem solving), and people ("horizontal" and interprofessional thinking, individual empowerment and ownership of problem solving, and coaching without usurping the process).[46]

A vast array of leadership models exists in business and other industries, but there is no universal skill set or proven formula for effective leadership. The same is true in the health care sector, though research and expert opinion suggest that certain qualities and skills are more advantageous in this realm. Demonstrating patient-centeredness, a service orientation, integrity, and strong relational skills are among the threshold

competencies for effective health care leaders.

VII. Health care leadership competencies

Health care leadership competencies are the combination of observable and measurable knowledge, skills, abilities, and personal attributes that effective leaders demonstrate. Although this list is not exhaustive, competencies in the following domains are frequently noted in the previously mentioned leadership models and appear to be required for managing change. The competencies may be arranged in the categories of foundational, self-management, team management, influence and communication, systems-based practice/management, and change management (or executing toward a vision); further detail within each domain is provided in Fig 9.2.



• **FIG. 9.2** Health care leadership competencies by domains of foundational competencies, self-management, team management, influence and communication, systems-based practice, and executing toward a vision.

A. Foundational competencies specific to health care

1. Maintaining patient-centeredness

Health care leaders often answer to multiple constituencies such as patients, staff, communities, and those with financial interests in the institutions they lead. Competing priorities are a routine challenge, and it is the responsibility of a leader to ensure that the best interests of patients remain central. The CEO of a hospital may be faced with deciding whether to close a financially unprofitable primary care clinic, or the dean of a medical school may have to prioritize which educational or research programs to support based on the impact and benefit to patients.

2. Professionalism

Leaders serve as role models for their institutions and constituents. Demonstrating excellence in one's professional field, commitment to ongoing professional development, and adherence to ethical and legal standards of practice allow a leader to serve as an example. Without the respect of those he or she serves, a leader cannot succeed. Consistent adherence to ethical standards, truth-telling, and fairness are fundamental attributes of leadership. Balancing competing interests can present challenges related to professionalism. Take the example of a health care worker with a substance use problem. If a leader accepts the disease model of addiction, how does he

or she simultaneously respect the rights of the recovering professional and the safety of patients? Should a patient come to harm due to care provided by an impaired physician or other health care professional, the hospital that knew of the impairment bears some liability.[47] But if an employee knows that seeking help for an addiction ends his or her career, he or she may avoid treatment. Taken a step further, does a patient have the right to know that his or her physician is in recovery? These issues have also been brought to the fore in times of emerging infectious diseases, such as AIDS. Do patients have the right to know that their nurse or physician has the condition?[48] Leaders in health care contribute to the evaluation of such issues on both local and broader scales and must balance truth-telling (full disclosure) with fairness.

B. Self-management

1. Serving selflessly

Putting the interests of others first is important to the success of a leader. Behaving with partiality can undermine credibility, especially if favors flow to the leader's own unit. Medical professionals accept the need to serve selflessly when they work with infectious patients or stay to care for unstable patients despite their nominal workday ending; similar altruism is demanded in leadership decision making.

2. Achievement orientation

Guiding individuals and institutions to higher achievement is part of the leader's job. Creating a culture that enables and rewards achievement, clearing barriers to the pursuit of excellence, and garnering sufficient resources to facilitate success is part of a leader's role. Modeling these ideals for the community can propel organizations forward. As the concept of accountable care is increasingly operationalized, leaders will be called upon to set and meet intermediate goals that combine to achieve externally determined care targets.

3. Emotional intelligence

Awareness of one's own and others' emotions can transform an adequate leader into an exceptional one by enabling him or her to defuse conflict as well as motivate and empathize with others. At the most senior levels, it may be difficult to stay connected to large constituencies. Many leaders structure routine opportunities for interaction with their staff to remain attuned. On a smaller scale, contemplating the needs, fears, and motivations of those with whom one interacts can often help facilitate team building and the construction of mutually beneficial strategies.

4. Accepting feedback

Leaders are humans with egos, strengths, and weaknesses like everyone else. The most effective leaders are able to learn, grow, and incorporate constructive suggestions without displaying defensiveness. Although not in health care, one of the most often

cited examples of this ability was President Lincoln's inclusion of his former political competitors in his cabinet. Doris Kearns Goodwin's book *Team of Rivals* delineated how effective this can be:

> This, then, is a story of Lincoln's political genius revealed through his extraordinary array of personal qualities that enabled him to form friendships with men who had previously opposed him; to repair injured feelings that, left untended, might have escalated into permanent hostility; to assume responsibility for the failures of subordinates; to share credit with ease; and to learn from mistakes. He possessed an acute understanding of the sources of power inherent in the presidency, an unparalleled ability to keep his governing coalition intact, a tough-minded appreciation of the need to protect his presidential prerogatives, and a masterful sense of timing.[49]

The importance of seeking and acting upon feedback is further illustrated by the Master Adaptive Learner model and strategies for self-regulated learning, discussed in Chapter 17 of this text.

5. Willingness to change

Adaptability of an organization is critical to its survival in the rapidly evolving field of health care. This same trait is essential for leaders: if executives cannot change course in response to new data or circumstances, they will not be effective in moving their institutions. More importantly, role models for change can be instrumental in amplifying new initiatives. Imagine if a hospital CEO refused to adopt the technology of the electronic health record (EHR). How effective would implementing it system-wide be? Leaders who embrace change can encourage the cascading of change throughout their organization. One such leader, Methodist Hospital of Southern California's Chief Medical Officer and Patient Safety Officer Bala Chandrasekhar, MD, MMM, said "Patients essentially want three things from their hospitals: don't hurt me, heal me, and be nice to me. And they want them in that order." By focusing his organization's officers on these goals, and by demonstrating his own flexibility in changing his antibiotic practice, he has led the hospital to safer antibiotic use, faster sepsis intervention, improved consistency in ventilator settings, and better data analytics and documentation.[50]

6. Self-care

Working in health care is personally challenging. The combination of long work hours, growing administrative burdens, and immersion in patients' tragedies on a frequent basis takes a physical and emotional toll. Traditional medical training created a culture that glorified the denial of normal human needs such as sleep, food, and time away from work. Recognition of the toll that fatigue places on safe performance led to a restriction on work hours but did not begin to address the broader concern. Many health care entities are now appointing wellness officers charged with fostering the

physical and mental health of employees and staff. Despite this and related efforts, professions that tout selflessness as a virtue do not foster habits of self-care.

There is now recognition of disengagement, low morale, and burnout within medicine. A lack of joy and meaning in work may also be contributing to difficulties maintaining a healthy, vibrant workforce. In response to this, some have expanded the Triple Aim to the Quadruple Aim, incorporating health care professional self-care as an important focus. Paying attention to physical wellness through healthy eating, activity, and rest, coupled with diligence in tending to emotional and spiritual vigor, are habits that need to be bolstered. Institutions are beginning to address this through policies such as flexibility in schedules, financial support for gym memberships, mindfulness workshops, and team-building activities. Incorporating self-care as a goal in training for these professions is a necessary next step. A joyful and engaged workforce provides safer care.

C. Team management

1. Relationship management

Leaders rarely attain success solely through their own efforts. Tending to the aspirations and needs of colleagues and staff, apportioning credit fairly, and treating others with respect are necessary. Creating and sustaining good working relationships include explicitly inviting subordinates and peers to provide candid feedback and to voice concerns. Receiving and learning from criticism is a mark of a mature leader, as is giving meaningful feedback to develop others.

2. Developing new talent

The talents and challenges that each individual brings to the work environment must be evaluated proactively. Leaders must identify ways to support, advance, and retain constructive and productive team members. Forging plans to reengage and redirect disruptive or nonproductive workers is often a harder task, but individuals deserve meaningful feedback and an opportunity to improve. Jim Collins, writing in *Good to Great*, suggested that a key to successful organizations is "getting the right people on the bus, the wrong people off the bus, and the right people in the right seats."[51] Facilitating interactions, managing diverse personalities and work styles, and troubleshooting dysfunctional interactions can convert lackluster groups into energetic teams with the strength to tackle significant issues and the resilience to ride out setbacks.

3. Human resources

Many leaders, especially those with clinical backgrounds, have no experience performing basic management tasks such as running a meeting. Health care professionals without formal management training particularly lack knowledge about the role of human resources in complicated institutions. Human resource skills include the ability to conduct effective interviews in order to hire based on values and qualities

consistent with those of the organization. Equally important is the ability to direct the work of teams and incentivize individual performance through reward or recognition programs that honor the achievements of others. Other human resource skills include delegating responsibilities, holding others accountable, and deciding when to discipline or terminate an underperforming employee. While these skills are best learned through firsthand experience, health care professionals can enhance their leadership capacity by acknowledging gaps in their human resources skills and forging a plan for personal development.

D. Influence and communication

1. Communicating effectively

Leaders cannot accomplish anything without crafting and conveying compelling messages that inspire, educate, and motivate people. Communication is multidirectional. A leader must understand the perspective of those being led; to gain that knowledge, one must, through oral or written means, be receptive to opinions, concerns, and suggestions. Some choose to structure such communication through surveys or town halls; others rely on sporadic or spontaneous information. The term *affirmative listening* refers to the practice of listening with sincerity and with the intent to learn and act. Creating a **Just Culture** in which subordinates feel empowered to voice concerns without fear of reprisal is the responsibility of leadership.

Creating and implementing a vision is a critical task for leaders. Doing so requires sharing that vision with those impacted by change. This may include both employees and the broader community. As an example, if an institution chooses to expand outpatient opioid addiction treatment programs, it would be important to share the rationale with staff who will need, in turn, to explain it to the community that might have concerns about a possible increased presence of individuals with past criminal behavior. Ideally, representatives of key stakeholders would have participated in making such decisions before they are solidified.

A delicate balance needs to be struck between sharing too much or too little information, releasing data too early or too late, and selecting how widely or narrowly to disseminate information. As the options for communication have expanded to include social media in addition to more traditional streams, savvy leaders need to construct communication strategies and policies for both themselves and their units. Both casual and structured communication can be effective tools to engage internal and external communities, allow nimble and timely responses to the opportunities presented by events in real time, and inspire confidence. Reactive e-mails or unrefined use of media can undo the best strategic endeavors. Successful leaders are attentive to the messages they and their institutions send, and they practice self-awareness in communication. During times of crisis, leaders may have to be creative in their methods of communication. Following Hurricane Katrina in 2005, students, residents, fellows, faculty, and staff from the hospitals and medical schools of New Orleans were distributed across a multistate area. Main methods of communication were down. The

power for the region was out, and there were many injured and dead.[52] Recognizing how critical it was to establish communication channels, one medical school communicated using a student listserv, and the other rapidly established a website hosted by an institution in another state. This required an extraordinary level of proficiency in communication that allowed the schools to literally weather the storm. Both institutions were able to resume classes within 4 weeks.

2. Advocacy

Leaders advocate for specific people, programs, and ideas within their institutions and advocate for their institutions within the larger world. While the ability to fundraise is often used as a scorecard to measure effectiveness in this domain, leaders serve as advocates in many other arenas. For example, common tasks for institutional leaders can include intervening with legislators to seek approval for new programs or funding for facilities. Advocating for the adoption of policies supporting public health goals is also a responsibility of health care leaders. Recent examples include hospital leaders lobbying for tobacco taxes, sugary beverage taxes, and the building of bicycle paths within urban communities.

3. Having challenging conversations

A successful leader manages conflict by rephrasing rants into heartfelt concerns and using fundamental values and motivations to redirect team members toward success. Clinicians are often adept at having difficult conversations with patients; having challenging conversations with colleagues and team members is equally important. A white paper cosponsored by the American Association of Critical-Care Nurses noted that "a majority of health care workers have sincere concerns about a coworker's performance, usually regarding broken rules, mistakes, lack of support, incompetence, poor teamwork, disrespect, or micromanagement, and asserts that 'silence kills.'"[53] Reasons cited for avoiding difficult conversations include lack of ability, lack of "ownership" (belief it is not "their job"), low confidence that it will result in change, time constraints, and fear of retaliation. Leaders must create a culture of safety for holding these challenging conversations and must artfully address poor teamwork and team concerns.

4. Navigating politics

Health care systems are complex organizations complete with internal politics and competition. While individual health care professionals might share a common goal to improve patient care, many are part of larger coalitions with parochial beliefs and interests, each seeking various forms of power or access to finite resources. Consider a common scenario playing out in many academic medical centers today, where large multispecialty practice plans are replacing previously independent clinical departments or private physician groups. Politics is a central theme in the consolidation of these various physician groups into systems of care. Inevitable conflicts arise related to sharing risk, compensation, governance structure, transparency, and, fundamentally,

power. In this context, the term *politics* often evokes strong negative feelings, and it is easy to grow cynical when political agendas corrupt important decisions, especially in health care. To be effective, health care leaders must first realize that politics and leadership are universally intertwined. In limited-resource environments such as health care, leaders can navigate politics more constructively by identifying key stakeholders and seeking to understand the interests of both supporters and adversaries. Indeed, political effectiveness draws on many leadership competencies simultaneously: articulating a vision, negotiation skills, team building, and strategic planning. Through practice and preparation, health care leaders can use political skill constructively to create more effective organizations.

Case study 2

After 5 years working as a physical therapist at a large community hospital, Mark was eager to go out on his own. When a retiring colleague offered to sell Mark his office practice, he jumped at the opportunity. As a new small-business owner, Mark soon realized he was in way over his head. The practice had an outdated computer system that led to delays in appointment scheduling, billing, and reimbursement. The front office employees he inherited were set in their ways. They resisted any change to the patient flow process as well as a proposed redesign of the clinic to maximize space and efficiency. Mark openly expressed his frustration over the group's skepticism and the slow pace of change. Within 3 months of his taking over, a dissatisfied administrator and a well-liked physical therapist resigned and left Mark short staffed. He began to wonder if he had the requisite skills and temperament to lead this practice. Every day, he thought about returning to his hospital-based job without all the headaches.

1. What type of person is well suited to serving in a leadership role?
2. Do certain personality traits predict effective leadership?
3. What leadership competencies are important for leading an office-based practice?
4. What are the unique challenges in this health care environment?

E. Systems-based practice/management

1. Knowledge of the health care environment

To shepherd a health care institution through the maze of regulations, accreditations, financial challenges, and evolving medical care models, a leader must commit to staying knowledgeable. Participating in regional or national peer group organizations and pursuing degrees such as a master's degree in health care administration or a master's degree in public health are common strategies to keep abreast of the ever-changing health care marketplace. As elements of the Affordable Care Act came on line, dramatic changes in health care reimbursement, auditing, and reporting requirements necessitated fluidity in the management of most health care enterprises. The imperative to implement EHRs and the requirement to meet successively higher targets for "meaningful use" with the EHR dramatically changed clinical practice patterns and

workflow, creating new challenges across the spectrum of individuals collaborating in the delivery of health care.

2. Business knowledge and skills

Guiding an institution through changes in delivery models, reimbursement, legislative support, and the impact of economic upswings and downturns requires in-depth understanding of business methods. A leader must be able to absorb and evaluate the streams of financial, market, and operational data to steward resources and negotiate favorable conditions for his or her institution. Engaging in strategic planning to chart an institution's direction involves assigning priorities to different programs or missions and allocating resources accordingly.

A bare minimum for a leader is the ability to read and interpret financial reports and budgets. Understanding the revenue and expense streams for his or her unit is essential for a leader making decisions about operations or planning for the future. Emotional reactions are normal in the business context of health care; a leader must make decisions driven by analysis of data and contextualized by the organization's mission, and use emotion in a purposeful way.

Clinics, hospitals, and health systems function within a dynamic universe. The development of new technology and the passage of new legislation are examples of common perturbations in health care environments. Mass casualty events or epidemics call for immediate responses. In 2014, the Ebola epidemic in West Africa required rapid development of new procedures and policies and led to changes in hospital practice around the world. The urgency of the situation overrode existing budgets and strategic plans and prompted revision of priorities. Despite tremendous fear associated with these events, health care leaders provided clear, calm, and transparent strategies.

Change in health care is not always emergent. Expanding or contracting clinical services, switching models of staff payment, responding to unionization of workers, and merging with other institutions are common long-term changes. A leader must be sensitive to the fears and concerns of those impacted and provide information and opportunities for input. He or she must address each stratum of employees, make the case for change, and foster a sense of ownership of the change. Where possible, a leader should incentivize joining the change. Assessing the organization's culture and directly addressing counterproductive elements are part of the strategy as the leader crafts his or her message.

Case study 3

Angela is a senior member of a midsized private neurology practice in the process of forming a multispecialty group with six other practices. Integrating these seven groups of varying sizes with different systems, cultures, and priorities has been a complex project. As head of the Compensation Working Group, Angela is charged with establishing the process by which annual profits will be distributed among physicians across all specialties. She has been approached separately by the practice leaders from each group trying to justify why their physicians should receive a disproportionate share of the group's revenues. Despite prior collegial relationships, she is surprised at how unwilling these leaders are to compromise and is concerned that this issue

will threaten the group's future.

1. What parallels can be drawn between the principles of ethical decision making in clinical care and those of ethical decision making in Angela's leadership challenge?
2.d How can the governance structure of an organization contribute to or detract from equity?

F. Executing toward a vision

1. Vision-setting and strategy

Identifying organizational goals and designing aligned strategies to achieve them is one of the most important responsibilities of health care leaders. The strata occupied and the urgency of needs will dictate the breadth of goals. The leader of a clinic will likely focus on improving the patient experience, operational efficiency, and financial viability. The head of a statewide health care system has the opportunity to impact the health of many people and should set goals accordingly. It can be challenging to motivate people around more routine operational goals, so clarity of organizational interdependencies must be emphasized. President John F. Kennedy inspired America by setting the goal of putting a man on the moon by the end of the 1960s, but seeking the same level of support for significant changes to the operating budget of the Department of Education would likely have been less exhilarating. Health care organizations often seek to raise funds for new hospitals or facilities and research to cure diseases; leaders communicate that replacing the hospital heating system may be just as necessary.

2. Creating culture

Creating the culture and climate in which positive change can flourish is of utmost importance for senior leadership. Creative solutions to challenging problems in health care can be stifled by poor leadership. In contrast, strong leaders can empower individuals and teams, implement exciting approaches that improve care delivery, enhance diversity and inclusion, save money, and improve resource utilization. Innovative solutions tackle ineffective tradition, standard operating procedure, and red tape. Strong leaders create space within an institution for such deviations from the norm. For example, Oregon's health care system has responded to individuals who use emergency department resources disproportionately with the institution of **case management** and the provision of items such as shoes and sleeping bags. By addressing needs not normally covered by health plans, the system provides these patients better care and benefits from dramatic drop-offs in emergency department visits while achieving greater patient satisfaction.[54] Convincing the system to pilot this approach required clear and effective messaging by leaders who framed the situation in patient-centered terms. Strong working relationships based on a track record of trustworthiness and accountability set the stage for this program to be accepted.

Beyond encouraging a culture of innovation, leaders are critical in creating a culture

of quality and safety. Industrial studies have long shown the importance of organizational culture (or climate) in creating and sustaining meaningful safety outcomes.[1,2] "Participative management," in which workers are involved in decision-making processes, has been shown to be a better predictor of safety outcomes than authoritative management.[4] This transformational management style involves communication, involvement, and empowerment in a setting of relationships characterized by trust, openness, and honesty. Participative management focuses less on individual blame (which is convenient though ineffective in preventing future problems) and more on analysis of root causes of problems. In 2010, Vogus and colleagues reviewed industrial safety and more specifically health care literature, proposing a participative culture model of "enabling, enacting and elaborating."[5] "Enabling" requires leaders to draw attention to safety within the organization and also to empower frontline workers to act deliberately when caring for patients. "Enacting" means having systems to act upon safety concerns expressed by enabled workers, as well as mobilizing resources to create safety systems and achieve goals. "Elaborating" focuses on the **Plan-Do-Study-Act (PDSA)** process (which has been found to be highly valuable in quality improvement collaboratives),[6] taking learning and processes from small-scale to larger-scale system-wide practices while continually learning and refining.

3. Creating sustainable solutions

Creativity and innovation are critical in solving health care problems, though innovative measures must be tailored, improved, and sustained for optimal benefit. Leaders can create sustainable solutions by employing the PDSA cycle, which is presented in more detail in Chapter 7 of this text. Like any other form of scientific problem solving, organizational solutions can be piloted, studied, implemented, analyzed, and revised over time. Organizational leaders capitalize on approaches such as Lean management principles, PDSA, and kaizen (continuous incremental improvement to create value while reducing waste) by applying and studying their role in health care. Leaders at ThedaCare in northeast Wisconsin instituted training and application of Lean management that led to sustained improvement and value creation.[55] All ThedaCare staff members must participate in an event week in which they have dedicated time to improve their work. Event weeks incorporate three tenets for change: respect for people, teaching through experience, and focus on world-class performance. Staff are asked to improve care through improving staff morale, improving quality (reducing error or defects), and improving productivity. Through event weeks and the overall change in culture, ThedaCare realized millions of dollars in savings, a decrease in accounts receivable (days to be paid for services), a 35% decrease in phone triage (hold) time, a 50% decrease in time to complete admission paperwork, and a decrease in medication distribution time to patients from 15 to 8 minutes.

4. Change management

Every organization faces large, complex challenges that share a common underlying

theme—they require major change. One could argue that guiding others through change is both a defining characteristic and an ultimate test of a leader. Fast and volatile changes in health care, including new delivery and payment models, shifting patient demographics, new technologies (e.g., EHRs), increased competition, and changes in the physician workforce, all suggest that how we do things today will not be an option tomorrow. While change is often viewed initially with some skepticism, it can drive improved organizational culture, enhanced quality, and elevated individual performance. When managing change, health care leaders must recognize (1) that change is usually a long process that goes through stages, (2) the common reasons for resistance to change, and (3) the need to monitor and manage the personal and organizational distress associated with change initiatives.

Kotter's foundational work[56] described an eight-step process that has become the defining framework for effecting organizational change. It begins by creating a sense of urgency for change and then compelling others by making "the status quo seem more dangerous than launching into the unknown." Subsequent steps include forming a powerful coalition, creating and communicating a vision for change, removing obstacles, and creating short-term wins. After that, the focus turns to building on successes and establishing new cultural norms. While this is a valuable theoretical framework, change invariably triggers emotional responses of loss and fear.[57] Leaders must understand the parallels between organizational change and the Kübler-Ross stages of grief to respond effectively to people's emotional needs.[58]

Kotter's subsequent work expanded on the original eight-step method and presented a model for change management in rapidly changing environments such as health care. The original stepwise process is modified with change "accelerators" that reduce hierarchy, engage many people from all parts of an organization, and create ongoing cycles of change management.[59]

Common sources of resistance to change and strategies that leaders can use to overcome them have been studied.[60] Frequently cited reasons to resist change include fear of losing something of value—be it status, expertise, or other self-interest; a differing assessment of the need for change; misinformation or lack of understanding; lack of trust; and organizational inertia that results in general low tolerance for change. It is critical for leaders to diagnose the source of resistance and then apply the right strategy to manage it. For example, if resistance derives from misunderstanding or lack of information, the right approach might include an aggressive educational campaign. If resistance is due to lack of commitment, countering it may require finding ways of increasing engagement and participation in the process. If adjustment fears or fears of being left behind result in hesitance, the appropriate strategy might include additional training or support.

G. Student development for leadership competency

Students can start developing the previously mentioned competencies within the context of coursework and rotations. Given their relative lack of authority within educational and health care systems, students may need to draw upon additional skills

useful to capitalize on opportunities to lead. The concept of "managing up" refers to proactively working with one's manager, team leader, or another person of authority toward mutual goals that are in the best interest of the organization. Managing up is characterized by making a leader's job easier by anticipating his or her needs and understanding his or her work habits and preferred communication style.[61] Practically, managing up requires followers to be reliable and dependable and to frame the work as a partnership with shared objectives. Adapting to a leader's behaviors and decision-making style can ultimately benefit followers as they become more influential and contribute more to organizational goals.

VIII. Specific attributes for health care leaders in different settings

Leadership in health care takes place through formal administrative structures as well as in an ad hoc situational fashion. The balance between leadership-specific and management-specific skill sets may vary in the distinct domain of health care leadership. At the front line, the abilities to engage, motivate, and problem-solve in teams are most critical and embody transformational leadership attributes. This is true in clinical care, education, and research. In the formal administrative realm (whether in private practice, running one's own laboratory, departmental management, or system-level management), a leader must still possess self-management and core leadership traits, particularly the abilities to set a vision, communicate effectively to broad audiences, and influence individuals and organizations. Beyond this, additional management knowledge and skills augment the leader's ability to execute change.

Table 9.1 describes opportunities for impacting health care delivery and outcomes by business function. Furthermore, specific knowledge and skills training that may be needed in formal and informal settings are described. Cross-cutting all of these functional areas are the foundations of patient-centeredness and professionalism and the competencies of self-management, team management, influence and communication, and systems-based problem solving.

TABLE 9.1

Suggestions for Leadership and Management Training by Specific Health Care Business Function

Business Function	Domain of Health Care Leadership	Training Required for Leadership/Management
Operations	Day-to-day patient care, quality and safety programs	Clinicians optimally positioned both informally and formally; Lean training; specific operations management training for chief operations officer (COO), chief quality officer (CQO), chief medical officer (CMO), chief nursing officer (CNO)
Marketing	Market analysis and positioning, needs assessment	Marketing-specific training; course-based and experiential training; advanced training for chief marketing officer (also labeled CMO, often not existing in health care administration)
Finance	Financial decision making, projections of volume and revenue	Chief financial officer (CFO) requires advanced business-specific degree and experience; chief executive officer (CEO) requires accounting and finance training for understanding

Inbound patient flow logistics	Referrals, scheduling	Physicians and advanced practitioners optimally positioned to engage front-office staff to optimize patient intake; Lean training; functions report to COO
Outbound patient flow logistics	Coordination of patients leaving the site of care (clinic, hospital)	Nursing and social work teams optimally positioned to improve transitions of care; Lean training; functions report to COO
Accounting	Billing (receivable), budgeting and purchasing (payable)	Course-based accounting training; functions usually report up to CFO with advanced training
Human resources (HR)	Hiring, scheduling, etc.	Course-based management training, legal training, conflict resolution experience; HR matters for faculty and professional staff often run through chief of staff, CMO, or both
Communications	Website, community presence	Communications training and experience; marketing experience and course-based training
Executive	Visioning, strategy, executive functioning	Advanced degree generally helpful for CEO; basic understanding of all business functions to oversee and coordinate; communications training

It is important to note that physicians leading smaller practices must address all of these functions without the benefit of a large management team. It can be difficult to conceive of clearing time from one's busy practice to seek training in these domains via the professional organizations and learning opportunities described earlier in this chapter. Investment in one's professional development, however, results in downstream efficiencies that recoup the time of training and generates a sense of control that can positively impact physician satisfaction.[62]

IX. Pathways to leadership

Formal pathways to leadership generally are through hospital or health system administrative structures, professional societies, nongovernmental organizations, and governmental/policy or political affiliations. Within health systems, elected positions such as chief of staff (COS) or other positions within the COS office are common launchpads for physician leaders in a formal setting. Appointment as the chief medical officer (CMO), chief nursing officer (CNO), or chief academic officer, or to a hospital or organizational board of directors, allows opportunity to gain experience and "big picture" understanding. CMOs, CNOs, and board members may be chief operations officers (COOs) or CEOs in training. Generally, formal training in organizational management is not required in the COS office or for board participation, but it is certainly highly valued. Networking is an important aspect of these positions, and management skills may be developed on the job. Within academics, departmental administration is another pathway to formal leadership. Traditionally, academic chairs have come to positions of authority through the ability to obtain grants and publish, as well as through networking and departmental service. Although these principles for climbing the academic ladder are well ingrained, there is a slow shift toward appointing chairs with more formal management and finance experience. From the chair position in academia, a further step may be dean or an institutional vice president for medical/health affairs.

Individuals with a pure business administration background tend to have little to no expertise in direct patient care. Physicians and other health care professionals without additional training generally have little to no expertise in business management (particularly human resources, logistics, strategy, accounting, and financial decision making on a systems level). Advanced training in management may be obtained through competency-directed courses (e.g., executive education programs at business schools or within faculty development programs) or degree programs such as master of business administration (MBA) or master of health care service administration (often within public health programs). Private for-profit and not-for-profit entities, such as the AAPL or the American College of Medical Practice Executives, offer certification programs toward Certified Physician Executive (CPE) or Certified Medical Practice Executive (CMPE) designations. In general, there is a trend away from health care service administration master's degrees with an increase in MBA degrees among physician executives. There are few data on certification programs and outcomes.

Organizational and specialty society leadership positions are more traditional pathways to formal health care leadership. Clinicians have the opportunity through organized medicine to be mentored by respected peers who possess experience in advocacy, policy, and communication. Local and regional roles may allow for the development of the knowledge and skills required for specialty- or domain-specific leadership, which in turn may lead to national roles.

Informally, clinicians in all settings are seen as leaders and can greatly impact patient safety and quality initiatives and directly improve outcomes. Clinicians can bring a

valuable perspective on operations management (the day-to-day functioning in a hospital or clinic). In 2005, the Canadian Medical Association conducted a series of focus groups and found that most physicians ended up in leadership roles unintentionally as "accidental leaders."[63] Because of professional commitments to patient welfare and continuing education, clinicians value improvement in health care and naturally end up leading transformation in health care. Once in these roles, additional training is often required. Through mentored problem solving, clinicians learn to respect the roles, expertise, and motivations of other team members. This can lead to a culture of empowerment and openness to change. Lean training and other domain-specific training opportunities are regionally abundant and often financially and administratively supported by local hospitals and health care systems.

Other leadership positions may require clinicians to step out of their clinical care roles and step into public health, media, or policy roles. There is generally no formal path or training for this, and again, clinicians in these roles frequently cite identifying a need and embracing the unique opportunity to have an impact via such roles.

X. New leadership roles

As health care and society change, needs are identified that were previously not as well defined. For example, the chief diversity and inclusion officer (CDIO) implements strategies and priorities to ensure equity of opportunity in hiring, advancement, and resource allocation, and develops programs that foster inclusion. The CDIO also impacts population health initiatives and investment decisions. Chief population health officers (CPHOs) create strategy and help institutions respond to emerging population trends. If the population an institution serves experiences an increase in immigrant groups, the CDIO and the CPHO would play key roles in preparing to meet the dual language and cultural needs of patients. Accountable care organizations coordinate care for a defined population "to ensure that patients get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors"[64]; the CPHO may engage the community in programs and policy to promote preventative health practices.

The roles of chief information officer (CIO) and chief information security officer (CISO) have developed in response to the rapid expansion of information and social media and the application of data analytics in improving health care and business outcomes. The CISO directs strategy and operations across the enterprise around its information assets. Protecting an organization from hacking, Health Insurance Portability and Accountability Act violations, and cybercrimes requires a sophisticated, knowledgeable leader. The CIO takes leadership in developing and implementing the vision for technology and communication across the enterprise. Critical decisions around selection and operation of an EHR, for example, require considerable leadership skills.

One of the newer C-suite roles is the chief wellness officer (CWO). This individual leads efforts to care for staff and address burnout, drug abuse, obesity, and other threats to the well-being of employees. Recruiting and retaining quality staff, minimizing absenteeism, and reducing costs due to employee health issues are corporate goals served by this position.

XI. Chapter summary

The ever-changing landscape of medicine has created an imperative for the health system to do a better job of preparing the emerging health care workforce to manage new therapies, new health care reimbursement models, new technologies, and the changing expectations of patients. This demands education and skills development in the domains of exerting influence and managing both one's self and teams. Significant preparation is necessary in practical management of clinical operations and the business aspects of health care. One of the most challenging competencies to master is change management, as it incorporates elements of the other competencies. Individuals who excel in these areas may exert influence informally or may pursue either elected or appointed formal positions of authority. As students and learners envision their careers, it would be prudent to invest some time and energy in developing the key competencies outlined in this chapter.

Exercise

Leadership has emerged as a crucial skill for everyone working in the health system. As you go through your day, think about how you are currently playing a leadership role or could potentially lead more effectively. How do you apply leadership skills as a student? As a resident? As a practicing physician? Discuss your leadership experiences with a mentor, adviser, or trusted colleague. Consider how you could increase your influence. How can you be a more impactful leader from your vantage point in the health care hierarchy?

Questions for further thought

1. What mental models and high-impact behaviors, as described by the IHI, enable health care leaders to promote change?
2. How do the personal qualities rewarded during the traditional education of clinicians match with those necessary to successfully lead change in our health care systems?
3. What opportunities exist outside of a formal leadership role for a health professions student to exhibit leadership?
4. Although leadership models may vary in how they define essential leadership qualities, what are some of the competencies that emerge from these models that are important for effective leadership?
5. What opportunities exist for health care professionals to gain experience in leadership positions or acquire additional expertise in leadership competency areas?

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Quinn RE. *Moments of greatness* entering the fundamental state of leadership 191 Harv Bus Rev 7, 2005;83: 74-83.

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leadership who describes the value of being results centered, internally directed, other focused, and externally open.

Swensen S, Pugh M, McMullan C, Kabcenell A. High Impact Leadership Improve the Health of Populations, and Reduce Costs. IHI White Paper 2013; Institute for Healthcare Improvement Cambridge, MA.

This paper describes mental models, attributes, and behaviors of high-functioning leaders in health care. Exemplars of leadership traits are identified within the paper, and the behaviors and outcomes of these exemplars are described.

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10

Clinical informatics

William R. Hersh, MD, Jesse M. Ehrenfeld, MD, MPH

CHAPTER OUTLINE

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In this chapter

This chapter begins by describing the importance and relevance of health

information technology and clinical informatics to the provision of safe and effective patient care. Applications of clinical informatics, particularly the electronic health record (EHR), are discussed. The value of the EHR in supporting high-quality patient care and the importance of EHR interoperability are emphasized. Next, the use of data analytics to support various information needs of physicians, health care professionals, and health systems are elucidated. Challenges and opportunities related to the use of EHRs and informatics are presented. Finally, recently developed competencies in clinical informatics are highlighted and future directions in this increasingly important area in health care and medical education are given brief reflection. Throughout the chapter, key terms and concepts are defined and described.

Learning Objectives

1 Define the major terminology of clinical informatics and related topics.

2 Describe the role of clinical informatics in health care delivery.

3 Discuss the ways that clinical data are reused.

4 Describe the outcomes of the applications of clinical informatics in health care delivery.

The optimal function of health systems requires data and information. The discipline devoted to the efficient storage, acquisition, and use of information in health care is called **biomedical and health informatics**.[1] The area within the discipline of informatics that is focused on health care delivery is known as **clinical informatics**. This chapter focuses on how clinical informatics can be used to improve the quality, safety, and efficiency of health systems and health care delivery. Some of the key limitations and drawbacks currently being addressed by the field are also discussed.

I. Rationale and terminology of clinical informatics

The importance of clinical informatics in health care delivery began to emerge in the latter part of the 20th century. A series of seminal reports from the National Academy of Medicine (NAM; formerly known as the Institute of Medicine) documented significant problems in health care delivery and led to proposed solutions based on best information technology (IT) and evidence supporting its use. The first NAM report documented the harms resulting from incomplete and illegible paper-based medical records.[2] Probably the most high-profile of these reports focused on errors in hospitals estimated to result in up to 96,000 deaths per year.[3] Another NAM report described deficiencies in the quality of health care as a "chasm" between known, evidence-based best practices and their actual use in the health care system. Constraints on exploiting the revolution in IT were named as one of the underlying reasons for inadequate quality of care, and increasing the use of IT was cited as a means of improving quality of care.[4]

A number of studies supported the conclusions of these reports. In 1995, Bates and colleagues documented error rates of 6.5 adverse drug events per 100 hospitalized patients.[5] Quality problems were quantified more clearly in 2003 by McGlynn and associates, who assessed the records of 6259 patients in 12 metropolitan areas and found that only 54.9% of care delivered was consistent with evidence-based known best practices.[6] Paper-based medical information was associated with clinical decisions being made with incomplete information, as Smith and colleagues showed that information was missing and impacted up to 44% of patients in primary care settings.[7]

A. Value of clinical informatics in improving the quality, safety, and efficiency of health care

Additionally, there was emerging evidence for the value of health IT. In 1993, Tierney and associates documented that **computerized provider order entry** (CPOE) in hospitals was associated with a 12.7% decrease in total charges and 0.9 days shorter length of stay.[8] Shortly afterward, Bates and colleagues showed that CPOE reduced serious medication errors by 55%, with adverse drug events reduced by 17%.[9] Other studies showed that CPOE led to a reduction in redundant laboratory tests[10] and increased prescribing of equally efficacious but less costly medications.[11] Much of this work culminated in a systematic review of 257 studies of health IT, documenting its association with increased adherence to guideline-based care, enhanced surveillance and monitoring, and fewer medical errors.[12]

Modeling studies were also being published demonstrating return on investment for electronic health records (EHRs) as well as for **health information exchange** (HIE), the exchange of information across the boundaries of health care organizations.[13] Johnston and colleagues assessed the potential benefit of CPOE in ambulatory settings and noted

savings of up to $28,000 per practice per year, although most of the savings went to laboratories and insurance companies, not the physician practices making the investment.[14] Another modeling study by Hillestad and coworkers applied results of known research in an attempt to scale them to the entire US health care system, finding that HIE could potentially result in savings of $81 billion per year to the system and a reduction of 200,000 adverse drug events per year.[15]

This evidence for the benefit of EHRs and HIE led to an effort to provide incentives for their adoption as part of the American Recovery and Reinvestment Act, the economic stimulus that was passed in an effort to rescue the economy in early 2009. The American Recovery and Reinvestment Act included the Health Information Technology for Economic and Clinical Health (HITECH) Act, which allocated about $30 billion for investment in adoption of EHRs.[16] There already existed a template for the concept of "meaningful use" of the EHR (i.e., applied to health care system goals) to measure adoption for incentive purposes that had been put forth earlier by Congressman Pete Stark.[17]

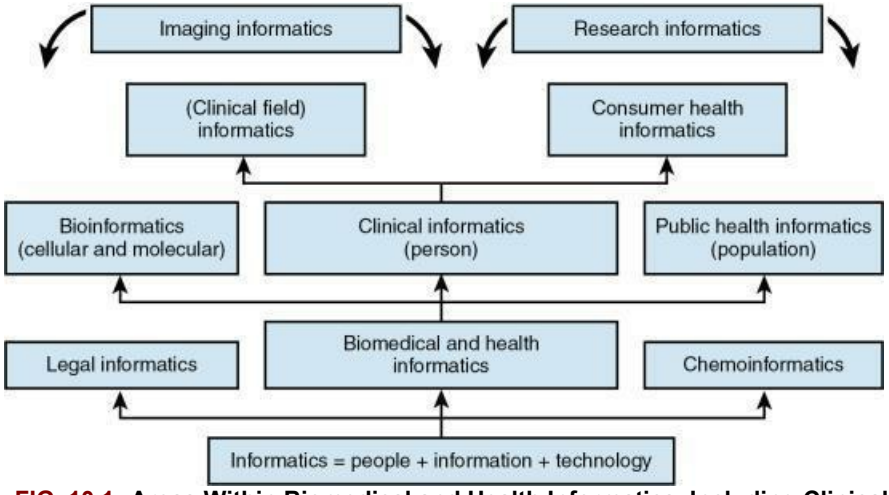
After its inception in 2010, the HITECH Act led to substantial growth of EHR adoption,[18] with nearly all hospitals (96%)[19] and over four-fifths of office-based physicians (87%)[20] using EHRs. However, many challenges have emerged with the introduction of EHRs into health care, such as disruption in workflow, increased time required for patient documentation, and distraction by the computer in the examination room,[21,22] providing further imperative for the optimal understanding and application of clinical informatics. One study estimated that for every hour ambulatory physicians spend providing direct patient care, nearly 2 additional hours are spent on EHR and desk work within the clinic day.[23]

B. Definitions of informatics and related terms

A critical aspect of informatics is its focus on information and not technology. While IT infrastructure (i.e., the networks, devices, and software) is essential for effective application of informatics, the larger goal is the benefit that information provides to health care and optimal health of individuals and populations.[1,24-26] Friedman has defined the "fundamental theorem" of informatics, which states that informatics is more about using technology to help people perform their work better than about building systems to mimic or replace human expertise.[27] He has also described what informatics is (information sciences applied in a biomedical application domain with the aim of helping people) and is not (any use of IT in health care).[28]

While informatics is a relatively new discipline compared to others in medicine, it has accumulated a history of over a half-century that has evolved with advances in IT.[29] The various areas within biomedical and health informatics are depicted in Fig. 10.1. Sometimes narrower words appear in front of the term *informatics. Clinical informatics* generally refers to informatics applied in health care settings.[30] Sometimes *medical informatics* is used to describe this application as well. Other uses of *informatics* in biomedical and health-related areas include:

- **Bioinformatics**—the application of informatics in cellular and molecular biology, often with a focus on genomics[31]
- **Imaging informatics**—informatics with a focus on imaging, including the use of systems to store and retrieve images across all types of informatics[32]
- The application of informatics focused on specific health care disciplines, such as nursing (**nursing informatics**),[33] dentistry (**dental informatics**), and pathology (**pathology informatics**)[34]
- **Consumer health informatics**—the field devoted to informatics from a consumer view, often with a focus on mobile health[35]
- **Clinical research informatics**—the use of informatics to facilitate clinical research, with increasing emphasis on translational research that aims to accelerate research findings into clinical practice[36]
- **Public health informatics**—the application of informatics in areas of public health, including surveillance, reporting, and health promotion[37]



• FIG. 10.1 Areas Within Biomedical and Health Informatics, Including Clinical Informatics. *Source:* (Adapted from Hersh W. A stimulus to define informatics and health information technology. *BMC Med Inform Decis Mak.* 2009;9:24.)

C. Subspecialty certification in clinical informatics

Even though not limited to the work of physicians, clinical informatics has been recognized as a medical subspecialty[30] and has been defined by the Accreditation Council for Graduate Medical Education as the field that "transforms health care by analyzing, designing, implementing, and evaluating information and communication systems to improve patient care, enhance access to care, advance individual and population health outcomes, and strengthen the clinician-patient relationship."[38] Since 2013, physicians who have worked in the field or completed a fellowship in informatics and have a primary board certification in their specialty have been eligible to become additionally board certified in clinical informatics. That subspecialty certification is

available to physician specialists who are certified by any of the 24 member boards of the American Board of Medical Specialties, which endorses the broad clinical relevance of expertise in clinical informatics.[30] Since the first certification examination was offered in 2013, over 1600 physicians have become board certified.

II. Use of clinical informatics in health care delivery

There are many applications of clinical informatics, with the EHR occupying a central role. The EHR serves several key functions to improve care delivery, not only in documenting data and information of care delivery, but also in providing access to other participants in the system, most importantly the patient.

A. Electronic health records

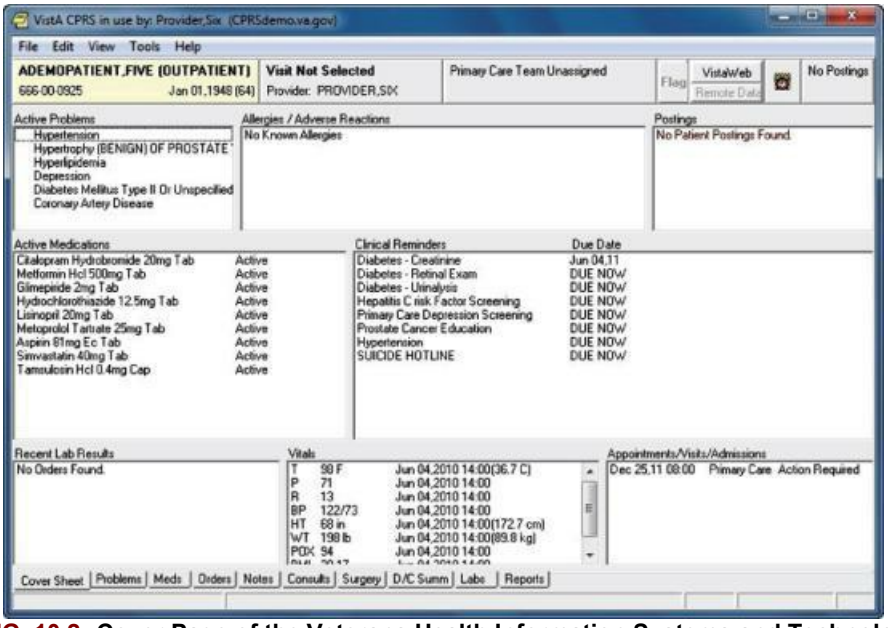
One of the most central applications of clinical informatics is the EHR. In the past, the term *electronic medical record* was more commonly used, but EHR implies a broader and more longitudinal collection of information about the patient. There is also increasing use of the term *personal health record* (PHR). This usually refers to the patient-controlled aspect of the health record and may or may not be tethered to one or more EHRs from health care delivery organizations. Growing numbers of health systems have adopted the OpenNotes approach, which provides patients access to clinical notes along with a substantial amount of other data.[39-41]

The EHR is not meant to be a mere replacement for the paper-based record; rather, it should ideally serve as a tool to transform and improve health care delivery. One major component of the EHR is **clinical decision support** (CDS), which allows detection of errors and adverse events and can facilitate improved care delivery and quality.[42] The most critical time for intervention is when the physician is entering patient orders, so the optimal time to make CDS readily available is within the functioning of CPOE. Related to CPOE is electronic prescribing (e-prescribing), which focuses more narrowly on the electronic ordering of medications. The major categories of CDS include:

- Information display—showing general or patient-specific information in the context of the current clinical situation
- Reminder systems—reminding clinicians to perform actions, such as preventive measures, when they are due
- Alerts or notifications—alerting to critical clinical situations (e.g., interacting drugs or abnormal laboratory values) that may negatively impact patient safety and health outcomes
- Clinical practice guidelines—guiding treatment to promote consistent care based on best evidence

An exemplar EHR is the Veterans Health Information Systems and Technology Architecture (VistA) system, which is used in 1800 locations around the world, including all Department of Veterans Affairs medical centers as well as the national health systems of Finland, Egypt, and Jordan. Fig. 10.2 shows the cover page of the EHR, which provides an overview of the patient, including his or her active problems

and medications as well as recent results. This page also shows an example of CDS, listing relevant clinical reminders. The tabs at the bottom of the screen allow the user to drill down into more details on specific aspects of the patient's care, such as medications and laboratory results. Many of these screens feature additional CDS, such as indicating drug-drug interactions. Current Department of Veterans Affairs plans include replacing VistA with a commercial EHR to better align with the commercial EHR system adopted by the Department of Defense so the care of military personnel can be seamlessly integrated as they transition to veteran status.



• **FIG. 10.2 Cover Page of the Veterans Health Information Systems and Technology Architecture (VistA) System.** *Source:* (VistA, http://www.ehealth.va.gov/vista.asp.)

As the use of EHRs has grown, it has become apparent that information does not seamlessly flow between physicians and health care professionals or across different health care organizations. This has led to growing advocacy for HIE, which is the exchange of health information for patient care across traditional business boundaries in health care. Even many health care organizations that have exemplary health IT systems have difficulty providing their patient information to other entities where the patient may receive care. An increasingly mobile population demands data that follow patients as they move into, out of, and across health care systems.

B. Standards and interoperability

One of the impediments to HIE has been suboptimal **interoperability** of EHR systems, with systems unable to seamlessly exchange data. Optimal interoperability requires adoption and adherence to standards to define data structures and formats. Although many standards exist for exchange of information and uniform use of terminology, they have not been consistently applied for a variety of reasons.[43] The major categories of

standards include:

- Identifiers—of patients, clinicians, health plans, insurance companies, etc.
- Transactions—eligibility, enrollment, payments, etc.
- Message exchange—transmission of data, images, documents, etc.
- Terminology—standard descriptions of diagnoses, tests, treatments, etc.

The longest-standing and most widely used messaging standard in health care is Health Level 7 (HL7) Version 2. However, in addition to a number of technological limitations, there are no formal standard terminology requirements for names of diagnoses, tests, and treatments in HL7 Version 2, which limits its accomplishing of interoperability. These limitations have led to a new messaging standard, the Fast Healthcare Interoperability Resources (FHIR). A key element of FHIR is Resources, which provide structured and standardized modeling of all data components of health care, from patients to observations to medications.[44,45] A complementary standard is Substitutable Medical Apps, Reusable Technology (SMART), which provides a standardized platform for building EHR and PHR applications ("apps," which can be web-based or run on mobile devices). These two have been married to form SMART on FHIR, which aims to provide new forms of interaction based on standardized data on top of the EHR.[46]

The presence of standardized interoperable data and systems not only leads to improved direct care of patients but also enables **reuse** (also called **secondary use**) of clinical data, wherein data from clinical settings is used for other applications, such as quality measurement and improvement, clinical and translational research, and public health.[47] All of these systems come together in the concept advanced by the NAM of the **learning health system**.[48,49]

It is important to mention that interoperability also requires the willingness of organizations, vendors, physicians, health care professionals, and patients to share data among themselves. There continue to be widespread concerns about so-called information blocking, or steps an organization may take to actively prevent data from being shared across platforms.[50] Additionally, in the United States the lack of a universal national patient identifier has complicated data exchange efforts compared to what has occurred in other countries.

C. Beyond the electronic health record

Clinical informatics is not limited to EHRs. Another vital component for optimal patient care is access to information and knowledge. The field devoted to indexing and retrieval of knowledge-based information is called **information retrieval** or **search**.[51] Searching is a requisite skill in the practice of **evidence-based medicine** (EBM), a skill set that includes the proper phrasing of clinical questions, seeking the best evidence to answer such questions, critically appraising what was retrieved, and applying such evidence to patient care. One recent textbook of EBM noted, "Searching for current best evidence in the medical literature has become a central skill in clinical practice. On average,

clinicians have 5 to 8 questions about individual patients per daily shift.... Some now even consider that 'the use of search engines is as essential as the stethoscope.'"[52] The importance of search goes beyond EBM, as clinicians must have skills in finding high-quality information for use by professionals and patients alike.

Additional important applications of clinical informatics are telemedicine and telehealth.[53] **Telemedicine** is the delivery of health care when the participants are separated by time, distance, or both, while **telehealth** has a larger aspect of all telecommunications applications devoted to health. As with informatics, the "tele-" terms sometimes reflect medical specialties in which they are applied (e.g., teleradiology and telepathology). A variety of practice models embracing telehealth have now emerged, including electronic intensive care unit (e-ICU) and telestroke services, which are commonly employed to deliver expertise to a broader population.

Table 10.1 lists some of the other chapters in this book and the role that informatics plays in topics discussed within them.

TABLE 10.1

Role of Clinical Informatics in Topics Covered in Other Select Chapters

Chapter	Title	Role of Clinical Informatics
5	Value in Health Care	Providing decision support to achieve value
6	Patient Safety	Early detection of, and action upon, safety issues
7	Quality Improvement	Measurement and improvement of quality
8	Principles of Teamwork and Team Science	Facilitating care coordination among teams
9	Leadership in Health Care	Allowing leaders to make better decisions
11	Population Health	Management and surveillance of populations
14	Health Care Policy and Economics	Evidence to inform policy decisions
15	Application of Health Systems Science Competencies in Patient Care	Access to evidence-based information
16	The Use of Assessment to Support Students' Learning and Improvement in Health Systems Science	Access to quality data and clinical evidence to improve delivery of care

III. Secondary use of clinical data

One of the promises of the growing critical mass of clinical data accumulating in the EHR is secondary use (or reuse) of the data for other purposes, such as quality improvement, operations management, and clinical research.[47] There has also been substantial growth in other kinds of health-related data, most notably through efforts to sequence genomes and other biologic structures and functions. The analysis of these data is usually called analytics or **data analytics**.[54]

A. Data analytics

The terminology surrounding the use of large and varied types of data in health care is evolving, but the term *analytics* is achieving wide use both in and out of health care. A long-time leader in the field defines analytics as "the extensive use of data, statistical and quantitative analysis, explanatory and predictive models, and fact-based management to drive decisions and actions."[55] The company IBM defines analytics as "the systematic use of data and related business insights developed through applied analytical disciplines (e.g. statistical, contextual, quantitative, predictive, cognitive, other [including emerging] models) to drive fact-based decision making for planning, management, measurement, and learning. Analytics may be descriptive, predictive, or prescriptive."[56]

Adams and Klein have authored a primer on analytics in health care that defines different levels of the application of analytics and describes their attributes.[57] They note three levels of analytics, each with increasing functionality and value:

- Descriptive—standard types of reporting that describe current situations and problems (e.g., reports of patients with certain diagnoses or outlier test results)
- Predictive—simulation and modeling techniques that identify trends and portend outcomes of actions taken (e.g., lists of patients who may be at risk for poor outcomes or repeated admissions to the hospital)
- Prescriptive—optimizing clinical, financial, and other outcomes (e.g., recommendations for patients to maintain health or to prevent poor outcomes)

Much work is focusing now on **predictive analytics**, especially in clinical settings attempting to optimize health and financial outcomes, including in clinical practice.[58]

There are a number of terms related to data analytics. A core methodology in data analytics is **machine learning**, which is the area of computer science that aims to build systems and algorithms that learn from data.[59,60] The field of machine learning has been around for decades, but it has been enabled more recently by several factors, including the availability of large amounts of data, powerful computers to process the data, and the development of so-called **deep-learning** algorithms based on computer programs called **neural networks**.[61] These systems may profoundly impact the practice of

medicine in the near future.[62]

Deep-learning algorithms have been developed for many tasks, especially those in physician specialties that use imaging. A sampling of these studies includes:

- Radiology—diagnosis comparable to radiologists for pneumonia,[63] tuberculosis,[64] and intracranial hemorrhage[65]
- Dermatology—detecting skin cancer from images[66-68]
- Ophthalmology—detecting diabetic retinopathy from fundal images,[69,70] diagnosing plus disease,[71] and predicting cardiovascular risk factors from retinal fundus photographs[72]
- Pathology—classifying various forms of cancer from histopathology images[73,74] and detecting lymph node metastases[75]
- Cardiology—cardiac arrhythmia detection comparable to cardiologists[76]
- Gastroenterology—assessing endocytoscopic images for diagnose-and-leave strategy for diminutive, non-neoplastic, rectosigmoid polyps[77]
- Hospital medicine—prediction of in-hospital mortality, 30-day unplanned readmission, prolonged length of stay, and the patient's final diagnoses[78]

A number of these computational approaches have come to be known collectively as **artificial intelligence**. Artificial intelligence can be described as using computational methods to perform tasks normally requiring human intelligence. In health care, however, a more appropriate term may be **augmented intelligence**, reflecting the enhanced capabilities of human clinical decision making when boosted by computational methods.[79]

As noted earlier, one of the reasons for the growth and success of data analytics and deep learning has been the development of "**big data**," which refers to the large and ever-increasing quantities of data that adhere to the following attributes[80]:

- Volume—ever-increasing amounts
- Velocity—quickly generated
- Variety—many different types
- Variability—variation in amounts, generation, and types

B. Making use of data

Hospitals and other health care organizations are generating a rapidly escalating amount of data. Clinical data take a variety of forms, from structured (e.g., images, laboratory results) to unstructured (e.g., textual notes, including clinical narratives, reports, and other types of documents). Additionally, health care organizations capture and generate data as a byproduct of the care delivery process. This can include billing, quality, management, and other financial data that are increasingly important in the optimization of health care delivery. Kaiser Permanente estimated in 2013 that its data store for its 9+ million members exceeded 30 petabytes (30 million gigabytes) of data.[81]

Other organizations are planning for a data-intensive future. For example, the American Society of Clinical Oncology has been developing its Cancer Learning Intelligence Network for Quality (CancerLinQ).[82] CancerLinQ will provide a comprehensive system for clinicians and researchers consisting of EHR data collection, application of CDS, data mining and visualization, and quality measurement for improvement.

The world's growing base of scientific literature is another source of data and can be linked with EHR and other patient data to improve outcomes of care. One approach to this problem that has generated attention is the IBM Watson project, which was made famous by winning at the TV game show *Jeopardy!*[83] One of the areas where IBM and its partners have been applying Watson is in the health care arena.[84]

The growing quantity of data requires that its users have a good understanding of its provenance, which is where the data originated and how trustworthy it is for large-scale processing and analysis.[85] A number of researchers and thought leaders have started to specify the path that will be required for big data to be applied in health care and biomedicine.[86-88] Bates and coworkers have elucidated a number of use cases in which big data methods might lead to improved outcomes[89]:

- High-cost patients—looking for ways to intervene early
- Readmissions—preventing
- Triage—providing appropriate level of care
- Decompensation—alerting when a patient's condition worsens
- Adverse events—raising awareness
- Treatment optimization—especially for diseases affecting multiple organ systems

Patients are increasingly interested in seeing more than just basic transactional data (i.e., a test result or notice of an overdue payment). They want summarized information of their health data, along with recommendations for care that are personalized for them. Similarly, payers, physicians, health care professionals, and health care institutions are all increasingly seeking insights, not just information, that can help them predict how to better serve their customers, clients, and patients.

A more peripheral but related term is *business intelligence,* which in health care refers to the "processes and technologies used to obtain timely, valuable insights into business and clinical data."[57] Another relevant term is the notion promoted by the NAM of the *learning health system.*[48,49] Advocates of this approach note that routinely collected data can be used for continuous learning to allow the health care system to better carry out disease surveillance and response, targeting of health care services, improving decision making, managing misinformation, reducing harm, avoiding costly errors, and advancing clinical research.[90]

Another set of related terms comes from the call for new and much more data-intensive approaches to diagnosis and treatment of disease, originally called personalized medicine[91] but now labeled **precision medicine** (i.e., identifying which approaches will be effective for which patients based on genetic, environmental, and

lifestyle factors).[92] Pharmacogenomics is a subset of precision medicine that studies how genetics affect a person's response to particular drugs. The US government has recently committed a substantial investment in research around precision medicine.[93] However, the major motivator for data-driven decision making in health care is probably the move from volume-driven (e.g., fee-for-service) to value-driven (where health systems and physicians share risk) reimbursement.[94]

As clinical data accumulate, so does the amount of metadata (or data about data). **Metadata** can be defined as data points used to identify data (e.g., who authored a particular clinical note), how data are linked together (e.g., vital signs from multiple records that represent a single patient), or how data have been utilized (e.g., data access and audit logs). Analysis of metadata, rather than the underlying clinical data itself, can be informative. In the United States, since 1996 the Health Insurance Portability and Accountability Act (HIPAA) has required that hospitals maintain audit trails for 6 years. Metadata have been used by many researchers to understand health care processes in support of quality improvement. For example, a study of preoperative anesthesia notes used EHR metadata to evaluate access patterns. This analysis revealed patterns of note utilization that had not been previously identified, including usage of anesthesia notes by surgical residents, surgical faculty, and pathologists both before and after the surgical event. In this case, knowledge of these dependencies revealed by the analysis of metadata directly informed efforts to restructure workflow.[95]

C. Formulating questions

The true utility of clinical data and metadata can only be realized when one is able to use these resources to answer relevant questions. Formulating such a question begins with a problem statement and an understanding of the underlying data that are available to help provide an answer. Treating the data and selecting an appropriate analytic approach should be the final step. For example, one might ask, "How often do medical students participate in vaginal deliveries?" or "How often are surgical cases canceled the morning of surgery?" Depending on the data available in the EHR, these types of questions might be easily answered by relatively simple case log queries. More complex questions such as "How often are dialysis patients readmitted within 30 days after arteriovenous fistula creation due to a surgical complication?" pose more challenges, depending on how the underlying data are stored. In the latter example, most EHRs can provide admission and readmission data, but fewer store the data on the reason for a readmission in a structured fashion. Depending on what data are available in a particular system, the question about readmissions from surgical complications may or may not be able to be answered using data queried from an EHR.

D. Clinical data warehousing, registries, and quality reporting

Clinical data warehouses are central repositories of data where information is integrated together from disparate sources. They are typically maintained at the

institutional level (i.e., within a hospital or health care system). **Clinical data registries** are collections of data about patients with a similar disease or therapeutic process. For example, the Cancer Genetics Network collects data about patients with cancer, and the Society of Thoracic Surgeons Database collects data from 1100 hospitals about patients who have undergone cardiothoracic surgery. The Multicenter Perioperative Outcomes Groups (MPOG) is a consortium of 47 medical centers that share anesthesia and surgical outcomes data. In 2014, the federal government created a standardized approach to reporting to clinical data registries through the Qualified Clinical Data Registry (QCDR) reporting mechanism. This was an attempt to foster quality improvement via reimbursement systems, incentivizing physicians to collect clinical data and penalizing those who did not.

The case study for this chapter describes the INPC, an HIE implementation that covers most of Indiana and provides data that facilitate care in hospitals, emergency departments, outpatient settings, long-term care facilities, and public health agencies.[96] Data from the INPC not only improve access to data for direct care but also facilitate population health management and calculation of quality measures. Although HIE efforts have been challenging to generalize, they have been associated with improved quality and efficiency of care.[97]

E. Challenges for data analytics

A concern for more intensive use of data is that data generated in the routine care of patients may be limited for analytic purposes.[98] For example, such data may be inaccurate or incomplete. The data may be transformed in ways that undermine their meaning (e.g., coding for billing priorities). For example, services or diagnoses that are highly reimbursed may be coded more reliably than other entities. The data may exhibit the well-known statistical phenomenon of censoring: the first instance of disease in the EHR may not be when it was first manifested (left censoring), or the data source may not cover a sufficient time interval to reflect the full course of disease (right censoring). Data may incompletely adhere to well-known standards, which makes combining them from different sources more difficult.

An emerging base of research demonstrates how data from operational clinical systems can be used to identify critical situations or patients whose costs are atypical. There is less research, however, demonstrating how these data can be put to use to improve clinical outcomes or reduce costs. Studies using EHR data for clinical prediction have been proliferating. One common area of focus has been the use of data analytics to identify patients at risk for hospital readmission within 30 days of discharge. The importance of this factor stems from the Centers for Medicare & Medicaid Services Readmissions Reduction Program, which penalizes hospitals for excessive rates of readmission.[99] This has led several researchers to assess the value of EHR data to predict patients at risk for readmission.[100-103]

Likewise, the deep-learning systems described earlier must be integrated into health systems and then assessed for their value in real-world settings. Indeed, one study assessing the clinical outcomes of patients with diabetic retinopathy found that while

the system provided value, its performance was not perfect, and indeed some patients had images that were not interpretable.[104] Clearly, more studies of real-world use are needed, and it is important to recognize the limitations of these systems.[62,105]

IV. Outcomes and implications of clinical informatics

With the massive adoption of EHRs in the United States driven by the HITECH Act, focused research on current systems and their impact on medical practice demonstrates a dichotomy between specific benefits and general dissatisfaction. Following the original systematic review in 2006, three subsequent reviews using a similar methodology published in 2009,[106] 2011,[107] and 2014[108] have shown persistent benefits for health IT.

A. Adverse effects of electronic health records

Simultaneously, there have been great concerns about the adverse impact of EHR use in health care delivery. A number of surveys have documented substantial dissatisfaction among EHR users[109] and identified EHRs as a major source of physician dissatisfaction in medical practice.[110] It is unknown whether this is a temporary transitional problem pending better systems or is indicative of likely ongoing problems with EHR use in medical practice.[21]

A growing number of problems have been identified related to the use of EHRs in clinical practice. One of these is excessive focus on the computer over the patient.[111,112] Another is the demise of traditional communications during care, such as radiology rounds.[113] There are also problems with losing the patient's story through use of documentation templates that replace the narrative with elements such as checkboxes.[114] While this structuring of data assists with the use of data for other purposes, it loses the nuance of the patient's and clinician's narrative. Finally, inappropriate use of "copy and paste" may propagate errors and lead to uncertainly as to which physicians or health care professionals rendered specific observations and recommendations (attribution).[115]

Another challenge is the increased time EHRs require of physicians and other clinicians, which takes time away from direct care of patients. Several recent time-motion studies have found that physicians spend up to half their work day interacting with the computer.[23,116,117] This has been shown as one of the major causes of the growing epidemic of physician burnout.[118] It is important to note that studies of physician time over several decades, even in the pre-EHR era, showed physicians spend up to half of their time in "indirect care." They are not in the presence of patients, but are performing tasks such as documentation; engaging in asynchronous communication with patients, other physicians, and other clinical staff; and in transit.[119,120] One reason for excess time requirements for the EHR in the United States is the increased billing and regulatory burden, as evidenced by the fact that physician notes in US EHRs are longer, sometimes severalfold, than notes of physicians in other countries where EHRs are used.[121] There is no question that US physicians spend too much time entering data

into the EHR, but it must also be determined what is the optimal time that should be devoted to documentation to enter data that informs the system to enable improved care.

Although EHRs have been touted to improve patient safety, there are also growing concerns that some aspects of their use may introduce new safety problems.[122] Two recent high-profile mishaps were CDS leading to massive overdosing of a common antibiotic[123] and poor communication between clinicians that resulted in the accidental discharge of a patient infected by the Ebola virus.[124] There are also growing concerns over the security of health information.[125] The year 2015 saw several massive security breaches, leading to exposure of records of over 100 million Americans.[126-128] The black-market value of a medical record has been estimated to be 10 times that of a credit card number due to it containing larger quantities of, and more sensitive, information.[129]

It is clear that EHRs must continue to improve in order to leverage their benefits and to improve health care delivery. Several professional organizations have issued white papers specifying improvements in the EHR[130] and patient documentation.[131] The American Medical Association has laid out a set of principles for improved usability and interoperability[132]:

- Enhance physicians' ability to provide high-quality patient care
- Support team-based care
- Promote care coordination
- Offer product modularity and configurability
- Reduce cognitive workload
- Promote data liquidity
- Facilitate digital and mobile patient engagement
- Expedite user input into product design and postimplementation feedback

A report from the Pew Charitable Trusts, the American Medical Association, and MedStar Health focused on methods for improving EHR safety.[133] The report noted seven usability or safety issues where efforts should be focused:

- *Data entry*—EHR data entry is difficult or not possible given the clinicians' work process, preventing the clinician from appropriately entering desired information.
- *Alerting*—EHR alerts or other feedback from the system are inadequate because they are absent, incorrect, or ambiguous.
- *Interoperability*—Interoperability is inadequate within components of the same EHR or from the EHR to other systems, hindering the communication of information.
- *Visual display*—EHR display of information is confusing, cluttered, or inaccurate, resulting in clinicians having difficulty interpreting information.
- *Availability of information*—EHR availability of clinically relevant information is hindered because information is entered or stored in the wrong location or is

otherwise inaccessible.

- *System automation and defaults*—EHR automates or defaults to information that is unexpected, unpredictable, or not transparent to the clinician.
- *Workflow support*—EHR workflow is not supported due to a mismatch between the EHR and intent of the end user.

B. Benefits of electronic health records

In balance, a (mostly) positive evidence base continues to accumulate on EHR use. Evidence in support of the value of EHRs shows that they detect and help overcome delays in cancer diagnosis,[134,135] reduce risk of hospital readmission,[136,137] and improve identification of postoperative complications.[138] EHRs have also been show to enhance patient-physician communication[139] and facilitate research through extracting phenotype information about patients.[140,141] Among surgical patients, EHRs have been shown to improve care in a number of ways by reducing postoperative nausea and vomiting, surgical site infections, and wrong-sided surgeries.[142,143] There are even emerging models for more optimal examination-room use of EHRs.[144] Optimists continue to note other benefits, such as the "data dividend" of EHR adoption from the HITECH Act.[145] Others note that diagnostic[146] and therapeutic[147] errors in health care persist, serving as continuing motivation for appropriate use of the EHR. One recent survey of physicians found that despite dissatisfaction with current systems, most physicians wanted to see EHRs improved and not abandoned.[148]

C. Clinical informatics research: Challenges and opportunities

Informatics has tremendous potential to facilitate both high-quality outcomes research and quality improvement efforts. EHRs, data warehouses, and clinical registries are all tools that have become ubiquitous across health care. New approaches to data storage, management, and analysis are enabling a growing number of end users to turn data into information with greater ease. These tools, when taken together, can be used to identify patients or processes of interests, obtain data, and study interventions in ways that have been impossible heretofore. Additionally, clinical data that are reused for these purposes often come at a fraction of the price of data that would otherwise be manually extracted or collected by research personnel. The success of these efforts, however, is dependent on data quality, standards, and availability. Additionally, overcoming the regulatory challenges associated with data sharing and privacy concerns remains a significant issue. Finally, none of this work is possible without expert informaticians who are able to lead these efforts.

V. Competencies of clinical informatics

Health care providers, including physicians and medical students, have been using health IT for decades. During this time, the role of health IT has changed dramatically from a useful tool for data access and occasional information retrieval to a ubiquitous presence that permeates health care and medical practice in many ways. But 21st-century clinicians face a clinical world that is quite different from that of their predecessors. The quantity of biomedical knowledge continues to expand, with an attendant increase in the primary scientific literature.[149] Secondary sources that summarize this information are proliferating, for use not only by clinicians but also by patients and healthy citizens interested in consuming health-related information. The accelerated adoption of EHRs under the HITECH Act requires competency in their use, including skills for secondary uses as described earlier. Patients want to interact with the health care system in a manner similar to the ways they have long interacted with airlines, banks, and retailers: through digital means using technologies such as the PHR.[150] Patients, payers, and purchasers demand more accountability regarding health care quality, safety, and cost.[151] There is an expectation of routine measurement and reporting of quality of care as part of participation in new delivery mechanisms such as primary care patient-centered medical homes and accountable care organizations. These trends emphasize the need for health care professionals to develop and maintain the knowledge, skills, and attitudes necessary to use clinical informatics optimally in delivering safe and effective patient care. Box 10.1 lists competencies developed for medical education, updated to cover machine learning and artificial/augmented intelligences, that apply to physicians beyond medical school as well as other health care professionals.[152]

• BOX 10.1

Competencies and Learning Objectives in Clinical Informatics for Health Care Professionals[152]

1. Find, search, and apply knowledge-based information to patient care and other clinical tasks.
    a. Information retrieval/search—choose correct sources for specific task, search using advanced features, apply results.
    b. Evaluate information resources (literature, databases, etc.) for their quality, funding sources, biases.
    c. Identify tools to assess patient safety (e.g., medication interactions).
    d. Utilize knowledge-based tools to answer clinical questions at the point of care (e.g., text resources, calculators).
    e. Formulate an answerable clinical question.
    f. Determine the costs/charges of medications and tests.
    g. Identify deviations from normal (labs/x-rays/results) and develop a list of

causes of the deviation.

2. Effectively read from, and write to, the electronic health record for patient care and other clinical activities.
    a. Graph, display, and trend vital signs and laboratory values over time.
    b. Adopt a uniform method of reviewing a patient record.
    c. Create and maintain an accurate problem list.
    d. Recognize medical safety issues related to poor chart maintenance.
    e. Identify a normal range of results for a specific patient.
    f. Access and compare radiographs over time.
    g. Identify inaccuracies in the problem list/history/medications list/allergies.
    h. Create useable notes.
    i. Write orders and prescriptions.
    j. List common errors with data entry (drop-down lists, copy and paste, etc.).
3. Use and guide implementation of clinical decision support (CDS).
    a. Recognize different types of CDS.
    b. Be able to use different types of CDS.
    c. Work with clinical and informatics colleagues to guide CDS use in clinical settings.
4. Provide care using population health management approaches.
    a. Utilize patient record (data collection and data entry) to assist with disease management.
    b. Create reports for populations in different health care delivery systems.
    c. Use and apply data in accountable care, care coordination, and the primary care medical home settings.
5. Protect patient privacy and security.
    a. Use security features of information systems.
    b. Adhere to Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations.
    c. Describe and manage ethical issues in privacy and security.
6. Use information technology to improve patient safety.
    a. Perform a root cause analysis to uncover patient safety problems.
    b. Maintain familiarity with safety issues.
    c. Use resources to solve safety issues.
7. Engage in quality measurement selection and improvement.
    a. Recognize the types and limitations of different types of quality measures.
    b. Determine the pros and cons of a quality measure, how to measure it, and how to use it to change care.
8. Use health information exchange (HIE) to identify and access patient information across clinical settings.
    a. Recognize issues of dispersed patient information across clinical locations.
    b. Participate in the use of HIE to improve clinical care.
9. Engage patients to improve their health care delivery though personal health records (PHRs) and patient portals.
    a. Instruct patients in proper use of a PHR.

b. Write an e-message to a patient using a patient portal.
c. Demonstrate appropriate written communication with all members of the health care team.
d. Integrate technology into patient education (e.g., decision-making tools, diagrams, patient education).
e. Educate patients to discern quality of online medical resources (websites, apps, patient support groups, social media, etc.).
f. Maintain patient engagement while using an electronic health record (EHR) (eye contact, body language, etc.).

10. Maintain professionalism through use of information technology tools.
    a. Describe and manage ethics of media use (cloud storage issues, texting, cell phones, social media professionalism).
11. Provide clinical care via telemedicine and refer patients as indicated.
    a. Be able to function clinically in telemedicine/telehealth environments.
12. Apply personalized/precision medicine.
    a. Recognize growing role of genomics and personalized medicine in care.
    b. Identify resources enabling access to actionable information related to precision medicine.
13. Participate in practice-based clinical and translational research.
    a. Use EHR alerts and other tools to identify patients and populations eligible for participation in clinical trials.
    b. Participate in practice-based research to advance medical knowledge.
14. Apply machine learning applications in clinical care.
    a. Discuss the applications of artificial/augmented intelligence in clinical settings.
    b. Describe the limitations and potential biases of data and algorithms.

While all physicians need basic competence in clinical informatics, there is also a need for a modest-sized cadre of experts in the area. Growing numbers of physicians assume roles in health care settings under titles such as chief medical informatics officer (CMIO).[153] There are also opportunities in industry, government, and other settings. These opportunities have led to the designation of the new medical subspecialty (of all medical specialties) of clinical informatics described earlier.[30] As such, fellowship programs accredited by the Accreditation Council for Graduate Medical Education have been established.[154] This underscores the need for introduction of the concepts and competencies of this clinical informatics subspecialty as part of medical training.

VI. Chapter summary

Across health care, major changes have been spawned by innovation, regulatory efforts, and consumer demands. All three are likely to play a role in shaping the future of clinical informatics. The United States will undoubtedly see continued innovation as technology evolves and continues to permeate our health care delivery systems. The government, through its purchasing power, regulatory requirements, and incentive programs, will shape the use of clinical informatics. What is less clear is what role consumers will play. Some predict that consumer demand for access to health care information will drive changes to EHRs, interoperability, information exchange, and the use of personal health records. Others have predicted that today's EHRs will be replaced entirely by cloud-based approaches to managing health IT. Regardless of what the future holds, clinical informatics will be an important tool in optimizing the care physicians and other health care professionals deliver to patients.

One of the ongoing challenges facing the health care system is the need for astute clinicians who understand how information systems work and what their limitations are. Astute clinicians who can provide leadership in the design and redesign of medical systems are necessary. Many challenges arise when information systems are either developed or implemented without a clear understanding of the clinical workflow or how end users (i.e., clinicians) intend to use them. This will be critically important as our society enters an era that heavily relies on artificial/augmented intelligence systems. Although many EHR vendors employ clinicians in a variety of advisory capacities, even well-intentioned systems can fail if not implemented in a way that matches the local workflow of a given clinical environment. Hence the increased demand for trained informaticians and for all clinicians to possess basic competency in informatics.

Questions for further thought

1. What forms of clinical decision support (CDS) are available for use in association with electronic health records (EHRs)? How might CDS help improve the safety and quality of health care while reducing costs?
2. What are the three types of data analytics, and how can each one help manage or improve the value of care provided to a population of patients?
3. What are some of the areas in which the use of big data can potentially lead to improved health outcomes?
4. Why have EHRs not obtained uniform support within the patient and physician communities?
5. Which of the clinical informatics competencies do you feel least comfortable with, and how can you target your learning activities and clinical experiences to improve your knowledge and skills in these areas?

Case study

One Saturday evening, an elderly patient who lives in a suburb of Indianapolis develops sharp abdominal pain while visiting her sister in northern Indiana. The patient, who has difficulty keeping track of her medicines, decides to go to the local emergency department. During the triage process, the patient is asked to provide information about her medical history and a current list of medications. She is unable to provide much information, given her limited capacity. Given that her regular doctor's office is closed and she is at a hospital she has never visited before, what steps can the treating team use to provide the best patient-centered care for this woman?

The Indiana Network for Patient Care (INPC) is part of the Indiana Health Information Exchange (IHIE; www.ihie.org), which is one of the largest and original HIE efforts in the world. The IHIE allows over 100 hospitals and 22,000 physicians, along with long-term care facilities, laboratories, and public health organizations, to share data for patient care, research, public health, and other purposes.[96] The INPC is the data repository that enables the IHIE, with over 11 million patients and 4 billion structured observations. The emergency departments of all hospitals can access the records of patients who have received care at any of the IHIE-connected hospitals, with the physicians able to query laboratory, radiology, and other reports of all patients in the INPC repository.

The INPC facilitates a number of best practices to use for improving patient care. A few examples include when patients present in the following situations[155]:

- Emergency department—accessing recent care activity and results from other care settings can reduce unnecessary redundant testing, facilitate medication reconciliation, and help clinicians identify patients at risk for medication abuse and "doctor shopping"; HIE is particularly helpful when patients present after hours for urgent conditions

- Inpatient—providing a more complete picture of the patient at admission and facilitating medication reconciliation
- Case management—allowing better coordination of care and reducing redundant testing
- Radiology departments and centers—providing results for comparative assessment and reducing cost and radiation exposure
- Outpatient—preparing a chart prior to patient arrival and providing information about past visits to develop a more informed care plan
- Quality and performance improvement—accessing data for quality measures
- Accountable care organization (ACO) managers—facilitating access to information about the patient's care, including outside the ACO
- Long-term care—improving transitions of care and providing information when the patient needs to visit the emergency department or outpatient settings

Consider your care of this patient if you had to rely on the limited information that she and her family can provide during the initial evaluation, versus how you might proceed if the INPC were available to help fill in the gaps.

1. How might your diagnostic process be accelerated?
2. What tests might be avoided?
3. What medication-associated risks could be mitigated?
4. A team member would typically devote significant time attempting to obtain external records; how would that time be redeployed toward care or learning?
5. How might the family's anxiety be assuaged knowing the care team is aware of, and acting upon, preexisting care information?

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11

Population health

Natalia Wilson, MD, MPH, Paul George, MD, MHPE, Jill Huber, MD

CHAPTER OUTLINE

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In this chapter

This chapter focuses on the dynamic and evolving area of population health, a topic that has attracted increasing attention in the United States over the past decade. Discussed are key influencers of population health that include the health care delivery system, the public health system, community organizations, health policy, and evidence generation. The role of population health in health care delivery is a primary focal point, with attention to new models of care, alternative payment models, new technology, and new, evolving roles for health care workers. The foundational work of the public health system through its core functions of assessment, policy development, and assurance is detailed, as is the role of organizations in the broader community. Drivers of a population health focus through health policy changes are introduced. Examples of population health initiatives bridging medical care, the public health system, and community organizations are provided to help illustrate ongoing work to develop and test new models and generate evidence for population health improvement. The chapter concludes with a focus on the future of population health, including new directions in health professions education.

Learning Objectives

1. Describe population health and its determinants.
2. Analyze the impact of the social determinants of health on population health.
3. Appraise the roles and contributions of the health care delivery system, the public health system, community organizations, health policy, and evidence generated through initiatives and research to population health improvement.
4. Summarize how population health is being implemented in medical care.

I. Introduction

The changing landscape of health and health care in the United States has fueled a shift in focus from individual care alone toward individual and population health management. This shift is driven by many factors, including greater attention to quality of patient care, patient safety, and the rapidly increasing cost of health care. Increased awareness of the limitations of US health care, including less than ideal national health outcomes despite the high cost of care and a growing consensus that the status quo in US health care is unsustainable, has helped expand the conversation from the health of individuals to the health of populations. Many key health issues facing the United States—chronic disease, obesity, disability, and behavioral health issues—are particularly well addressed through a population health focus from both disease management and prevention perspectives. Finally, there is growing recognition of the acute need to address the determinants of population health, particularly the social determinants of health, which fall outside of the usual purview of the health care arena.

A population health focus within health care delivery broadens perspective from the traditional 1:1 individual focus of medical care to include considerations of a group of individuals, a community, or population(s). The goal is to improve health outcomes through health care delivery changes, including the use of new strategies and tools that are discussed further in this chapter as well as through awareness of and integration with efforts and resources from other key influencers of population health, such as the public health system, community organizations, and new models of care being developed and tested through initiatives or research. Population health, both as a concept and a field of study, is undergoing considerable evolution and growth and is garnering increased attention from the traditional health care delivery sectors in the United States. Several factors have contributed to this new focus, including shifting health care reimbursement to alternative payment models (APMs), moving from volume care (fee-for-service) to value-based care, and giving heightened attention to measuring quality outcomes in health. Other factors reinforcing the increased focus on population health within health care delivery include the Institute for Healthcare Improvement's goals of improved patient experience of care, improved health of populations, and reduced per capita cost of health care, termed the Triple Aim,[1,2] and the movement toward new models of care delivery, such as those supported by policy change through implementation of the Affordable Care Act (ACA). The Triple Aim has been augmented by a fourth goal, focusing on the clinician experience, wellness, and burnout.[3] These four goals are collectively termed the Quadruple Aim and are referenced throughout this chapter.

The increased emphasis on population health is supporting a growing number of initiatives focused on collaborative efforts between health care delivery, the public health system, and community organizations. Greater attention is being given to the impact of social and behavioral determinants on population health, and medical schools are increasingly including population health content in their curriculum.

II. What is population health?

A. Definition and characteristics

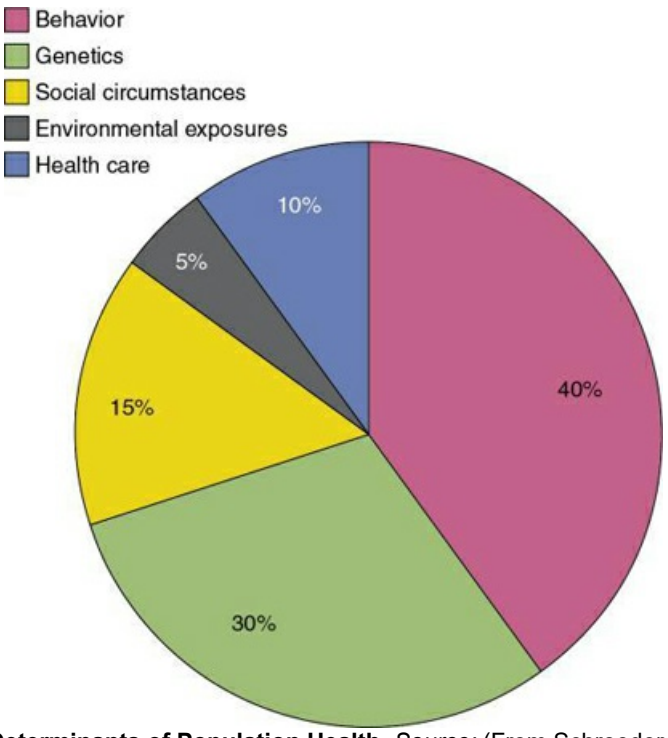
Population health has been viewed through different lenses and within different contexts, but is most commonly defined as "the health outcomes of a group of individuals, including the distribution of health outcomes within the group."[4] The National Academy of Medicine Roundtable on Population Health Improvement further elaborated on this definition: "while not part of the definition itself, it is understood that such population health outcomes are the product of multiple determinants of health."[5] Population health extends beyond the individual patient focus of traditional medical care and encompasses health outcomes of groups, communities, or populations of individuals. Individuals are members of a variety of populations, communities, or groups, and collectively individual health constitutes the health of populations. US population health is the health of the nation as a whole, including members of various subpopulations, communities, and groups.

Populations may be defined in multiple ways, and the definition is often dependent on the view of the stakeholder. Physicians and others in the health care setting typically define populations within a designated clinical setting or with particular medical diagnoses. A population may be a patient panel in a medical practice; a patient-centered medical home (PCMH) or an accountable care organization (ACO); patients with certain identifying characteristics, such as ethnicity or age; or patients with a specific medical condition such as diabetes mellitus or cardiovascular disease. The public health system typically defines populations within a specific geographic area or community. Community organizations define their population based on who is in need of their services. Focus could be on support for a particular medical condition, health care coverage, economic security, housing, transportation, food access, or other nonhealth areas that can be very impactful on health and health outcomes. Employers typically view their employees as the population, whereas payers view individuals within their health insurance plan.

Population health has been described as having four major pillars: chronic care management, quality and safety, public health, and health policy.[6] Population health encompasses the influence of multiple stakeholders, including those in health care delivery, the public health system, community organizations, health policy, employers, insurers, and those generating evidence through research and other initiatives. Population health is strongly focused on analysis of outcomes to drive process change and new policy.[6] Chronic care management, quality, and safety are activities that historically have been primarily delivered within health care settings but increasingly extend into the community. The public health system has traditionally focused on the community setting. Health policy is a significant driver to influence change in many stakeholder groups as well as across groups.

B. Determinants of population health

The overall measure of the health of populations results from the interplay of **determinants of health**, which are the multiple factors that influence an individual's health and the health of populations. Determinants are typically characterized as behavior, genetics, social circumstances, environmental exposures, and health care, as indicated in Fig. 11.1.[7,8]



• **FIG. 11.1 Determinants of Population Health.** *Source:* (From Schroeder SA. Shattuck Lecture. We can do better—improving the health of the American people. *N Engl J Med.* 2007;357(12):1221-1228. Adapted from McGinnis JM, Williams-Russo P, Knickman JR. The case for more active policy attention to health promotion. *Health Aff [Millwood].* 2002;21[2]:78-93.)

Behavioral determinants of health include smoking, risk-taking behaviors, exercise, and nutrition. Examples of genetic determinants are age, biologic sex, and inherited health conditions. Social determinants include income, social support, and education. Physical and environmental determinants include the natural environment, such as green spaces, as well as the built environment, housing quality, conditions, and exposures. Health care determinants include the availability of quality health care, access, and health insurance.

Historically, initiatives and programs provided through the US public health system have been designed to address behavioral, social, and environmental determinants of health. The health care system has concentrated on providing disease-based diagnosis, care, and treatment, and while it also works to address the additional determinants of health, its historic focus on these areas has generally not been robust. It is noteworthy

that only 10% of the determinants of population health are attributed to medical care, yet medical care is the predominant focus in the health arena in the United States. The vast majority of population health determinants fall into the collective realm of behavior or lifestyle choices, social circumstances, and environmental exposures. Improving US population health will necessitate broad, prolonged, and determined change and collaboration across multiple stakeholders.

C. Social determinants of health

A significant focus on social determinants of health (SDOH) and their influence on population health has followed the recognition that health begins where people live, work, play, and age.[9-11] SDOH broadly encompass the social circumstances, environmental exposures, and health care determinants of health.[10] The social environment, physical environment, and health care services all contribute to "the social patterning of health, disease and illness."[9] They are recognized as interacting with and influencing behavior and contributing substantially to differences in health outcomes between groups of people.[10]

Healthy People 2020, a national initiative focused on promoting health for all, has identified five key areas of the SDOH: economic stability, education, social and community context, health and health care, and the neighborhood and built environment.[11] Examples of unique factors in these categories, outlined by Healthy People 2020, include:

1. Economic stability: poverty, food security, employment
2. Education: quality of education, rate of high school graduation, secondary education, early childhood education and development
3. Social and community context: civic participation and sense of community, perceptions of discrimination and equity, incarceration
4. Health and health care: access to health care and insurance, health literacy, prescription coverage
5. Neighborhood and built environment: access to healthy foods and areas to exercise, quality of housing, crime and violence

A population health focus recognizes that an individual's health status is linked to his or her home, work, school, and other environments and not just determined by his or her interactions with the health care system. New strategies are needed to improve the health of populations, working beyond the health care setting with enhanced collaboration with the public health system and organizations in the broader community, including organizations that have traditionally not been focused on health care. For example, immunization programs in the schools help avoid challenges with health care access, transportation, or the ability to take time away from school and work for appointments. The goal is to work collaboratively to support positive change in the places in which people live, work, and learn, thereby promoting the ability to live healthy lives.

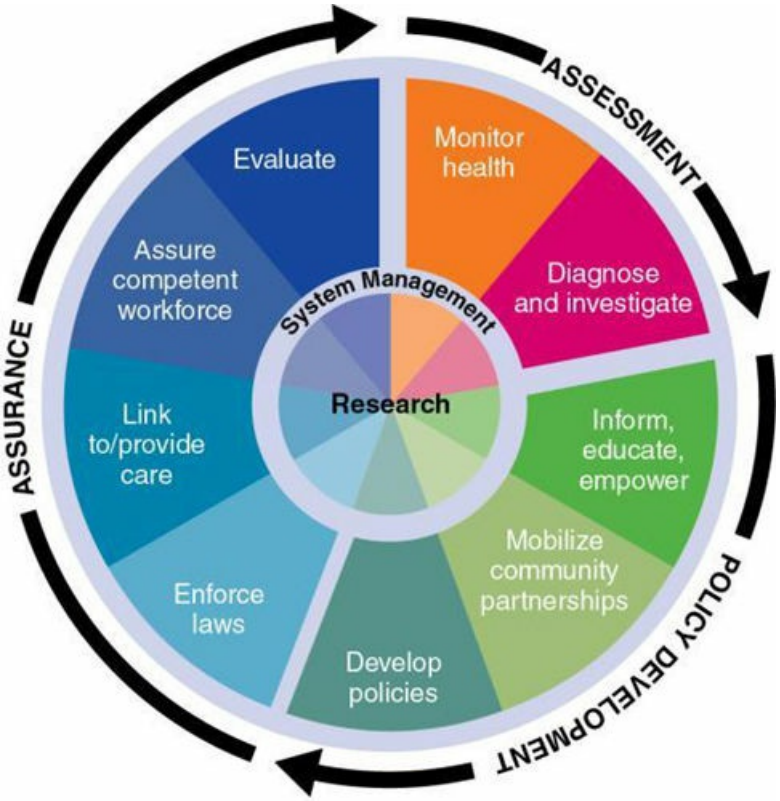
As an example, consider a 21-year-old woman with insulin-dependent diabetes mellitus. She has been hospitalized six times in the preceding 6 weeks with diabetic ketoacidosis (markedly elevated blood sugars causing acid buildup in the blood). The patient is homeless, cannot afford food or insulin, and has no transportation to get to regularly scheduled health care appointments. Without addressing her social determinants of health and working to find her support for the barriers she faces—lack of housing, food insecurity, and lack of transportation—her diabetes cannot be treated adequately. More detailed information on SDOH is provided in Chapter 12.

D. Key influencers of population health

Population health ("the health outcomes of a group of individuals") is impacted by more than one sector or discipline. Health care delivery, the public health system, organizations in the broader community, health policy, and evidence generated through initiatives and research all have a key influence on current population health and its improvement.

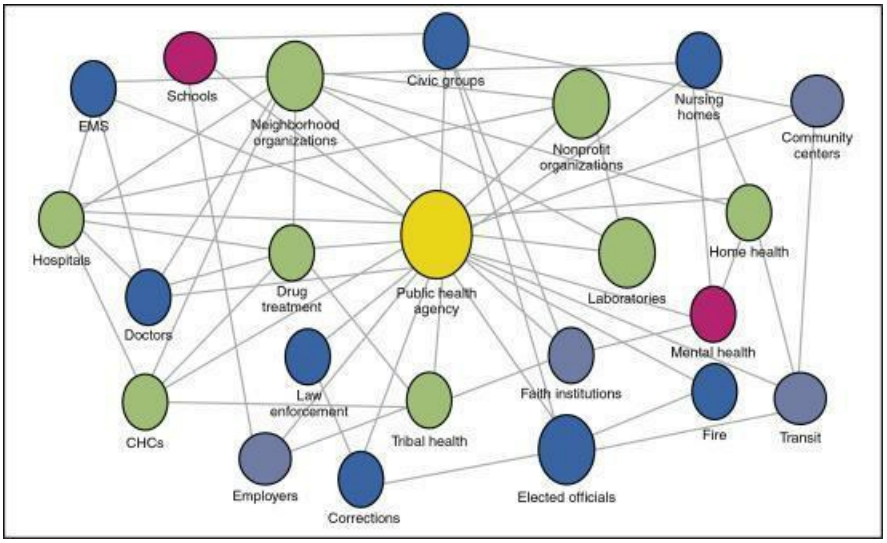
Population health within health care delivery has been described in more than one way. Population medicine is defined as "The design, delivery, coordination, and payment of high-quality health care services to manage the Triple Aim for a population using the best resources we have available within the health care system."[12] Population health management is commonly defined as "The iterative process of strategically and proactively managing clinical and financial opportunities to improve health outcomes and patient engagement, while also reducing costs."[13] A population health focus within health care delivery has been driven in large part by health policy changes. The ACA has supported implementation of new models of care and APMs, with a shift of priority and reimbursement from volume to value and required reporting of quality and cost metrics. More recently, the Medicare Access and CHIP Reauthorization Act (MACRA) created a Quality Payment Program, the new method to reimburse physicians and other health care professionals, inclusive of enhanced reporting and link of reimbursement to quality and cost-related metrics.

Public health has been defined as "What we as a society do collectively to assure the conditions in which people can be healthy."[13] Public health is a long-standing discipline that has focused on the health of entire populations, communities, states, countries, and even regions of the world. Public health is organized through agencies at the federal, state, local, and tribal levels, although primary responsibility rests at the state and local levels. Important public health fundamentals include prevention of disease, promotion of health, protection against environmental hazards, disaster preparedness, and assurance of health care quality and accessibility.[14] The public health system is not focused on individual medical care and private sector health care delivery. Public health has three core functions—**assessment**, **policy development**, and **assurance**—and 10 essential services (Fig. 11.2).



• **FIG. 11.2 Public Health Core Functions and Essential Services.** *Source:* (From Centers for Disease Control and Prevention, Office for State, Local, Tribal, and Territorial Support. National public health performance standards overview. Atlanta, GA: Centers for Disease Control and Prevention.)

The reach of public health is extensive and includes public, private, and voluntary entities[15] (Fig. 11.3). The broader community encompasses many resources and types of support in addition to those available through traditional public health. These are made available through other government-funded agencies, not-for-profit or faith-based groups, or collaborative initiatives. Examples of resources include work groups, classes, educational materials, research projects, and initiatives. The focus can be on health and health care, such as the prevention, self-management, or overall education on a particular disease, or support to obtain insurance coverage, as well as on nonhealth areas that impact person and population health. Examples of the latter include support in the areas of economic stability, housing, transportation, or food access.



• **FIG. 11.3** **Reach of the Public Health System.** *Source:* (From Centers for Disease Control and Prevention, Office for State, Local, Tribal and Territorial Support. National public health performance standards overview. Atlanta, GA: Centers for Disease Control and Prevention.)

Health policy has been defined as "A law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions."[16] Health policy plays an important role in driving change. In the case of the population health focus within health care delivery, national-level policy has particularly driven change through its impact on reimbursement and requirements for extensive quality and cost reporting.

Evidence for new population health initiatives is developed through traditional research and ongoing initiatives that are maturing and testing new models of care and reimbursement, addressing SDOH, assessing new tools and strategies, and working on integration between population health stakeholders. Funding is available not only through traditional routes but also through new funding sources implemented as part of national-level policy change, such as the Center for Medicare & Medicaid Innovation and the Patient-Centered Outcomes Research Institute.

E. Why is population health not public health?

A question commonly asked is "Why is population health not public health?" The answer has several parts. As mentioned previously, the public health system is not focused on individual medical care and private sector health care delivery. Instead, the public health system has traditionally focused on the health of entire communities, populations, states, countries, and regions. In addition, public health interventions tend to be at a higher organizational level than the individual or practice, such as clean air and healthy food initiatives. Although the public health system is a key pillar for population health and its improvement, population health is significantly influenced by more than one sector, as indicated earlier. As an important example, health care delivery, which is not under the purview of public health, is a key influencer of population health.

As we consider presented definitions, “the health outcomes of a group of individuals” is truly a result of “what we as a society do collectively to assure the conditions in which people can be healthy,” but they are not synonymous.

III. Why a focus on population health?

A. Limitations and outcomes in US health and health care

A number of significant limitations in US health care must be overcome in order to achieve improved population health. These include:

- *A focus on sick care over prevention and wellness*. Clinical training has traditionally emphasized acute illness and chronic disease care over prevention and wellness. The fee-for-service reimbursement system has been more heavily based on acute care and procedures.[17] Prevention, chronic disease management, nutrition, and behavioral health have been traditionally undervalued and reimbursed at a rate less than acute care. There is minimal reimbursement for nonclinic follow-up, such as an online portal communication or telephone calls, which are commonly used strategies for surveillance in chronic disease prevention and management. Preventive services for patients are also generally more difficult to receive than acute care services in the United States, with some speculating that one contributing reason may be more medical school graduates entering specialties rather than primary care.[18] In addition, the public health sector, with its focus on prevention and health promotion, has been relatively underfunded when compared with acute care reimbursement[19] and has not been well integrated with medical care.[20]
- *Siloed and fragmented efforts for health and health care*. Health care is often organized and prioritized around the health care delivery system rather than the patient. Patients typically must initiate contact and access many different points in order to receive their health care. Lack of coordination, integration, and communication between different points of a patient's care all contribute to fragmentation of the health care system. Frequent changes in a patient's insurance coverage or changes in provider networks for insurance companies can also contribute to fragmentation as patients may need to access new physicians or other health care professionals based on requirement of their current insurance coverage.[21] Connections between medical care, public health, and community resources for patients to support their health and health care have been limited.[22]
- *Inadequate assimilation and use of data.* Communication and sharing information between the various parties involved in the care of a patient is often limited. Barriers to greater communication and coordination of care include interoperability of electronic health records (EHRs) and limitation in capability for health information exchange.[23] For data that are available, clear delineation of information needed, goals for data analysis, and data analysis itself are often inadequate and inconsistent. Medical care and public health data sources are not well connected.

- *Suboptimal patient engagement*. Lack of defined teams for patient care, lack of tools, and time constraints on an individual physician impact the ability for greater engagement of patients in their health care. Patient-centeredness and shared decision making, as well as the methods to operationalize these concepts in a busy clinical practice, have typically not been robust areas of emphasis in clinical training. Patient education resources and tools are often inadequate. Additionally, most care has been delivered via an in-clinic setting; however, it may not be feasible for patients to take time away from school, work, family, or other obligations to be optimally engaged in their health and health care. Strategies for ongoing surveillance of health that patients find convenient and cost effective and are reimbursed are not optimally developed.
- *Inequality and inequity in health and health outcomes.* Where people live; their socioeconomic status; and their race, ethnicity, gender, age, sexual orientation, and disability status have historically impacted health and health outcomes.[24] Comprehensive solutions to address the impact of the SDOH on health outcomes have been difficult to develop. Root causes are often complex, and policy, funding, and support targeted at these areas have not been robust.[25]
- *Reimbursement systems, incentives, education, and culture that support the status quo.* A fee-for-service reimbursement system often reinforces fragmented efforts as individual physicians are paid separately for their part of a patient's care. In many systems, physicians are not held accountable, and often not reimbursed, for the quality of care provided or care coordination in a traditional fee-for-service system. Finally, as mentioned previously, incentives are often misaligned in health care as acute care and procedures are reimbursed at a greater rate than preventive care. This is accentuated by the training of medical students, residents, and other health professionals in hospitals where sick care is most often provided.

Outcomes of these limitations are significant from a clinical, cost, and population health perspective. Challenges include a significant prevalence of chronic disease (including diabetes, hypertension, and cardiovascular disease), an obesity epidemic, an aging population, and dysfunctional behavioral health care. Data illuminating these challenges are eye-opening. Fifty percent of US adults have at least one chronic disease.[20,26] In 2016, the leading causes of death were a chronic disease or were generally associated with patients with a chronic disease.[27] Forty percent of US adults are obese, and 18.5% of children and adolescents are obese.[28] Obesity is associated with significant comorbidities, including cardiovascular disease, hypertension, type 2 diabetes, and cancer.[29] Evidence is accumulating of cardiovascular damage in obese children.[30] Projections indicate that by 2030, one in five persons in the United States will be an older adult.[31] Dysfunctional behavioral health care with a siloed focus on physical and mental health is not a new problem; however, there is greater awareness of the impact of mental health on physical health.[32,33]

National health care expenditures were 17.9% of the gross domestic product (GDP) in

2016, with total health care expenditures at $3.5 trillion.[34] The breakdown of expenditures included 32.4% spent on hospital care, 19.9% on physician and clinical services, and 9.8% on prescription medications.[35] Eighty-six percent of health care costs are attributed to treating chronic disease.[36]

In a global comparison, the United States spends the highest percentage of GDP on health care by far. However, in comparison to countries of similar income, the United States lags on key outcome measures, including life expectancy and prevalence of chronic disease.[37,38]

Optimal disease management necessitates coordinated care along with use and exchange of data and patient engagement. In addition, physicians and other health care professionals must have greater knowledge of and connection with the resources outside of the health care system, including those resources in the public health sector and the broader community where individuals spend the majority of their time. Finally, in order to optimize the health of a population, there needs to be much greater focus on and support for prevention. All of these areas are limitations in the current US health care system. The overall impact is relatively poor population health in the United States and comparatively poor population health in relation to countries of similar income globally.

Case study 1

Mr. Reed is a 66-year-old male with type 2 diabetes whose blood sugar control has not been optimal. Additionally, he is overweight and is not physically active. His primary care physician (PCP) has had multiple discussions with Mr. Reed about the importance of good blood sugar control, optimal weight, and regular exercise. The PCP has discussed concerns about development of comorbidities, particularly coronary artery disease. Mr. Reed has been referred to the dietitian at the local hospital, but the PCP has had to make alterations to Mr. Reed's diabetes medication multiple times as his diabetes markers continue to show inadequate glycemic control.

Mr. Reed's PCP recently became part of an ACO and is evaluating and optimizing support for the population of diabetic patients, including Mr. Reed. Steps taken include:

- Obtaining data from the electronic health record on all of the patients with diabetes for the past 2 years, including hemoglobin A_{1c} values, number of emergency department visits, number of hospitalizations, and compliance with routine office visits.
- Risk-stratifying patients with diabetes into high-, medium-, and low-risk categories based on these data.
- Developing a process for follow-up with high- and medium-risk patients to ensure that they are taking their medications, keeping routine office visits, staying up to date with their preventive care, and do not have problems or barriers to controlling their diabetes. A nurse care manager in the PCP's office has been designated with this job.
- Creating a patient portal where patients can access their lab results; send e-mails to the PCP or his or her nurse/medical assistant; make office appointments; and access resources, including transportation options, listed with contact

information.

- Providing patient education brochures and materials to be made available in the waiting room and exam rooms as well health educators to help patients gain understanding of their medical conditions and gain skills in self-management.
- Providing support for patients with diabetes to optimize their diet and physical activity. After investigation by the PCP's office staff, the PCP becomes aware of a number of resources available in the community. These include diabetes self-management classes; nutrition classes where patients are taught how to shop, cook, and make choices while eating out; and exercise programs at both the local YMCA and the senior center. The PCP is able to get a list of locations, dates/times, and contact information for these classes to provide to patients in the office and through the patient portal. Additionally, a local supermarket chain offers reduced prices for fruit and vegetables with a physician's prescription "coupon."
- The local hospital's Community Health Needs Assessment and the county's Health Improvement Plan both indicate diabetes as a high-priority condition and are instituting a number of planned targeted initiatives at the community level. The local hospital is now offering a sustainability program for seniors.

1. How might these changes to the PCP's practice impact Mr. Reed's health status? How might they affect his health outcomes? How might they impact his quality of life?
2. Are there any other changes that the PCP should consider to further improve the health of Mr. Reed and other patients with diabetes in the practice?
3. How will the type of practice affect the types of interventions that are possible?
4. What if the PCP is in a solo private practice? A small primary care group practice of fewer than five physicians? A midsized practice? A large multispecialty practice? An academic practice? A hospital-owned practice?

B. Health disparities and inequity

A fundamental health care question is "Why are some Americans healthier than others?" The answer is complex. Differences in health and health outcomes between groups of people are considered *health disparities*. There are a number of proposed definitions for health disparities or health inequalities, terms often used interchangeably, and the definition applied is often related to the context in which it is used.[39] Additional discussion of these concepts and terms is provided in Chapter 12.

Healthy People 2020 defines a health disparity as "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."[40] These differences are significantly influenced by SDOH at the individual and population levels and

associated differences in the allocation of resources. These differences are often considered avoidable, unjust, or unfair and sometimes referred to as *health inequity*.[39]

Sadly, there are innumerous examples of health disparities in the United States. In Chicago, the difference in life expectancy is 16 years between the Washington Park neighborhood on the South Side, which is predominantly black, and the Loop in the city center just 5 miles away and predominantly white.[41] Nationally, infant mortality remains highest for non-Hispanic black women.[42] Diabetes prevalence is highest among males, persons age 65 years or older, non-Hispanic blacks, those of mixed race, Hispanics, persons with less than a high school education, those who are poor, and those with a disability.[42] These disparities often relate to the complex interplay between social, economic, environmental, and systemic factors, making it difficult to design readily applicable solutions.

In addition, the absence of disease does not necessarily denote health. For example, there remain differences in an individual's ability to lead a healthy lifestyle and avoid disease. In 2011, 30% of people did not have close access to stores with healthy foods.[42] The combined cost of health inequalities and premature deaths in the United States between 2003 and 2006 was estimated to be $1.24 trillion.[43]

Ultimately, health and health care efforts aim to achieve health equity, or the state in which all individuals achieve their full health potential. As the cause for health disparities is complex, the solution to eliminate avoidable disparities is also complex. This requires a collaborative effort with policymakers, national initiatives focused on health promotion, and research on health outcomes, disparities, the health care system, public health agencies, social services, and community programs.

C. Constraints in health care delivery

Prior to the passage of the ACA in 2010, health care delivery focused primarily on the care of individual patients. As an example, when a physician saw a patient with diabetes, he or she would likely prescribe medication to control the patient's blood sugar, ensure that the patient had received influenza and pneumonia vaccines, ensure that the patient saw an ophthalmologist for eye care and a podiatrist for foot care, and check laboratory values, such as a hemoglobin A_{1c}, every 3 to 6 months. The physician was likely solely focused on and responsible for ensuring that the individual patient received recommended care. If this patient presented to the physician's office with a hemoglobin A_{1c} that was markedly elevated, his or her diabetic medications would be increased. If it was noted that the same patient may not have seen an ophthalmologist for 2 or 3 years, he or she would be counseled on the importance of having an eye examination.

Despite the potential to provide excellence in individual care, both patient and physician face limitations. These included siloed and fragmented efforts impacting coordination, integration, and communication between different points of a patient's care; less use of technology and data analysis to inform clinical decision making and better track patient adherence with recommendations; time constraints on an individual physician or other health care professional impacting the ability for greater patient

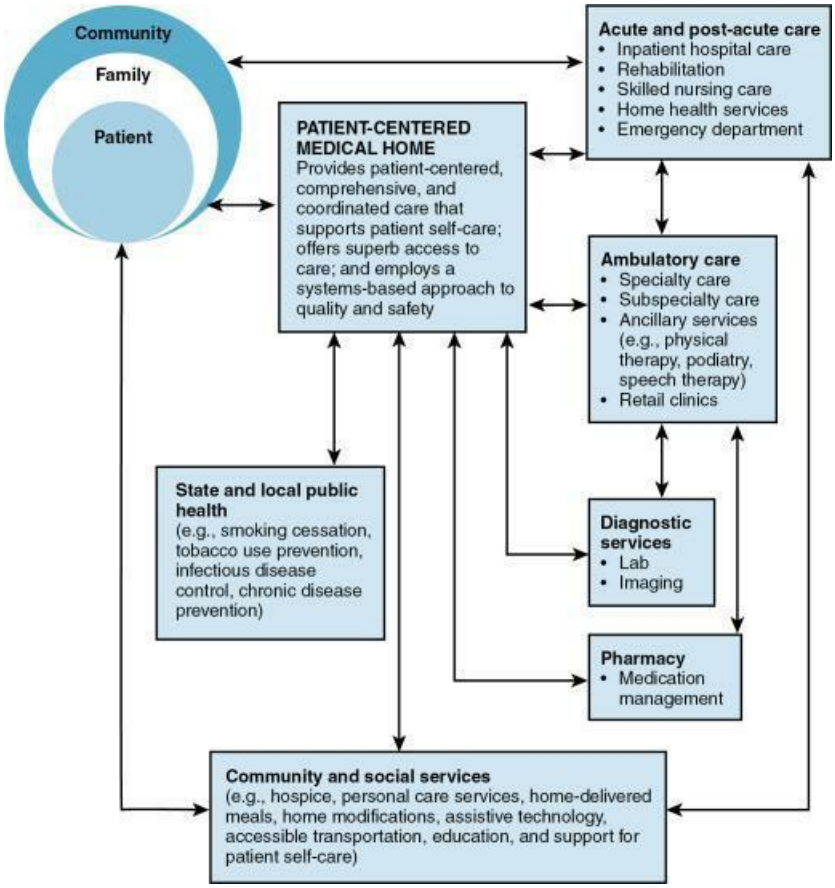
engagement in a patient's health care; lack of priority to probe the impact of social determinants of health and other barriers outside the walls of the clinic on the patient; and a lack of requirement in the fee-for-service reimbursement system for achieving a level of quality, outcomes, or accountability.

IV. Solutions to improve population health

A. Regulatory drivers

The Quadruple Aim of improved patient experience, improved health of populations, lowered per capita cost, and improved clinician experience focuses attention on key outcome goals for US health care delivery. The ACA instituted new models of care and alternative payment models, such as PCMHs, ACOs, and bundled payments, that are focused on and responsive to these goals. Through these models the 1:1 medical care focus is being broadened to incorporate a population health focus that includes population health management. Physicians and other health care professionals are expected to manage individual patients but are also increasingly responsible for managing populations of patients.[44]

The PCMH is a model of primary care that provides comprehensive, team-based, patient-centered, coordinated, accessible care focused on quality and patient safety. PCMHs are additionally focused on patient engagement in self-management, utilization of community support and resources, and population health management.[45] The patient-centered medical neighborhood (Fig. 11.4) is a framework to further enhance PCMHs by linking primary care, specialty care, health care delivery sites, public health, and community resources, consistent with a population health approach.[46] The ACO, which is an entity in a formal agreement with a payer to care for a population of patients, is accountable for quality, cost, and outcomes of its population of patients.[47] This accountability has prompted ACOs to focus on a number of areas, including process improvement, judicious use of data, transitions of care, and optimal patient follow-up. In bundled payment arrangements, the clinicians and the hospital are accountable for the quality and cost of the patient's episode of care (e.g., total knee arthroplasty), encouraging care coordination.[48] Important to consider is that process improvement, greater care coordination, and enhanced quality impact not only the individual patient, but also the population of patients who may experience the particular episode of care.



• **FIG. 11.4** **The Patient-Centered Medical Neighborhood.** *Source:* (From Taylor EF, Lake T, Nysenbaum J, Peterson G, Meyers D. *Coordinating Care in the Medical Neighborhood: Critical Components and Available Mechanisms.* AHRQ Publication No. 11-0064. Rockville, MD: Agency for Healthcare Research and Quality; June 2011.)

Other programs impacting traditional reimbursement, such as value-based purchasing, the Medicare Hospital Readmission Reduction Program, and the Medicare Hospital-Acquired Condition Reduction Program, were designed to drive higher quality and accountability for the care of both individual patients and populations. Hospitals have had to analyze process, quality, transitions of care, and patient satisfaction. Their efforts have also had to be grounded in evidence in order to achieve high quality of care and avoid financial penalties. These improvements benefit not only the individual patient but also the population of patients that may be hospitalized. The ACA requirement for a community health needs assessment (CHNA)[47] also contributes to broadening the population health focus and consideration of the health needs of communities beyond the walls of a clinic or hospital. Some hospitals are working collaboratively with local public health agencies on the CHNA and solutions.

In addition, MACRA, passed by Congress in 2015, repealed the Sustainable Growth Rate in which physicians faced annual reimbursement cuts through Medicare. This act created a framework for physicians to provide higher quality care through the Quality Payment Program and further incentivized a population health focus. The Quality Payment Program includes two tracks: the Merit-based Incentive Payment System, in

which physicians report data from four categories (quality, cost, interoperability, and improvement activities), and the Advanced Alternative Payment Model track.[49]

New models of care and APMs have made a significant contribution to the paradigm shift toward population health. Data collection, analysis, and research on the success of these programs are ongoing to determine the most effective interventions to disseminate for population health improvement.

B. Solutions within health care delivery

1. New tools supporting population health

In addition to new models of care and APMs, new technology is being introduced to help manage a population's health. These tools include:

- Electronic health records
- Risk stratification and analytic software
- Patient portals
- Wearable devices and biosensors
- Virtual health

a. Electronic health records

According to the US Department of Health and Human Services (HHS), EHRs "are built to go beyond standard clinical data collected in a provider's office and are inclusive of a broader view of a patient's care. EHRs contain information from all the clinicians involved in a patient's care, and all authorized clinicians involved in a patient's care can access the information to provide care to that patient. EHRs also share information with other health care providers, such as laboratories and specialists. EHRs follow patients—to the specialist, the hospital, the nursing home, or even across the country."[50]

The goal is for EHRs to allow timely, efficient access to large sets of population data, such as hemoglobin A_{1c} readings for populations of diabetic patients, blood pressure readings for populations of hypertensive patients, and cholesterol data for populations of patients with lipid disorders. Access to these data allows individual physicians, other health care professionals, medical practices, and health care systems to analyze how well clinicians are managing both acute and chronic disease processes for individual patients and populations of patients.

While an EHR allows for timely and efficient access to data, there are limitations at this time. Many EHR systems do not communicate with each other, limiting the generalizability of data to settings outside of the population the EHR is serving. In addition, EHRs may not contain retrievable data on the SDOH (such as socioeconomic status), and thus a complete picture of a population's health status may not be achievable solely through use of an EHR.

b. Risk stratification and analytic software

The use of risk stratification and analytics to manage populations of patients is

becoming increasingly prevalent. In order to effectively utilize risk stratification and analytics to manage populations, systems must be able to:

1. Integrate data from multiple health sources across the continuum of care, including from EHRs but also from mobile applications, wearable technology, and other data sources with which a patient may interact.
2. Develop and then integrate clinical risk algorithms into the care of patients and populations to ensure that those who need treatment receive it and those who do not need treatment are not "overtreated."
3. Deliver the analysis of data to those who must act on it, such as health care administrators, who must allocate resources based on population need; clinicians, who must act on their data to improve the clinical care of patients and populations; and individual members within the population, who can use the data to advocate for their own health and health care needs.

c. Patient portals

A patient portal is "a secure website that can interface with an EHR. It serves as a 24/7 access point for patients and can provide two-way communications between patients and practices, including providers, care teams, and administrative staff."[51] Patients can typically access the following through a portal:

- Summaries of recent physician visits
- Hospital discharge summaries
- Medications
- Immunizations
- Allergies
- Laboratory results

Depending on the patient portal, patients may also be able to schedule physician visits, e-mail their physicians with nonurgent questions about their health, and request prescription refills.[52]

Patient portals may benefit physicians, other health care professionals, and patients and are important for patient- and population-focused care. Physicians, other health care professionals, and patients may e-mail each other with nonurgent questions, decreasing the need for phone calls. Patients have access to their health care record and can check to ensure medications and refills are correct. Portals are designed to allow easier, more direct communication between patients and physicians or other health care professionals. For example, if a medicine needs to be adjusted for better diabetes or blood pressure control, a physician or other health care professional may simply e-mail a patient through the portal instead of trying to track a patient down by phone or making the patient come for an office visit.

d. Wearable devices and biosensors

Wearable technology can be defined as "mobile electronic devices that can be

unobtrusively embedded in the user's outfit as part of the clothing or an accessory."[53] Wearable technology allows for monitoring of factors influencing an individual's health, including monitoring of vital signs (such as heart rate and blood pressure) and number of steps an individual has taken. The information gathered from this wearable technology can then be integrated with other health care data to more effectively manage the health of an individual or a population.

One recent example of wearable technology is the Apple Watch (a trademark of Apple Inc., registered in the United States and other countries). The Apple Watch, like many smart watches, can monitor an individual's heart rate along with other measures of health, such as calories burned and steps and miles walked (or bicycled). The Apple Watch, however, has gained approval from the US Food and Drug Administration for an electrical heart sensor, capable of performing an electrocardiogram.[54] Another example of wearable technology is Google Glass, which is placed on an individual's face as a set of eyeglasses would be. Google Glass is voice control enabled to record both audio and video. Among its different functionalities, Google Glass allows surgeons to record their surgery from a first-person perspective, allowing for the teaching of a procedure to a multitude of learners. Google Glass also allows for remote consultations (e.g., by transmitting an image of a rash to a remote dermatologist).[55]

e. Virtual health

According to the American Academy of Family Physicians, virtual health "is the use of medical information that is exchanged from one site to another through electronic communications. It includes varying types of processes and services intended to enrich the delivery of medical care and improve the health status of patients."[56] Examples include:

- A dermatologist in a remote setting providing care to a patient in a rural setting through an Internet connection to examine a newly developed rash; or the broader use for dermatologic screenings of populations of farmers with a history of sun exposure
- A patient admitted to an intensive care unit at a rural hospital being monitored remotely by a team of physicians and nurses
- A panel of diabetic patients monitoring their blood sugars at home and uploading their blood sugar values to an endocrinologist, who will then adjust insulin doses to improve hemoglobin A_{1c} values across a population
- A patient with a sore throat who sees his or her primary care physician virtually through a smartphone application

2. New types of health care workers

The health care system of the 21st century still requires the knowledge and skills of traditional health care providers, including physicians, nurses, and pharmacists. However, as health care becomes increasingly complex and physicians and other health care professionals are asked to manage both individual patients and populations, other interdisciplinary health care providers with new knowledge and skills are required.

These new types of health care professionals include:

- Nurse care managers
- Community health workers
- Patient navigators
- Integrated behavioral health specialists

a. Nurse care managers

Nurse care managers coordinate and organize clinical care around individual patients as well as populations of patients.[57] Nurse care managers may perform some or all of the following tasks:

- Act as a conduit between patient and physician
- Answer patient questions
- Assist in managing chronic medical conditions
- Facilitate the transfer of information among a patient's providers, including specialty physicians
- Conduct home or hospital visits

Nurse care managers often serve as a bridge between patients and their physicians and health care professionals in primary care or specialty practices. For example, in a busy primary care practice, a primary care physician may have only 15 minutes to spend with a patient who has multiple chronic medical issues, such as diabetes, chronic obstructive pulmonary disease (COPD), and hypertension. A nurse care manager may reach out between office visits to ensure that this patient's blood sugars are controlled, the patient has oxygen for his or her COPD, and the patient is taking blood pressure medications.

b. Community health workers

The American Public Health Association defines a community health worker as "a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served."[58] Community health workers are located not only in the United States but also worldwide. Their role is typically adapted to the needs of the community they serve. For example, a community health worker in an urban location in the United States may provide counseling around sexually transmitted diseases or provide directly observed therapy for tuberculosis. The role of community health workers is expanding to integration into hospital and clinic health care teams with a greater focus on chronic disease management.[59]

c. Patient navigators

A patient navigator is defined as "a member of the health care team who helps patients 'navigate' the health care system and get timely care. Navigators help coordinate patient care, connect patients with resources, and help patients understand the health care system."[60] Patient navigators are often found in physician offices and help navigate

patients through one or more chronic health care conditions, such as diabetes or cancer. Some medical schools now train early medical students to serve as patient navigators to gain an understanding of the health care system prior to taking care of patients.[61]

The roles of a patient navigator and a community health worker overlap to some extent. However, for the purposes of this text, a patient navigator does not necessarily need to be a trusted member of the community in order to serve a population.

d. Integrated behavioral health specialists

Behavioral health specialists, such as psychiatrists, psychologists, social workers, and other mental health workers, are frequently being incorporated into primary care clinic settings. These behavioral health specialists are often available for initial consults, ongoing management, and medication management as needed by primary care physicians to care for patients' behavioral health concerns.

There are many other types of health care professionals who contribute to the care of individual patients and populations, including physicians, nurses, nurse practitioners, physician assistants, diabetes educators, pharmacists, dentists, social workers, and medical assistants. These health professionals and others are discussed in Chapter 8.

Case study 2

Mr. Reed, the 66-year-old male with type 2 diabetes introduced in Case Study 1, presents to the emergency department with a complaint of weakness. Workup in the emergency department is significant for elevated blood pressure and elevated nonfasting blood sugar. In light of Mr. Reed's complaint and medical history, he is admitted to the hospitalist service at the hospital to rule out a cardiac event. During his hospitalization his blood pressure is controlled and his blood sugar improves with a diabetic diet and rest. A myocardial infarction is ruled out. Mr. Reed is discharged home on a new medication for blood pressure.

In the past, Mr. Reed would have received discharge instructions and a new prescription and would have been instructed to schedule a follow-up appointment with his PCP. Mr. Reed might not have done this. The hospital discharge summary may have arrived in the PCP's office several days later or may have had to be requested when Mr. Reed next had an appointment and said he had been hospitalized.

In this current situation, the hospital where Mr. Reed was hospitalized is part of the same ACO as his PCP. New changes are instituted to support Mr. Reed:

- Upon discharge, Mr. Reed is assigned a nurse care manager to oversee his transition from the hospital to home.
- His care manager is tasked with ensuring that his PCP receives discharge paperwork, contacting Mr. Reed by phone within 48 hours of his hospital discharge, and helping facilitate a follow-up primary care appointment.
- Mr. Reed will also receive a visit from a community nurse within 30 days of discharge through a hospital program. The hospital is working to optimize support for the population of patients in the ACO.

1 How might these interventions impact Mr. Reed's health status? How might they affect his health outcomes and risk of readmission? How might they impact his

quality of life?

2 Are there any other interventions that the hospital or PCP should consider to further improve the health of Mr. Reed and other patients with diabetes?

C. Community-focused approaches for health disparities and inequity

Through a population health focus, disparities and associated SDOH at the local, community, and national levels can be analyzed to identify trends and associated solutions. In addition, contributing to ongoing population health research efforts, including community engagement designs such as translational research and community-based participatory research, is important.

Health care organizations can collaborate with public health agencies, community residents, and local organizations to define health priorities for communities through CHNAs. A CHNA is a "process that uses quantitative and qualitative methods to systematically collect and analyze data to understand health within a specific community. The data can inform community decision-making, the prioritization of health problems, and the development, implementation, and evaluation of community health improvement plans."[62]

Innovative health care delivery models focusing on value, using enhanced technology, incorporating team-based approaches, and integrating community resources and support are key new initiatives with promise to improve population health. National initiatives, such as Healthy People 2020, the National Partnership for Action to End Health Disparities sponsored by the Office of Minority Health within the HHS, and the National Institutes of Health Centers for Population Health and Health Disparities are important because they further inform health policy and legislation designed to eliminate health disparities and lead to improved population health (Table 11.1).

TABLE 11.1

Key Influencers in a Population Health Approach to Type 2 Diabetes

Key Influencer	Approach
Health Care Delivery	1. **Identify patient population—patients with type 2 diabetes in practice** 2. **Use data** a. Aggregate EHR data: HbA_{1c}; emergency department visits and hospitalizations; compliance with preventive care and clinic follow-ups b. Risk-stratify patients: high, medium, low c. Identify common determinants 3. **Optimize process and engage** a. Team approach to care b. Nurse care manager to prioritize high-risk/medium-risk patients c. Method to ascertain social determinants of health and address barriers d. Innovative use of technology such as communication via patient portal systems or texting e. Aggregated community resources for patient referral f. Method for post-hospitalization i. Care management for transition ii. Outpatient visit by community nurse iii. Timely data exchange of records g. Checklists/protocols 4. **Maintain ongoing evaluation** a. Quality and process improvement b. Utilizing evidence-based medicine while also considering patient preferences and capacity c. CHNA 5. **Develop relationships** a. Community b. Public health
Organized Public Health	1. **Identify community—geographic area** 2. **Use data** a. Establish and monitor prevalence of type 2 diabetes in community i. Use national and state data sources (e.g., BRFSS) ii. Routinely collect local epidemiologic data 3. **Optimize process and engage** a. Assessment of community needs and identification of barriers b. Community initiatives and events focused on diabetes c. Provision of resources for diabetes education and services d. Development of guidelines and toolkits for school and worksite wellness and nutrition e. Health services for vulnerable populations 4. **Maintain ongoing evaluation** a. CHNA b. Improvement plans 5. **Develop relationships** a. Health care delivery organizations b. Broader community c. Policymakers d. Evidence generators

Organizations in the Broader Community	**Examples of community-based resources** 1. National Diabetes Prevention Program, multiple locations in United States—focus on prevention of type 2 diabetes: CDC-approved curriculum, classes led by lifestyle coach 2. Camden Coalition of Healthcare Providers, Camden NJ—Faith in Prevention: exercise, wellness, and cooking classes 3. St. Vincent de Paul, Phoenix AZ—diabetes self-management education: classes 4. Farm Express, Phoenix AZ—mobile affordable produce market in a food desert
Health Policy	**Examples** 1. Medicare—coverage of Diabetes Prevention Program 2. Affordable Care Act—insurers cannot discriminate based on preexisting condition (e.g., diabetes) 3. National Clinical Care Commission Act—evaluation of existing prevention programs; support of integrated care, education, dissemination of information for diabetes
Evidence Generation	**Evidence basis for Diabetes Prevention Program** 1. Tuomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med.* 2001;344(18):1343-1350. 2. Diabetes Prevention Program Research Group. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. *Lancet.* 2009;374(9702):1677-1686. 3. Ali MK, Echouffo-Tcheugui JB, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? *Health Aff (Millwood).* 2012;31(1):67-75. **Other examples** 4. Collinsworth A, Vulimiri M, Schmidt KL, Snead C. Effectiveness of a community health worker-led diabetes self-management education program and implications for CHW involvement in care coordination strategies. *Diabetes Educ.* 2013;39(6):792-799. 5. Kaufman S, Ali N, DeFiglio V, Craig K, Brenner J. Early efforts to target and enroll high-risk diabetic patients into urban community-based programs. *Health Promot Pract.* 2014;15(suppl 2):62S-70S. 6. Reiss-Brennan B, Brunisholz KD, Dredge C, et al. Association of integrated team-based care with health care quality, utilization, and cost. *JAMA.* 2016;316(8):826-834.

BRFSS, Behavioral Risk Factor Surveillance System; *CDC*, Centers for Disease Control and Prevention; *CHNA*, community health needs assessment; *EHR*, electronic health record; *HbA_{1c}*, hemoglobin A_{1c}.

D. Population health initiatives

1. Hotspotting: Camden coalition of healthcare providers

Camden, New Jersey, is a city located across from Philadelphia, Pennsylvania, and the Delaware River runs between the two very different cities. Camden has the highest rate of crime of any city in the United States[63] and is one of the poorest cities in the United States, with over one-third of its population living below the poverty line. The Camden Coalition of Healthcare Providers is a prime example of a local organization integrating public health, clinical medicine, and the community in a poor, urban area through innovative use of data, care management, focus on critical barriers, and development of

resources, tools, and strategies.

Founded by Jeffrey Brenner, MD, the Camden Coalition of Healthcare Providers is a nonprofit "citywide coalition of hospitals, primary care providers, and community representatives that collaborate to deliver better health care to the most vulnerable citizens." Its mission is to "spark a field and movement that unites communities of caregivers in Camden and across the nation to improve the wellbeing of individuals with complex health and social needs."[64]

At the center of the Coalition's work is "hotspotting."[65] This is a data-driven process in which the highest utilizers of health care resources are identified (e.g., in many communities, as few as 10% of hospital patients account for 75% of health care spending). The Coalition uses insurance data to identify these high health care utilizers and uses real-time data through its health information exchange to identify those who are hospitalized. Once these patients are identified, resources are mobilized. These resources include a care management team composed of multiple health care professionals, including social workers, nurses, community health workers, and others, who visit the patient while in the hospital and once discharged to help manage disease, address complex social issues, reduce readmissions to the hospital,[66] and maximize health.

2. Homeless patient aligned care teams

An example of a national initiative integrating population health into clinical medicine is the Homeless Patient Aligned Care Teams (H-PACTs). H-PACTs are being implemented nationally at Veterans Administration (VA) medical centers. The goal of the H-PACTs is to end veteran homelessness in this high-risk population.

H-PACTs are located on the campuses of VA medical centers. H-PACTs integrate many health professionals, including physicians, nurses, social workers, behavioral health specialists, and substance abuse counselors. This team provides services to homeless veterans, including helping find permanent housing. Patients can also receive medical care through H-PACTs as well as a warm shower and clean clothes, if needed. One of H-PACT's main tenets is that improving health goes beyond medical care. H-PACTs espouse the idea that providing safe, stable housing is providing health care.

While the data analyzing H-PACT outcomes are pending, preliminary results demonstrate that patients enrolled in an H-PACT are hospitalized and use the emergency department less than patients not enrolled. This decrease in hospital utilization translates to savings for the VA system of about $5 million per year.[67]

3. Million hearts 2022

Million Hearts is an extensive national-level initiative whose goal is to prevent 1 million heart attacks and strokes by 2022. Priorities of the initiative include keeping people healthy, optimizing care, and improving outcomes for priority populations. Keeping people healthy is a targeted focus on changing the environment to decrease smoking, reduce sodium intake, and increase physical activity. Optimizing care includes improved ABCS: aspirin use, blood pressure control, cholesterol management, and

smoking cessation. It also includes increased use of cardiac rehabilitation and engaging patients in heart-healthy behaviors within a framework of health technology and tools and innovation in health care delivery. Priority populations are "Blacks/African Americans with hypertension, 35- to 65-year olds, people who have had a heart attack or stroke, and people with mental and/or substance use disorders."[68]

Million Hearts has extensive partners from the public and private health care sectors, inclusive of federal agencies, state departments of health, national specialty and disease-focused associations, health care systems, physician groups, local associations, and payers. The partnership includes 100 Congregations for Million Hearts. This faith-based program includes congregations that have committed to strengthening relationships with community resources, including community health centers and community health workers, for their members.[69]

Through Million Hearts, a significant number of protocols, guides, and tools have been made available for clinicians, patients, public health agencies, and employers to focus on control of hypertension and cardiovascular health. Collaborations are bringing together public health and medical care surrounding cardiovascular health and prevention.[70,71]

V. Future of population health

Population health is growing and evolving. A number of new initiatives set the tone for this growth to accelerate and to continue to impact medical care. The HHS has been increasingly focused on payment for quality over quantity. Goals have been set to tie certain percentages of traditional payments from Medicare to APMs such as ACOs or bundled payments and tie all Medicare payments to quality or value through value-based purchasing or the Hospital Readmission Reduction Program.[72] In addition, full implementation of MACRA and the Quality Payment Program is likely to affect population health while reducing the cost of care.

The Health Care Payment Learning and Action Network was created in 2015 by the HHS to bring together public and private payers to delineate best practices and acceleration of transition from the traditional fee-for-service payment model to APMs focused on improved quality, health outcomes, and lowered costs.[70] Hospital providers in an industry consortium, the Health Care Transformation Task Force, have committed to 75% of their business operating in value-based payment arrangements by 2020.[71] ACOs may be required to take on greater risk in the near future.[73] Increased accountability and financial risk are accelerating the focus in medical care on optimizing quality, cost, outcomes, and health for individual patients and populations of patients.

Significant work is ongoing through the State Innovation Models initiative to test state-led multipayer health care delivery and payment models. This is inclusive of work focused on Accountable Health Communities[74] as well as other collaborative efforts among primary care providers, public health agencies, community organizations, and social services.[75] Particular focus is being paid to the SDOH.[76]

The American College of Cardiology advanced its focus on population health through the creation of a population health committee. Its goals include a focus on primary prevention, health promotion, greater collaboration with primary care, and greater attention to the behavioral and social determinants of health. This is a significant paradigm shift for a specialty group that has been historically procedure based rather than focused on prevention and population health.[77]

Significant opportunity exists for collaborative efforts among medical care, the public health system, and initiatives in the broader community. The siloed nature of these key influencers on population health as well as different sources of funding and reimbursement have been barriers. However, ongoing initiatives such as the Camden Coalition of Healthcare Providers, Homeless Patient Aligned Care Teams, and Million Hearts are bridging health care delivery, public health, and the community. The ACA has supported assessment and connection to community resources through new models of care and other requirements. Outcomes of State Innovation Models, including Accountable Health Communities, are expected to provide insight into ways to support health care delivery–public health–community collaborations.

Despite these encouraging efforts, there is still much work to do. A population health focus in medical care needs to expand to all specialties and sites of care. As noted

earlier, health care is deemed to be responsible for only 10% of the determinants of population health, yet health care in the United States garners the most attention and financial support. The health care delivery system–public health–community collaboration needs to become much more comprehensive so that resources, attention to prevention and health promotion, efforts focused on disease management and self-management, and data are shared more effectively. Attention and action to address the SDOH and their root causes need to be much more robust. Population health will achieve its greatest improvement in the future with the broad acceptance of responsibility beyond one sector or one determinant and with multi-stakeholder engagement and collaboration.

VI. Education initiatives in population health

Realizing that physicians must possess the knowledge and skills related to population health in a rapidly evolving health care system, medical schools across the United States are responding by integrating population health content into curriculum. The following are examples of schools integrating population health content:

- **The Warren Alpert Medical School of Brown University (AMS):** The AMS created a dual degree program. Students receive a medical degree and a Master of Science in Population Medicine degree in 4 years. A proportion of all of their students enter this program each year. Students take courses directly related to population health, including courses on health disparities, social determinants of health, leadership, health systems, biostatistics, epidemiology, and the intersection of population health with clinical medicine.
- **Mayo Clinic Alix School of Medicine:** The Mayo Clinic, in collaboration with Arizona State University's College of Health Solutions, has developed a required certificate in the science of health care delivery for their medical students. Both online and classroom teaching is delivered throughout the 4 years of medical school in the areas of population-centered care, high-value care, team-based care, leadership, person-centered care, health policy, economics, and technology.[78,79] Expansion of the curriculum has included global health and unconscious bias. Students have the option to complete a Master of Science in the Science of Health Care Delivery degree through Arizona State University to expand knowledge and tools in biostatistics, process engineering, health care management, and finance and to complete an applied project.
- **Pennsylvania State University College of Medicine:** Penn State created a longitudinal course that all students take directly related to population health. This course intertwines content on evidence-based medicine, teamwork, and leadership. In addition, all students at Penn State become patient navigators, helping patients navigate through the different facets of the health care system.

Other examples of schools responding to the need to integrate population health into their curriculum include Case Western Reserve University School of Medicine, which introduced a similar patient navigator program into its curriculum; Florida International University Herbert Wertheim College of Medicine, which has integrated the social determinants of health into its curriculum; and Rutgers Robert Wood Johnson Medical School, which is training its medical students in care coordination. The American Medical Association's Accelerating Change in Medical Education grant initiative has provided support for these innovative changes in medical school education.[80]

VII. Chapter summary

Population health as a concept and field is gaining significant momentum due to policy, regulatory change, research funding, and multi-stakeholder engagement through collaborative initiatives at the national, state, community, public health, and medical care levels. The population health agenda is aligned with the goals of the Triple and Quadruple Aims, new models of care, and APMs with a population health focus. National and local population health initiatives and the Center for Medicare & Medicaid Innovation funding are establishing new models that can be disseminated and emulated more broadly. Integration of population health content into health professions curriculum is producing a new generation of health care professionals ready to employ the principles of population health to improve the health of individuals and groups across the United States.

Much work remains, but current efforts are creating a foundation for both a focus on population health and a means for improvement of population health in the United States.

Questions for further thought

1. What are drivers of the population health focus in the United States?
2. How do the key influencers of population health contribute to population health improvement?
3. What are the determinants of population health, and how much does health care play a role?
4. What is setting the tone for the future of population health?
5. How is a population health focus being operationalized in the medical care setting?

Exercise

Population health is increasingly a focus of health care professionals and the health system. Consider one of your recent interactions with a patient. How is a population health focus currently impacting that patient's health care and health status, if at all? Consider how a population health focus could have more or less of an impact on that patient's health in the future. What types of interventions could provide the most benefit? What interventions could provide the least? What are the barriers to implementing population-based interventions for this particular patient?

Annotated bibliography

Bodenheimer T, Grumbach K. Understanding Health Policy, 7th ed. 2016; McGraw-Hill New York, NY.

This textbook on health policy is edited by two leading health policy experts, Dr. Bodenheimer and Dr. Grumbach, both from the Department of Family Medicine, University of California, San Francisco, School of Medicine. The text focuses on multiple aspects of medicine related to population health, including access to and paying for health care; the organization of health care, including primary, secondary, and tertiary care; costs of care, including how to control costs; and other health care systems. Throughout the text, examples of the Triple Aim and population health are emphasized, including quality health care, controlling costs, and enhancing the patient experience.

Healthy. People 2020 Updated June 19, 2019; US Department of Health and Human Services, Office of Disease Prevention and Health Promotion Washington, DC Available at https://www.healthypeople.gov Accessed June 19, 2019.

Healthy People 2020 is managed by the Office of Disease Prevention and Health Promotion within the US Department of Health and Human Services but is a collaboration with other federal agencies as well as local community organizations. This initiative is a nationwide program to improve the health of all through a focus on disease prevention and health promotion. The original health goals were issued in 1979. Updates were subsequently made with new goals for improved health over 10 years by 2000, 2010, and 2020. Current goals are to attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; achieve health equity; eliminate disparities; improve the health of all groups; create social and physical environments that promote good health for all; and promote quality of life, healthy development, and healthy behaviors across all life stages.

Kindig D, Stoddart G. *What is population health* Am J Public Health 3, 2003;93: 380-383.

This is a seminal article on population health. Dr. Kindig from the Department of Population Health Sciences, University of Wisconsin–Madison School of Medicine, and Dr. Stoddard from the Department

of Clinical Epidemiology and Biostatistics, McMaster University Health Science Centre, very thoughtfully consider the meaning of population health based on prior definitions and considerations. They discuss population health as a concept of health that most appropriately involves health outcomes, determinants of health, and policy. In the article, they put forth a definition of population health to provide some consensus for the field. Their definition—"the health outcomes of a group of individuals, including the distribution of such outcomes within the group"—is now widely used and respected. The authors further discuss the concern of population health with interactions between determinants of population health and the importance of multi-stakeholder "attention and action" for improved population health. Lastly, they put forth population health as a framework to consider health outcomes and their distribution, and to assess the determinants of population health, forcing broad responsibility for population health beyond one sector or one determinant.

McGinnis JM, Williams-Russo P, Knickman JR. *The case for more active policy attention to health promotion* Health Affairs 2, 2002;21: 78-93.

This article, authored by a group from the Robert Wood Johnson Foundation, provides a comprehensive review of the determinants of health, genetics, social circumstances, environmental conditions, behavioral choices, and medical care, to emphasize the importance of supporting policy and funding of health promotion initiatives to meaningfully improve population health. Included is a review on factors limiting these initiatives and recommendations for further progress.

Nash DB, Fabius RJ, Skoufalos A, Clarke JL, Horowitz MR. Population Health Creating a Culture of Wellness, 2nd ed. 2016; Jones & Bartlett Learning Burlington, MA.

This textbook on population health is edited by a group of educators including Founding Dean David Nash, MD, MPH, from the Jefferson School of Population Health. Particularly aimed at those training and working in health care delivery sites, the book focuses both on key aspects of population health management and on a strategy for creation of a culture of wellness in the United States. The impact of the ACA on population health is woven throughout the book. The book is organized into five sections that highlight key concepts of population health; the role of the consumer in a health

care system characterized by population health; consideration of the continuum of care; population health and the business case for a value-driven health care delivery system; and future directions in research. Put forth are four pillars of population health inclusive of chronic care management, quality and safety, public health, and health policy. Discussed is the broad set of initiatives that define population health, including health promotion, disease prevention, and engagement of multiple stakeholders in the areas of prevention, health care delivery, medical intervention, public health, and policy. Lastly, the book emphasizes the strong focus of population health on analysis of outcomes to drive process change and new policy.

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12

Structural and social determinants of health

Ian Kim, MD, Elizabeth Baxley, MD, Sara Teasdale, MD, Alicia Gonzalez-Flores, MD, Kimberly D. Lomis, MD, Tonya Fancher, MD, MPH

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In this chapter

The structural and social determinants of health are crucial to overall population health and to the equitable distribution of health within a population. Exploring the reasons why structural, social, and economic conditions are so strongly correlated with health outcomes helps explain the wide health disparities that exist in the United States and in many other places around the world. This chapter describes the evidence base and impact of structural and social determinants of health and concludes with suggested steps to address these determinants.

Learning Objectives

1. Describe the relationship between structural and social determinants of health, health equity, health disparities, and health inequities.
2. Describe how structural and social determinants of health and health inequity lead to adverse health outcomes for patients and populations.
3. Describe examples of structural and social determinants of health and how each impacts health outcomes.
4. Describe how physicians, health care professionals, health systems, and communities can address structural and social determinants of health and health inequity.
5. Describe opportunities for physicians and health care professionals to be advocates for patients and populations.

"Health inequalities result from social inequalities."[1]

—Michael Marmot

I. Introduction

Americans tend to see health as a function of access to health care services, assuming that those who are unhealthy are so primarily because they lack access to health care. However, direct care delivery accounts for only a fraction of health outcomes. As leading social epidemiologist Ichiro Kawachi put it, the fact that aspirin treats fever does not imply that the cause of fever is lack of aspirin.[2] Simply put, health is not equivalent to health care.

This chapter explores how the conditions in which people live, work, play, and age—commonly known collectively as the social determinants of health—influence health outcomes. Such factors, however, are not simply attributable to individual life choices. There are structures in place that drive inequities in health and predetermine many of the social determinants impacting an individual or community. Social stratification results in differential exposure to health-damaging conditions and results in differential consequences of ill health for more and less advantaged groups.[3] In arguing the need for structural competency, Metzl and Hansen[4] proposed that:

> clinicians require skills that help them treat persons that come to clinics as patients, and at the same time recognize how social and economic determinants, biases, inequities, and blind spots shape health and illness long before doctors or patients enter examination rooms.

The chapter elucidates these factors that profoundly influence health and outlines the roles health providers can serve in addressing the needs of individual patients, communities, and society.

II. Case studies and exercise

As you read through this chapter, keep in mind the experiences of the patients presented in these case studies. Look for relevant information and consider the questions about each situation.

Case study 1

G.C., 22 years old, is coming into your clinic to establish care and discuss hormone therapy. When you walk into the room and introduce yourself and ask, "What brings you to the clinic today?" G.C. says, "I identify as a man, and I want to talk about starting hormone therapy." G.C. goes on to say that when he was 7, he started to realize that he did not feel like the girl everyone told him he was. He started to dress and act like a boy at around 10, but his parents were never supportive. His pediatrician would not discuss his gender with him. He got really depressed by the time he was in high school and started drinking and using drugs at 15. He had a few car accidents while under the influence of alcohol and did attempt to cut his wrists out of anger. He denies suicidal intent or attempts. He dropped out of high school during his senior year. He had met some friends online who also identified as male and decided to move to the city to find people who were more like-minded. For the last 2 years he has been living as a man, working odd jobs, and feeling happier with his new peer group. He has cut back drinking to about two to three times per month and never more than four drinks at a time. He does have sex with both men and women and uses condoms most of the time. He has not been screened for sexually transmitted infections in the last 8 years. After his experience with the health care system, he has been hesitant to see a doctor and has not had any age-appropriate vaccines or screenings since he was 16.

1. What about the health care system leads transgender individuals to develop mistrust of physicians and other health care professionals? What strategies can physicians, other health care professionals, and health systems use to improve the experience for transgender individuals or other groups of patients?
2 How are health outcomes different in transgender populations? What strategies can physicians, health care professionals, and health systems use to improve health outcomes for this population?

Case study 2

M.K. is a 65-year-old African American man presenting to establish care in your clinic. He has a history of anxiety and tobacco dependence. The last time he saw a primary care doctor was 20 years ago. He uses the emergency department as needed for care. His primary complaint is intermittent chest pain. When you ask more about the chest pain, you learn that it comes on when he is thinking about his grandson's night job. M.K. has helped raise his grandson from the time he was a small child. His grandson is in high school and works at night to earn money in hopes of attending college. M.K. is troubled by stories on the news about racial profiling. In a recent incident in their neighborhood, a young Black man was shot by the police. M.K. loses sleep over his grandson being out on the streets at night.

1 What are the chronic effects of structural racism?
2 What factors might be contributing to M.K.'s use of the emergency department rather than accessing primary care? How might you help him to navigate the health system?

Case study 3

R.L. is a 30-year-old, Thai-speaking woman with a history of gestational diabetes presenting to the student-run free clinic for headaches. She has a headache that is on both sides of her head, occurs most days, and improves with rest. She has no photophobia or changes in vision, and her blood pressure is normal. The headaches start around 2 pm when her children get home from school. She is working part time and managing the household. She is married and has three children, ages 5, 7, and 11. Her husband works in construction. R.L. does not have time to exercise and finds that she eats a lot of fast food because the kids like it and it is easy for her. Her support system is limited; most of her family is in Thailand, where she grew up. R.L. comfortably volunteers that she is undocumented as she talks about her situation. Her children qualify for supplemental nutrition programs and free meals at school.

1. How do immigration and documentation status impact R.L.'s health?
2. What strategies can providers and health systems use to improve health outcomes for individuals like R.L.?
3. Consider who is responsible for R.L.'s reliance on fast food outlets. How might you ask about food insecurity? What other social determinants would you want to ask about? How would you go about exploring this family's needs?

Exercise

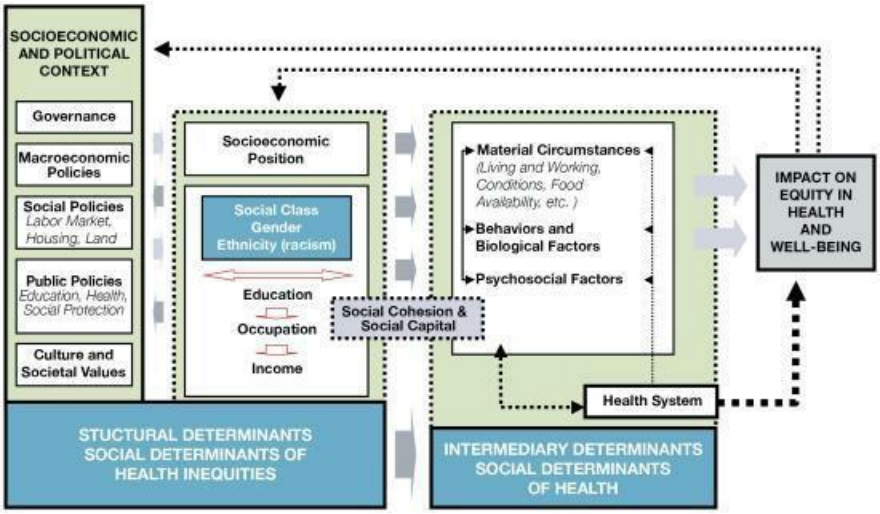
The Adverse Childhood Experiences (ACE) study revealed powerful connections between long-term health and the social and environmental circumstances of an individual during his or her childhood. Ask permission to interview people in the local community about their childhood experiences using the ACE Questionnaire and calculate their ACE scores:

- ACE Questionnaire:
https://www.ncjfcj.org/sites/default/files/Finding%20Your%20ACE%20Score.pdf
- ACE background:
https://acestoohigh.com/got-your-ace-score/

Discuss your findings with a fellow student or a mentor. What surprised you about the results of the interviews? Did you identify "resilience factors" among those sharing distressing experiences that may protect them from long-term adverse health outcomes? Are there modifiable risk factors currently exhibited by any of these individuals that could be addressed?

III. How structural and social determinants lead to adverse health outcomes

The World Health Organization (WHO) published a framework (Fig. 12.1) in 2010 to conceptualize the impact of social structures on the health of populations and individuals.[3] Clarity about the sources of health inequities is important to appropriately direct action on the social determinants of health; differing issues demand differing responses. This model describes structural drivers of health inequities that predetermine the distribution among individuals of more immediately visible social determinants of health, such as housing and access to nutritious foods. Such framing helps physicians and other health care professionals understand that individuals do not freely chose to pursue unhealthy behaviors; many people are placed in situations beyond their control.



• FIG. 12.1 Final Form of the World Health Organization's Commission on Social Determinants of Health Conceptual Framework for Action on the Social Determinants of Health. *Source:* (From Solar O, Irwin A. A conceptual framework for action on the social determinants of health. *Social Determinants of Health Discussion Paper 2 [Policy and Practice].* Geneva: World Health Organization; 2010.)

The ultimate impact of social pressures is a strong correlation between socioeconomic position, educational attainment, and health outcomes. The effect of poverty is visible in undesirable living conditions, poor nutrition, and inadequate access to health care. For almost every condition, there are differences in mortality and morbidity related to socioeconomic position. This finding is compounded by a vicious cycle—poor health in turn diminishes one's socioeconomic status—making it difficult for individuals to overcome the original structural drivers.

It would be an oversimplification, however, to assume that socioeconomic position alone accounts for differences in health outcomes. The American culture values the

concept of social mobility—that an individual has opportunity to better his or her situation. However, upwardly mobile individuals have been found to have worse health outcomes than others in the class that they enter.[5] For example, studies have documented that the risk of preterm birth among African American women is about 50% higher than among white women, even after correcting for household income and education levels. Contemporary research seeks to understand how socioeconomic status itself is an etiologic factor that influences biologic functions.[6] A national working group funded by the MacArthur Foundation and led by physician and researcher Nancy Adler produced a body of research and reports tackling the question of mechanisms for how social conditions impact health.[7]

The central model that has gained wide acceptance focuses on stress. Most of the time, stress does not lead to illness. However, repeated exposures to stress over time can accumulate in an individual, referred to as **allostatic load**, and may contribute to adverse health outcomes.[8] This allostatic load hypothesis begins with the neuroendocrine fight-or-flight response. In reaction to a noxious stimulus, the body is flooded with stress hormones, including cortisol. After neutralizing or avoiding a threat, the physiologic response typically shuts off and the body gradually returns to its baseline.[8] But what happens if the fight-or-flight response does not shut off? What happens if it stays switched on, for days, weeks, or months at a time? Physician and epidemiologist Camara Phyllis Jones has described this in the context of racism, by likening the stress of structural discrimination to an automobile running at high RPMs continuously for days, weeks, and months.[2] Eventually, the automobile breaks down. The human body is not all that different in this way. Stressors can be physical or social and can be acute or chronic. Human stress responses are typically measured via the accumulation of cortisol, and persistently high cortisol levels have been strongly linked with multiple morbidities and mortalities,[8] including many of the most prevalent diseases in the United States today.[2,9-11] The persistent accumulation of cortisol may be especially damaging during the sensitive and critical period of early childhood. Indeed, a number of studies have documented the ways in which the accumulation of stress hormones is neurotoxic and can actually disrupt the architecture of the developing brain with lifelong (and perhaps even intergenerational) consequences.[12] Sustained psychosocial stress is associated with shorter telomeres. Reduced telomere length, a proxy for cellular aging, is linked with chronic diseases such as diabetes, cancer, and heart disease.[13]

Other mechanisms under investigation to explain how inequities within the social determinants impact health include negative impacts in neuroanatomy and neuroplasticity (early childhood stressors and trauma influence brain architecture and development, impacting the ability to learn new skills, regulate stress, and adapt to future adversity)[13,14]; immune dysregulation (interleukins and immune proteins create chronic inflammation that increases the risk of heart disease and other chronic diseases)[15]; and epigenetic changes (chronic stress affects methylation of DNA and causes epigenetic changes that "turn on" expression of genes that may cause cancer and other diseases).[16]

IV. Structural determinants of health inequities

A. Class

The term *socioeconomic position* or *socioeconomic status* refers to the social standing or class of an individual or group and is often measured as a combination of education, income, and occupation. The Whitehall Studies—a longitudinal cohort study initiated in the 1950s of British civil servants who all had access to medical services through the National Health Service—evaluated the impact of different variables on the participants' health.[17] Since all participants had health care provided through the National Health Service, health disparities could not be attributed to differences in access to care. The Whitehall Studies found that employment grade, as a proxy for socioeconomic status, has a strong and graded relationship with health. A graded relationship between socioeconomic status and health has been found in nearly every industrialized country in which it has been studied.[7]

While socioeconomic position can drive health outcomes, the reverse is also true—health status can affect an individual's ability to earn or retain wealth. Medical bills are a leading cause of bankruptcy in the United States. Elements of socioeconomic position are cumulative. Race, social class, and early childhood education are each strongly and independently correlated with population health, so people of color from families whose income is low and who are without access to preschool education face a convergence of disadvantages that are interwoven and that may multiply negative impacts on health outcomes.

B. Gender

Gender is socially constructed, defining expected roles and relationships. In many cultures, women have systematic unequal access to power and resources. A physical manifestation of the impact of gender on health is apparent in violence against women—battery and rape. The recent #MeToo movement has demonstrated women's pervasive experience with sexual harassment and assault.[18]

Gender-based discrimination also impacts educational and employment opportunities. Young women are dissuaded from pursuing education in certain fields, such as science, technology, engineering, and math (STEM).[19] Repeated studies demonstrate a pay gap between men and women in the same jobs.[20] Women are more likely to reduce hours or leave work related to the responsibilities of maintaining a household, which in turn limits advancement. This impact of gender persists even among the highly educated and professionally employed. For example, in a study of dual-physician couples,[21] weekly hours worked by women with children were lower than among women without children, whereas similar differences were not observed among the male physicians. In a survey of practicing surgeons,[22] female surgeons were more likely than their male counterparts to be married to another professional, yet the

female surgeon partner in those dual-profession relationships was more likely to have responsibility for child care and grocery shopping.

Women of color and female immigrants suffer disproportionately from gender effects, partially due to the compounding effects of other variables such as socioeconomic status and racial discrimination. Kimberlé Williams Crenshaw described the concept of "intersectionality" to illustrate the limitations of political advocacy based on identity—women of color do not have the same experiences as other women related to gender discrimination nor the same experiences as Black men related to racism, so larger identity-based advocacy movements commonly fail them. As with all social determinants, differing solutions are needed to fully address variations in individual circumstances.[23]

C. Race and ethnicity

Health disparities by race are pervasive and persistent. According to the Centers for Disease Control and Prevention[24,25]:

- Blacks have significantly higher early death rates compared to whites from heart disease, cancer, stroke, diabetes, kidney disease, hypertension, and homicide. Blacks have higher rates of preterm births and infant mortality, independent of educational attainment and income.
- Rates for drug-induced deaths are highest among American Indians/Alaska Natives and non-Hispanic whites.
- Suicide rates are higher for American Indian/Alaska Natives and non-Hispanic whites compared with non-Hispanic Blacks, Asians/Pacific Islanders, and persons of Hispanic ethnicity.
- People of color experience higher rates of human immunodeficiency virus (HIV) diagnosis; Blacks are less likely to be prescribed antiretroviral therapy than whites.
- Mexican Americans with hypertension experience poorer blood pressure control than members of all other racial/ethnic groups.
- The likelihood of working in a high-risk occupation is greatest for those who are Hispanic.
- Asian Americans and Pacific Islander Americans are more likely to have diabetes and end-stage renal disease, tuberculosis, hepatitis B, and liver cancer compared to whites.[26]

National data show that disparities by race are present after controlling for socioeconomic status, and at every level of socioeconomic status.[27] In one national study, after adjusting for income, education, gender, and age, Blacks had higher measures of blood pressure, inflammatory markers, and total disease risk compared to whites. This was true even after adjusting for health behaviors.[28]

What role do genetics play in these disparities? Researchers have suggested that genetic predispositions can explain only a portion of the noted racial health disparities.

Similar racial health disparities exist all over the world among divergent genetic ancestry groups.[29,30] Additionally, disparities are observed based on not only race but also ethnicity, which refers to cultural factors, including nationality, religion, regional cultures, and languages. Most social epidemiologists argue that the primary explanation is **structural racism**.

The term *racism* refers to an organized system that categorizes population groups into "races" and uses this ranking to preferentially allocate societal goods and resources to groups regarded as superior.[31,32] Americans often think of racism in terms of individual behavior, but to understand racism, one must examine how it operates in institutions and systems of society. This concept is often referred to as structural racism. Gee and Ford offer the useful metaphor of an iceberg.[33] Obvious, individual acts of racism are the visible tip, while inequitable policies and procedures form the hidden base of the iceberg below the waterline. Interventions directed at the former may do little to address the latter. Structural racism is evident in many facets of American society, including allocation of educational funds, juvenile and criminal justice policies and procedures, housing and real estate, and the health care system.

D. Education

Education—generalized education from preschool to high school graduation and continuing in young adulthood with postsecondary education—has a profound impact on health for individuals, communities, and populations.[34-37] Importantly, the United States has near-universal commitment to K–12 compulsory schooling.

Access to, and quality of, education are impacted by socioeconomic status. In turn, education leads to health benefits by multiple mechanisms, both direct and indirect. Education directly contributes to cognitive skills, problem-solving ability, learned effectiveness, and personal control, all of which contribute to a greater ability to pursue healthy behaviors and can mediate an individual's exposure to and management of stress and allostatic load. Higher education indirectly boosts health status by improving access to jobs and social resources. Individuals with educational advantage can better avoid economic hardship such as unemployment, and secure employment enhances the likelihood of having the resources to minimize and manage the consequences of disease once it occurs.[38]

There is a persistent and growing gap in health status between Americans with high and low educational attainment.[37] The relationship between years of education and health benefits is graded. In the K–12 pathway, each additional year of completed education has accumulating reduction in mortality risk, becoming more pronounced at high school graduation, which has a fivefold greater reduction in mortality risk compared to completion of any preceding year. This suggests particular importance of the high school diploma as a credential. Education beyond high school also has comparatively larger health benefits.

Causality also operates in the reverse direction. Those dealing with chronic illness have greater difficulty succeeding in school. Basch proposed five pathways by which health affects motivation and ability to learn: sensory perceptions, cognition, school

connectedness and engagement, absenteeism, and temporary or permanent dropping out.[39] Intuitively, learning depends on adequate vision, hearing, cognition (executive function, memory, and attention span), and consistent school attendance; health conditions can affect any of these factors. Facilitating health care access can help ensure that identified problems (e.g., with vision, asthma, or attention-deficit/hyperactivity disorder) are addressed.

Health care professionals should consider advocating for policy that can overcome educational inequalities just as they might "advocate against smoking or in support of early childhood immunization."[36] The connection between educational attainment and early childhood development is especially significant. Unlike many other industrialized nations, the United States does not ensure universal preschool for families. Preschool is available only to those communities or those families that have the resources to provide for it, likely giving rise to significant disparities in development and health. The evidence is strong showing that the kind of education and environments that occur in early childhood are uniquely important in determining population health across the entire life span. The reliance on local and municipal resources for funding public schools contributes to educational inequalities. Towns and communities have widely variable tax bases, and poorer communities have fewer resources to support educational programs in and out of schools. These variable resources lead to widespread educational inequalities, which then correlate strongly with health disparities.[35,36]

V. Social determinants of health

A. Material circumstances

1. Neighborhood and built environment

A person's zip code is a better predictor of health outcomes than his or her genetic code. The National Collaborative for Health Equity characterized the impact of neighborhood and zip code on health under the heading "Place Matters."[42]

Residential segregation in the United States may be one of the most pernicious and health-adverse dimensions of structural racism. As Williams and Mohammed observed, "Historically, two pronounced patterns of residential segregation in the United States have been the geographic isolation of American Indians on reservations and the residential concentration of African Americans in poor urban areas."[31] The practice of redlining is a primary factor responsible for racial residential segregation and refers to the practice of refusing a home loan to someone due to a belief that the individual lives in an area of high financial risk. The Federal Housing Administration (FHA), created in the 1930s after the Great Depression, established and promoted race-based redlining. The FHA systematically assigned its highest-risk category to African American neighborhoods, channeling funding away from those neighborhoods. As a result of these policies, the vast majority of FHA mortgage loans went to borrowers in white middle-class neighborhoods, and very few were awarded to Black neighborhoods in central cities.[43] Because homeownership is an important step in developing personal capital, this limited the ability of many families to advance economically. Businesses were discouraged from investing in these neighborhoods deemed "high risk," resulting in poor infrastructure. Although redlining was made illegal in 1968 with the Fair Housing Act, the ongoing, persistent consequences for population health cannot be underestimated.[44] Braveman elaborated:

> A legacy of racial residential segregation continues to track many Blacks and Latinos into neighborhoods not only with directly unhealthy influences on nutrition and physical activity, but also with poor employment opportunities and poorly performing schools. Because educational attainment shapes employment opportunities, racial segregation propagates the inter-generational transmission of poverty and the ill health that accompanies it.[45]

Braveman and colleagues offered a three-level analysis emphasizing (1) physical conditions within homes, (2) conditions in the neighborhoods surrounding the homes, and (3) housing affordability.[46] Avoidance of investment in poor communities perpetuates poor conditions at all three levels. Taking these in order, one can understand how physical conditions within and around homes can shape overall

health.

First, a home that features high levels of mold can be dangerous to its occupants, especially where one or more of the inhabitants experiences a respiratory illness such as asthma or reactive airways disease. An estimated two-thirds of the time American families spend indoors is spent at home, with children being home an even larger proportion of that time.[46] Another example of a dangerous condition in the home that can disproportionately impact child health and development is the presence of lead-based paint. According to the US Department of Housing and Urban Development's 2011 American Healthy Homes Survey, almost 35% of American homes (37.1 million homes total) have lead-based paint located somewhere in the relevant structure, with children younger than 6 years of age being exposed to this hazard in 3.6 million homes.[47] The hazards of lead exposure are distributed along a wealth gradient, with low-income households experiencing a higher prevalence of lead-based paint hazards.

Second, neighborhood conditions also matter. Braveman and colleagues pointed out the following:

> [A] neighborhood's physical characteristics may promote health by providing safe places for children to play and for adults to exercise that are free from crime, violence and pollution.... Social and economic conditions in neighborhoods may improve health by affording access to employment opportunities and public resources including efficient transportation, an effective police force and good schools.[46]

Lighting and sidewalks are correlated with perceived safety and willingness to exercise outdoors. Living in a neighborhood experiencing higher crime rates and violence impacts exercise, physical health, and mental health.

Third, housing affordability also has a significant health impact:

> the shortage of affordable housing limits families' and individuals' choices about where they live, often relegating lower-income families to substandard housing in unsafe, overcrowded neighborhoods with higher rates of poverty and fewer resources for health promotion.[46]

Developers avoid investment in areas in which they anticipate lesser profits. The ability to afford a given level of housing is obviously connected to wealth, income, and class.

Homelessness is the extreme experience of an inadequate built environment. As defined in the Stewart B. McKinney Homeless Assistance Act[47a] (H.R.558, enacted in July 1987), homeless includes:

- an individual who lacks a fixed, regular, and adequate nighttime residence [or]

- an individual who has a primary nighttime residence that is:
  - a supervised or publicly operated shelter designed to provide temporary living accommodations (including welfare hotels, congregate shelters, and transitional housing for the mentally ill);
  - an institution that provides a temporary residence for individuals intended to be institutionalized;
  - a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings.

Despite society's common focus on individual attributes, structural drivers of homelessness include unavailability of low-cost housing, high poverty, poor economic conditions, concentrations of minorities and female-headed families, and insufficient mental health care for the indigent. The results of a multivariate analysis show that the availability of low-income housing and of mental health care are the strongest predictors.[48] A recent report from the Chicago Coalition for the Homeless estimated that among the 86,000 homeless people in the city, some 18,000 have completed some college and another 13,400 have some form of employment.

Homelessness is associated with a disproportionate burden of illness. According to the Street Medicine Institute,

> Street people in the United States die on average nearly three decades earlier than their housed peers, most commonly due to preventable and treatable chronic medical conditions. Meanwhile, their health care utilization costs are more than five times the national average, primarily as a result of over reliance on the emergency room for routine medical care and increased hospitalization rates for illnesses presenting in advanced stages. These observations provide evidence that mainstream health care delivery models are failing to meet the complex needs of this vulnerable population in a socially responsible manner.[49]

It is estimated that 60,000 families with children are homeless on any given night in the United States.

2. Food environment

Limited access to healthy foods is a common problem associated with chronic poverty and has significant implications for health. This section defines and discusses food insecurity, healthy-food deserts, and the known health problems associated with these.

The US Department of Agriculture defines food security as

> Access by all people at all times to enough food for an active, healthy life. Food security includes at a minimum: (1) the ready availability of nutritionally adequate and safe foods, and (2) an assured ability to acquire acceptable foods in socially acceptable ways (e.g., without resorting to emergency food supplies, scavenging, stealing, or other coping strategies).[50]

Food insecurity is a structural process that can and should be addressed by public policy.

Screening for food insecurity in the clinic is an important method for understanding the challenges patients face in managing their health. Food insecurity has three components:

- Availability (Does enough food physically exist to meet caloric and nutritional needs?)
- Access (Can existing food be obtained in socially acceptable ways?)
- Utilization (Do individuals and households make good and appropriate use of the food that they have accessed?)

These components are hierarchical. Access requires availability, and utilization requires access. A fourth component, stability, considers whether food security is consistent and can withstand stressors and disruptions to livelihoods and economies.[50]

Food security can be categorized as "low" and "very low." Those in "low-food-secure" households report anxiety about running out of food, the experience of running out of food, and the inability to afford balanced meals. In addition to these patterns, those in "very low-food-secure" households cut the size of their meals or skip meals, eat less than they feel they should, and experience the physical sensation of hunger.[51] Note that hunger is not the same as food insecurity. Hunger is a physical discomfort or pain caused by a lack of food. Hunger is a potential, although not necessary, consequence of food insecurity.

Food insecurity is often cyclic and episodic. Many families have food budgets that provide enough for the first few weeks of the month, when paychecks or Supplemental Nutrition Assistance Program (SNAP) benefits are distributed, but food money often runs out by the last week of the month. For other families, food insecurity does not arise monthly but is a recurring struggle whenever food budgets are strained. For example, difficulties may arise during winter months when heating bills are high or in summer months when school-based breakfast and lunch for children are not always available. Unpredictable expenditures (temporary unemployment, episodes of ill health, or other recurring adverse events) are also drivers of recurring food insecurity for many households.

A large number of Americans experience food insecurity. The US Department of Agriculture reports that nearly one in eight American households faced low or very low food security in 2017.[52] Rates of food insecurity are disproportionately high in African American and Latino households.[51] Other strong risk factors for food insecurity include old age, pregnancy, households with children (particularly single-parent households), lack of employment, and undocumented residency.[53]

Food insecurity in the United States is generally not due to a lack of available food. It is a socially patterned problem largely determined by policy and economics. Indeed, the vast majority of food insecurity is associated not with catastrophes such as natural disasters, but rather with chronic poverty.[54]

SNAP, formerly known as the Food Stamp Program, is a national program funded by the federal government to address food insecurity. This program reached 42 million people in 2017.[55] SNAP is available to households earning less than 130% of the federal poverty line, as well as seniors and those with disabilities. Of note, about one-third of households with food insecurity have incomes too high (greater than 130% of the poverty line) to qualify for SNAP.[56] SNAP provides modest financial support that varies based on need (on average, about $1.40 per meal). About half of all SNAP participants are children, and over two-thirds of all SNAP participants live in families with children.[57] Other federal programs—such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the National School Lunch Program, and Temporary Assistance for Needy Families—as well as various state-level supplemental programs, play important roles supporting those facing food insecurity.

The term *healthy food deserts* refers to limited supermarket access in low-income neighborhoods.[58] Studies have demonstrated that low-income neighborhoods have fewer supermarkets and those markets are farther away compared to high-income neighborhoods. In a national survey, the lowest-income neighborhoods had nearly 30% fewer supermarkets than the highest-income neighborhoods.[58]

Healthy food deserts make it even more difficult for food-insecure households to purchase fresh fruits, vegetables, and perishable foods. Meanwhile, energy-dense "empty calorie" foods are readily available at nearby convenience stores and fast food restaurants.[58] Many low-income households make a single monthly shopping trip to a large supermarket, usually right after receiving SNAP benefits or a paycheck.[56] Additional shopping during the month to replace perishable items often occurs at nearby convenience stores, where fresh fruits and vegetables are rarely stocked.

Households with low income may struggle with transportation to supermarkets outside of their immediate neighborhood. They are less likely to own or have access to cars. Features of their neighborhood built environment, influenced by real estate developers and banks, may make walking less safe. Public transit may be less available, difficult to afford, and challenging to transport and carry purchased goods. Meanwhile, individuals may face significant time constraints due to work schedules or single parenthood.[58]

Healthy food deserts involve significant racial disparities. For example, a study found that the availability of chain supermarkets in neighborhoods populated predominantly by Black families was only 52% of that in neighborhoods populated by white families.[59] These differences still existed after controlling for neighborhood income. Partnerships between local government and supermarket leaders have been developed to bring supermarkets into underserved areas, with significant examples in multiple cities including Pittsburgh, Boston, and New York.[60,61] These partnerships seek to increase supermarket access within neighborhoods that have historically been avoided by food retailers.

Households facing food insecurity engage in commonly observed strategies to avoid the physical sensation of hunger, such as relying on low-cost, energy-dense ("empty calories") foods that have low nutritional value. These compensatory strategies are

experienced first among adults in the household and only affect children as household food insecurity becomes more severe.[56] In the United States, foods with the highest energy density tend to cost the least, enabling individuals to meet or exceed their daily caloric needs while saving money. "Oil, shortening, butter, cookies, sugar, bread, pasta, and rice all cost far less per calorie of energy than fruits, vegetables, meat, and most dairy products."[56,62]

Food insecurity is associated with poor health outcomes. Food insecurity has a well-established association with a myriad of health problems among children. Among school-age children, food insecurity negatively affects cognitive, academic, and psychosocial development.[63] Among infants and toddlers, food insecurity confers greater risks of illnesses serious enough to require hospitalization.[64]

Food insecurity is associated with obesity, hypertension, and diabetes, which then places people at greater risk for cardiovascular disease.[65] The risk of diabetes is about 2.5 times higher in very low-food-secure households compared to food-secure households in the United States. Diabetes is also more likely to be poorly controlled, even after controlling for income level. In one study, only 46% of those living in food-secure households had poorly controlled diabetes, compared to 70% of those living with very low food security. These individuals are more likely to have higher hemoglobin A_{1c} values and more frequent hypoglycemic episodes.[56]

The recurring experience of food insecurity may result in disordered eating, in particular binge-fast cycles, in which individuals overconsume at times when food is available in expectation of food shortage later in the month. Disordered eating may also be a consequence of the high levels of stress that accompany food insecurity.[66]

B. Socio-environmental circumstances

1. Early childhood development and adverse childhood experiences

The evidence linking early childhood development to health across the life span is so impressive that it has given birth to an entire subfield of epidemiology, typically referred to as life course epidemiology.[67] Early childhood is an epidemiologically critical and sensitive period. A critical period is defined as "a limited time window in which an exposure can have adverse or protective effects on development and subsequent disease outcome."[67] Outside this window, this developmental mechanism for mediating exposure and disease risk is no longer available. A sensitive period is "a time period when an exposure has a stronger effect on development and hence disease risk than it would at other times."[67] Taken together, this means that experiences during early childhood have a disproportionately strong impact on health across the lifespan.

Adverse childhood experiences (ACEs) describe all types of abuse (sexual, emotional, physical), neglect (physical, emotional), and trauma (violence, substance misuse, or mental illness in the household; parental separation or divorce; incarcerated household member) that occur during childhood and adversely impact health and well-being in adulthood. A graded dose-response relationship links ACEs to subsequent risky

behavior, poor physical and mental health, and premature death.[68]

Adverse conditions in early childhood can have major negative health impacts later in life. A 1998 study led by the Centers for Disease Control and Prevention and Kaiser Permanente asked adults about childhood exposures and assigned a score based on the accumulation of ACEs.[69] Health outcomes linked to childhood adversity include:

- Alcoholism and alcohol abuse
- Chronic obstructive pulmonary disease
- Depression
- Fetal death
- Ischemic heart disease
- Liver disease
- Risk for intimate partner violence
- Multiple sexual partners
- Sexually transmitted diseases
- Smoking
- Suicide attempts

The connection between adverse childhood conditions and health is so strong that it can be demonstrated intergenerationally. Epidemiologists have found connections between the social conditions of parents in their early childhood and the longitudinal health outcomes of their offspring later in life.[67,70] One group of researchers even found an attenuated but statistically significant effect of early childhood hardship on the longitudinal health outcomes of grandchildren.[71]

Public investments in early childhood development are critical. Many cases of adverse childhood events are preventable with appropriate social services and improvement of home conditions. As with all social determinants, there is an economic benefit to addressing the root causes. Nobel laureate economist James Heckman, for example, produced an important longitudinal study known as The Abecedarian Project. Heckman and colleagues documented remarkable results: every $1 invested in intensive early childhood development would return approximately $2.50 in avoided costs.[72] Heckman and colleagues concluded that such investment would "prevent costly chronic diseases, increase productivity and potentially reduce health spending."[73]

2. Populations subject to societal discrimination

Socioeconomic position leads to stratification of stressors. According to the WHO, "Different social groups are exposed in different degrees to experiences and life situations that are perceived as threatening, frightening and difficult for coping in the everyday. This partly explains the long term pattern of social inequalities in health." In addition to the profound influence of race and ethnicity discussed earlier in this chapter, other populations are subject to systematic discrimination that impacts their health.

a. Persons with differences of sexual orientation and gender identity

Lesbian, gay, bisexual, transgender, intersex, and questioning (LGBTIQ+) individuals experience unique health disparities. Until 1973, homosexuality was labeled as a psychiatric condition, so named in the *Diagnostic and Statistical Manual of Mental Disorders*. LGBTIQ+ individuals have been largely discriminated against and oppressed through laws and barriers to care that stigmatized nonheterosexual and gender-diverse individuals. For example, legal discrimination in access to health care, marriage, adoption, and housing all impact physical and emotional health. There is a shortage of physicians and other health care professionals with adequate training to treat LGBTIQ+ patients in both a scientifically and culturally competent manner. For transgender patients in particular, the *Diagnostic and Statistical Manual* continues to pathologize transgender/gender-diverse individuals with the current diagnosis of "gender dysphoria," leading to delegitimization and ongoing stigma. Lack of awareness (or outright refusal) among physicians to appropriately address the needs of this group—for instance, refusing to use a patient's preferred name and pronouns—has created a long-standing distrust in the medical system, producing barriers to safe, effective, and lifesaving care.

In 2011 the Institute of Medicine issued a report on the health status and research needs of the lesbian, gay, bisexual, and transgender (LGBT) population.[74] The framework for these recommendations was based around four concepts:

1. Events at each stage of life influence subsequent stages, and experiences are shaped by age and history (life course framework);
2. Sexual and gender minorities experience chronic stress due to stigmatization from being minorities (minority stress model);
3. Individuals' multiple identities and how they interact (intersectionality); and
4. Individuals are surrounded by spheres of influence made up of families, communities, and society (social ecology perspective).

Prior to the report, few data had been collected on sexual orientation and gender nonconformity, partly due to an absence of queries on federal surveys and the lack of a standardized method for collection in electronic health records (EHRs).[74]

Identifying as LGBT is associated with exposure to increased risks and unequal health outcomes. For example, compared with heterosexual cisgender youth, LGBT youth experience higher rates of violence, victimization, and harassment, particularly school bullying. Overall, LGBT youth have higher rates of smoking, alcohol and substance use, and homelessness. As a result, they have increased risks for depression and suicide.[75,76] Higher rates of mood disorders among LGBT individuals persist into adulthood. Lesbian, bisexual, and gay adults, particularly women, have higher rates of smoking, alcohol use, and substance use.[77,78] In the 2012 National Transgender Discrimination Survey, 41% of respondents reported attempting suicide, compared to 1.6% of the general population.[79] Gaps in education on LGBT health have resulted in decades of physicians undertrained in cultural, gender, and sexuality sensitive care. As a result, lesbian and bisexual women use fewer preventive health services, contributing to disparate health outcomes such as higher rates of breast cancer than are found in

heterosexual women.[80] HIV/AIDS disproportionately affected the gay community at the onset of the epidemic and still disproportionately affects young men who have sex with men, particularly Black and Latino men.[81] In the 2015 US Transgender Survey, "Respondents were living with HIV (1.4%) at nearly five times the rate in the US population (0.3%). HIV rates were higher among transgender women (3.4%), especially transgender women of color. Nearly one in five (19%) Black transgender women were living with HIV, and American Indian (4.6%) and Latina (4.4%) women also reported higher rates."[82] Opportunities to help advance and improve social determinants of health include better collection of data on LGBT populations on national and local levels, decreasing violence toward LGBT populations in schools and communities, and increasing and improving medical education in LGBT-related health needs. Protective factors for youth include family support and community support, awareness of isolation of LGBT elders, development of social programs to assist in their needs, and recognizing and standardizing care.

b. Persons with disabilities

Disability arises when people with health conditions or impairments are confronted by social conditions that limit their everyday activities and social participation.[83] A disability is not an intrinsic characteristic of a person; it is a socially determined outcome based on environmental factors and interaction with culture and society. There is an abundance of evidence that people with disabilities experience poorer health outcomes compared to nondisabled peers. Disabilities can lead to other health problems that are not directly related, including mental health conditions, obesity, hypertension, diabetes, heart disease, and stroke. Family caregivers of disabled children and adults also experience poorer health outcomes.

Disability often intersects with other social determinants of health. For example, the direct and indirect financial costs of caring for a child or adult with a disability can lead to economic hardship and loss of socioeconomic status for a family. Persons with disabilities are often excluded from educational and employment opportunities. The effects of discrimination against those with disabilities are also linked to poorer health outcomes. Such discrimination leads to social exclusion and loss of social capital. Furthermore, the experiences of discrimination itself can lead to an allostatic load that has negative impacts on physical and emotional health.

Of note, health literature generally treats disability as a health condition, without recognizing disability as a social determinant of health. As pointed out by Emerson and colleagues,

> Disability, just like health in general, is not the outcome of a particular disease or condition. It is an outcome of being a particular person in a particular society at a particular point in time who experiences a particular health condition. One potentially discriminatory consequence of conflating disability and health conditions (e.g. in the use of health metrics based on disability-free life expectancy) is that interventions will, by definition, prove less effective for disabled people.[84]

Greater research and discourse are needed to understand and address disability as a social determinant of health. Physicians and other health care professionals should approach the disabilities of their patients not just in a biomedical fashion, but also with an appreciation for how disabilities interlock with other health risks and outcomes as well as other social determinants of health.[84,85]

c. Persons with mental illness

The nature of some mental illness limits one's ability to seek medical care and to appropriately follow care plans. The illness itself may generate a lack of motivation, impaired judgment, or diminished cognitive ability, and the effects of medications used in treatment may compound these issues. However, societal stigma has a much more profound impact on health outcomes for this population.

Stigma around mental illness is multifactorial.[86] Misunderstanding about locus of control and the idea of personal responsibility is one important aspect. For example, differences in behavior related to drug addiction may be perceived as the individual's choice, whereas similar behavior following a head injury is not deemed the fault of the individual. Opinions about responsibility can generate emotional responses among others of anger or pity, both of which are limiting. Persons with mental illness are often viewed as unpredictable, with risk for danger or violence.

Stigma is a strong deterrent to seeking care. Persons with mental illness fear labeling and adverse consequences related to discrimination. This is illustrated even among medical students. Although multiple studies document a significant rate of mental illness among medical students—with depressive symptoms reported by nearly one-third—students also admit they hesitate to seek care due to perceptions of personal weakness, public devaluation, and social/professional discrimination.[87,88] Access to care is further limited by a lack of parity in funding, even in an insured population.

C. Psychosocial intermediaries

Psychosocial consequences arise from structural and social inequities. Almost without exception, studies find that higher levels of discrimination are associated with poorer mental health status.[31] The WHO defines mental health as "a state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community."[89] Many studies have shown associations between poverty measures and mental health. For example, in European countries, higher rates of depression and anxiety are associated with lower education levels, unemployment, and social isolation with aging. A cycle then develops whereby mental illness leads to reduced income and employment, making it more difficult to get out of poverty, leading to worsening mental illness.[90] In the United States, the prevalence of mental illness results in a high burden of disease.[91] Suicide was the 2nd leading cause of death in 10- to 34-year-olds and the 10th leading cause of death in 2016 in all age groups.[92]

Mental health is strongly linked with socioeconomic status. For example, it has been shown that mothers experiencing food insecurity have higher rates of depression and anxiety disorders, even when controlling for physical health, substance use, and domestic violence. Their children, not surprisingly, experience high rates of behavioral problems as levels of food insecurity increase.[93] Income inequality, in and of itself, is linked with mental health outcomes. Societies with greater inequality have a higher prevalence of depression, even factoring in per capita income, education, and age.[94] Individual and systemic racism and discrimination are associated with poor mental health.

As was discussed in the adverse childhood events section, many disadvantages start before birth and accumulate through life, leaving lasting impacts on individuals. When thinking about how social determinants ultimately affect mental health, it is important to understand needs at different stages of life.[90] The WHO developed areas to target strategies and interventions to reduce mental disorders. These include:

1. Life course: prenatal, pregnancy and perinatal periods, early childhood, adolescence, working and family-building years, and older ages
2. Parents, families, and households: parenting behaviors/attitudes, material conditions (income, access to resources, food/nutrition, water, sanitation, housing, employment), employment conditions, parental physical and mental health, pregnancy and maternal care, social support
3. Community: neighborhood trust and safety, community-based participation, violence/crime, attributes of the natural and built environment, neighborhood deprivation
4. Local services: early-years child care and education provision, schools, youth/adolescent services, health care, social services, clean water and sanitation
5. Country-level factors: poverty reduction, inequality, discrimination, governance, human rights, armed conflict, national policies to promote access to education, employment, health care, housing and services proportionate to need, social protection policies that are universal and proportionate to need[90]

Improving the mental health of individuals and communities is a considerable challenge. It requires work at the individual level to assess and improve access to food, shelter, financial support, and safety. It also requires advocacy at the local, state, and national levels to improve access to basic needs and medical care, while challenging oppressive and discriminatory laws.

D. Behavioral and biologic factors

Factors such as diet, smoking, and drug and alcohol use were historically framed in medical training as individual lifestyle choices. The structural drivers of these health risk behaviors are now better understood. In the case of cigarette smoking, years of manipulation by the tobacco industry culminated in multiple class-action lawsuits that made the harmful effects known to the public.[95] Smoking among more affluent citizens

declined, but low socioeconomic position remains strongly associated with initiation of smoking and inversely with the ability to successfully quit.[3] Now similar concerns are arising related to e-cigarettes and "vaping," with advertising and product development (candy-like flavors and compact dispensers) targeted to youth.[96] The opioid epidemic[97] and the "diseases of despair"—referring to the interconnected trends in fatal drug overdose, alcohol-related disease, and suicide—also demonstrate significant racial and socioeconomic inequities in impact and access to treatment. Trauma is a leading cause of premature death and debilitation in the United States, associated with risk-taking behaviors that are linked to socioeconomic status.[98]

Gun violence has been identified as a public health crisis in the United States by a coalition of medical societies.[99] A societal choice to permit guns to be readily accessible contributes to approximately 30,000 deaths annually by suicide, homicide, and accidents.[100] There is a disproportionate impact on communities of color, contributing to the finding that Black males are twice as likely as white males to die before age 20.[100] Participation in criminal activity is associated with significant health risk and is now more clearly recognized to be linked to structural and social determinants. Systematic differences in prosecution of similar crimes across race, coupled with privatization of prison systems operated by for-profit corporations, has contributed to mass incarceration with dire health consequences. Now one in three Black male youths and one in six Latino male youths are projected to go to jail or prison in their lifetimes, sequestering entire populations, with deleterious effects on families.[101]

Physicians and other health care professionals who are more aware of the structural and social determinants of these behavioral intermediaries may be more empathetic when caring for the resultant health consequences and can serve as advocates to address the underlying drivers of behavior.

E. The health system

The system of delivery of health care is itself a social construct and is thus vulnerable to contributing to disparities in health outcomes. As described elsewhere in this text, access to care is strongly linked to employment and varies significantly across socioeconomic positions. Additionally, many groups of patients have suffered frank discrimination in the process of care, which leads to a lack of trust in current systems. Other social constructs that limit the effectiveness of care for certain individuals and populations include health literacy and a lack of diversity of the health care workforce.

1. Health literacy

Health literacy is the ability to read, comprehend, and analyze information, instructions, symbols, charts, and diagrams to make appropriate health decisions.[102] Limited health literacy affects people of all ages, races, incomes, and education levels, but its impact disproportionately affects lower socioeconomic, immigrant, and minority groups.[103-105] Patients with low health literacy may experience difficulty understanding prescription labels and navigating complex health forms and systems, resulting in

poorer health outcomes and higher costs. Addressing health literacy for all patients is a necessity that includes the need to provide verbal and written information that is appropriate for all patients.[102] Language barriers further confound this.

2. Physician workforce

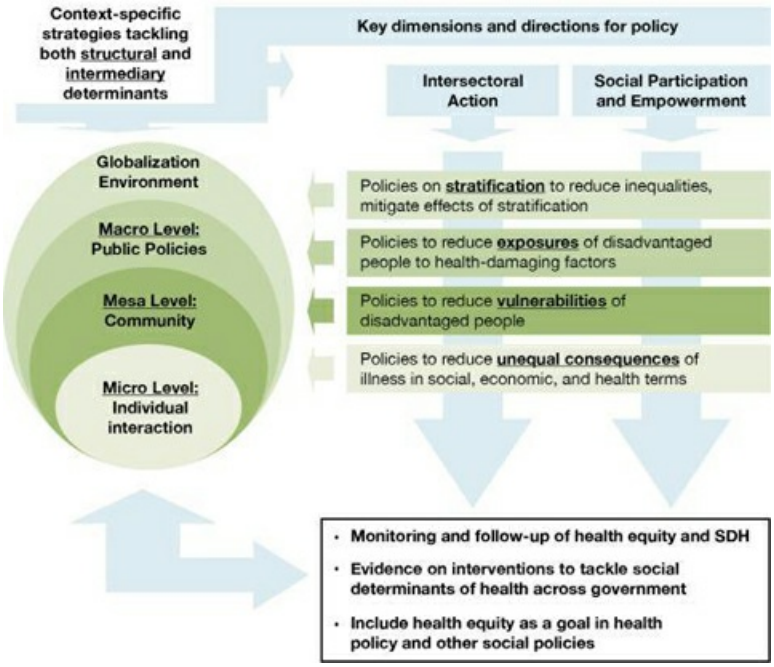
The US health workforce does not match the patient population in terms of social or economic background.[107] For example, most medical students are children of parents with high levels of education.[108] Roughly one-half of medical students' fathers have a graduate degree compared with 12% of men in the US population. Similarly, roughly one-third of medical students' mothers have a graduate degree compared with approximately 10% of US women. There are similar trends for parental income.[108] The fraction of medical students from the lowest quintile of parental income in the United States has never been greater than 5.5%. The race and ethnicity of physicians is skewed compared to the US population. In California, less than 5% of physicians self-identify as Latino, whereas nearly 40% of Californians report Latino race.[109] The number of Black men in medicine is declining.[110] Similar demographic skew is seen in other health care professions. According to the American Association of Colleges of Nursing, gender bias is significant, with men comprising only 11% of students in baccalaureate programs, 10% of master's students, 8% of research-focused doctoral students, and 10% of practice-focused doctoral students.[108]

Diversity of physicians impacts health outcomes. Studies have demonstrated that patients are more likely to pursue preventive measures presented by a race-concordant provider.[111] Physicians are more likely to practice in underserved communities when they come from such communities.[112] Physicians underrepresented in medicine are more likely to practice primary care.[113] Further, more diversity among medical trainees can improve the cultural humility and structural competency of the entire group. Like all people, physicians carry implicit bias that can impact care; personal experience with diverse people can break down bias.[114] Cultural humility incorporates a "lifelong commitment to self-evaluation and self-critique, to redressing the power imbalances in the patient-physician dynamic, and to developing mutually beneficial and nonpaternalistic clinical and advocacy partnerships with communities on behalf of individuals and defined populations."[115] The lack of diversity in the health care workforce is a structural issue that must be addressed via efforts to encourage more diverse students to pursue health careers, a close examination of admissions processes to mitigate against bias, and provision of appropriate support structures to promote the success of diverse students (pathways, recruitment, selection, and retention).

VI. Interventions focusing on root causes

Health care professionals have ample opportunities to address structural determinants of health inequities and social determinants of health. Education and training in the recognition and mitigation of structural and social determinants should occur across the continuum of medical education (from premedical to continuing professional development). The Association of American Medical Colleges and the Liaison Committee on Medical Education (the accrediting body for Doctor of Medicine programs in the United States and Canada) call on medical school curricula to prepare students to recognize social determinants of health and the potential impact of behavioral and socioeconomic factors on health.[116,117] Similar requirements (or strong suggestions of a requirement) are found for the education of health care professionals at all levels, including practicing professionals, medical residents, nurses, public health providers, and physician assistants, among others.[118,119] Health care professionals are influential allies when speaking alongside communities to campaign for better social conditions. Some educators feel that skill-based curriculum in advocacy should be mandatory for all medical trainees.[120]

Interventions to address social determinants of health can be initiated at multiple levels: in the care of individual patients, by actively partnering with communities, and by serving as allies and advocates in policymaking, as summarized in Fig. 12.2. Health professions students can lead in all these areas to improve health equity and health outcomes for their patients and the populations they serve.

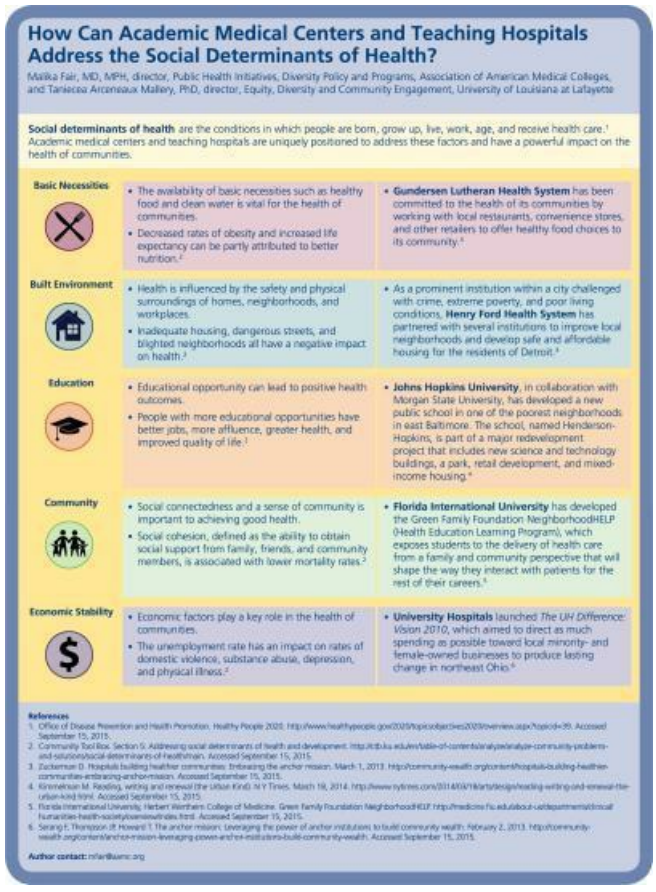


• **FIG. 12.2 World Health Organization Framework for Tackling Social Determinants of Health Inequities.** *SDH,* Social determinants of health. *Source:* (From Solar O, Irwin A. A

conceptual framework for action on the social determinants of health. *Social Determinants of Health Discussion Paper 2 [Policy and Practice].* Geneva: World Health Organization; 2010.)

A. Individual interventions

Health care professionals often equate addressing social determinants with the need to change the social, political, and economic causes of disease that lie outside the health care system.[121] While such advocacy is critical, this view largely ignores the potential to address social determinants on a routine basis within the process of health care delivery.[122] Numerous health care systems, physicians and other health care professionals are working to incorporate processes that would support identification and documentation of social needs and appropriate interventions (Fig. 12.3).



How Can Academic Medical Centers and Teaching Hospitals Address the Social Determinants of Health?

Malika Fair, MD, MPH, director, Public Health Initiatives, Diversity Policy and Programs, Association of American Medical Colleges, and Tanjecea Arceneaux Mallery, PhD, director, Equity, Diversity and Community Engagement, University of Louisiana at Lafayette

Social determinants of health are the conditions in which people are born, grow up, live, work, age, and receive health care.[1] Academic medical centers and teaching hospitals are uniquely positioned to address these factors and have a powerful impact on the health of communities.

Basic Necessities	• The availability of basic necessities such as healthy food and clean water is vital for the health of communities. • Decreased rates of obesity and increased life expectancy can be partly attributed to better nutrition.[2]	• **Gundersen Lutheran Health System** has been committed to the health of its communities by working with local restaurants, convenience stores, and other retailers to offer healthy food choices to its community.[3]
Built Environment	• Health is influenced by the safety and physical surroundings of homes, neighborhoods, and workplaces. • Inadequate housing, dangerous streets, and blighted neighborhoods all have a negative impact on health.[2]	• As a prominent institution within a city challenged with crime, extreme poverty, and poor living conditions, **Henry Ford Health System** has partnered with several institutions to improve local neighborhoods and develop safe and affordable housing for the residents of Detroit.[4]
Education	• Educational opportunity can lead to positive health outcomes. • People with more educational opportunities have better jobs, more affluence, greater health, and improved quality of life.[2]	• **Johns Hopkins University**, in collaboration with Morgan State University, has developed a new public school in one of the poorest neighborhoods in east Baltimore. The school, named Henderson-Hopkins, is part of a major redevelopment project that includes new science and technology buildings, a park, retail development, and mixed-income housing.[4]
Community	• Social connectedness and a sense of community is important to achieving good health. • Social cohesion, defined as the ability to obtain social support from family, friends, and community members, is associated with lower mortality rates.[2]	• **Florida International University** has developed the Green Family Foundation NeighborhoodHELP (Health Education Learning Program), which exposes students to the delivery of health care from a family and community perspective that will shape the way they interact with patients for the rest of their careers.[5]
Economic Stability	• Economic factors play a key role in the health of communities. • The unemployment rate has an impact on rates of domestic violence, substance abuse, depression, and physical illness.[2]	• **University Hospitals** launched *The UH Difference: Vision 2010*, which aimed to direct as much spending as possible toward local minority- and female-owned businesses to produce lasting change in northeast Ohio.[6]

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Author contact: mfair@aamc.org

• **FIG. 12.3** *Source:* Reprinted with permission from Fair M, Arceneaux Mallery T. AM Last Page. How can academic medical centers and teaching hospitals address the social determinants of health? *Acad Med.* 2016;91:443.

Just as detailed symptom, medical, and family history forms the foundation of accurate diagnosis, a patient-level assessment of social needs is essential to each patient's care. For example, in treating a patient with diabetes, the physician must

consider: Are they able to afford the medication prescribed? Do they have sufficient food security to manage their blood sugars? Is something in their life, such as abuse, high stress, or lack of support for lifestyle change, standing in their way of reaching mutually set goals for care? A broader contextual understanding of the patient's needs informs care teams and improves patient engagement and outcomes.[123]

Standardized screening for social determinants and documentation in EHRs is endorsed by the National Academy of Medicine (formerly the Institute of Medicine), the 2016 Centers for Medicare & Medicaid Services' Quality Strategy, and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), as well as many professional organizations. Starting with simply asking the question "Do you have difficulty making ends meet at the end of the month?" is a sensitive and specific predictor for detecting individuals living below the poverty line.[124] Questions about basic needs, such as food, shelter, and safety, can be asked by clinical staff, or patients can directly respond to paper-based or electronic questionnaires that are subsequently imported into the EHR.

Screening questions should be asked of all patients, in all practice settings, at every visit, not just of patients from disadvantaged areas.[125] Predictions about which families are at increased risk of exposure to adverse social conditions are fraught with problems, as social determinants have potential impact on health risks for everyone.[126] Targeting families based on such characteristics as residence, age, education, or underrepresented minority status may only reinforce stereotypes and prejudicial presumptions, as well as stigmatize the screening process.

Tools assessing social needs should be integrated into the EHR to enable a routine clinic workflow and to make this information available to all members of the care team.[127] The Institute of Medicine's Committee on Recommended Social and Behavioral Domains and Measures for Electronic Health Records suggested a set of demographic and social domains for inclusion in all EHRs (Box 12.1).[128] These include factors such as race and ethnicity, education, employment, financial resources, country of origin, sexual orientation, psychological assets and stressors, health literacy, mental health issues, physical activity, nutritional patterns, social connections or isolation, and use of or exposure to tobacco, alcohol, and drugs. Documentation of such information not only aids individual care discussions and shared decision making, but facilitates the ongoing tracking of social constructs across service providers in the health care system or community, thus expanding the capacity to better address population health needs.

• BOX 12.1

Social and Behavioral Domains for Inclusion in Electronic Health Records

Sociodemographic domains

- Sexual orientation
- Race and ethnicity
- Country of origin/US born or non-US born

- Education
- Employment
- Financial resource strain: Food and housing insecurity

Psychological domains

- Health literacy
- Stress
- Negative mood and affect: Depression and anxiety
- Psychological assets: Conscientiousness, patient engagement/activation, optimism, and self-efficacy

Behavioral domains

- Dietary patterns
- Physical activity
- Tobacco use and exposure
- Alcohol use

Individual-level social relationships and living conditions domains

- Social connections and social isolation
- Exposure to violence

From Institute of Medicine. *Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2.* Washington, DC: National Academies Press; 2014. https://www.nap.edu/catalog/18951/capturing-social-and-behavioral-domains-and-measures-in-electronic-health-records. Accessed October 28, 2019.

Operationalizing a comprehensive strategy to address social determinants of health in a busy practice environment has challenges. Barriers to adoption include the time-limited office visit, the difficulty of incorporating the processes into daily workflows, the additional workload due to the volume of social needs, concerns that screening creates a fragmented view of the patient, and difficulty finding community resources, particularly in more rural or remote communities. Of interest, in one study, only 15% to 21% of patients with an identified social need actually wanted help with addressing the need(s) that had been identified. This added to the perception that screening may be too time consuming when no follow-up was wanted.[129]

Screening for social determinants does not need to be administered by a physician, and it can be performed upon check-in or while rooming so that it does not disrupt the flow of the visit while promoting more comprehensive care.[122] Having patients or family members complete a screening tool before the visit can help streamline workflow and provide value-added time during waiting periods. Individuals may be more likely

to disclose sensitive information, such as interpersonal violence, when the screening questionnaire is self-administered. Other health care team members can facilitate the screening and referral process.

Many clinicians feel ill prepared or unable to address social determinants of health.[130] Discomfort with inquiring about adverse social circumstances, lack of personal experience with such needs, and inadequate training on how to respectfully elicit and respond to patients' concerns are deterrents to action. Screening may detect adverse exposures and conditions that typically require resources well beyond the scope of clinical care. The limited capacity of community resources such as affordable housing, behavioral health services, workforce development and employment, and public transportation also contribute to a system failure to meet patient needs. Thus, despite the potential benefits of identifying and addressing social needs, there is the potential for unintended harm. Screening for any condition in isolation without the capacity to ensure referral and linkage to appropriate treatment is ineffective and, arguably, unethical.[131] This reinforces the need to link actively with the local community.

Current volume-based fee-for-service payment mechanisms are perceived by some physicians as a financial disincentive to take additional time with patients to address their social determinants of health. However, this stance recalls the hesitance of land developers to invest in poor neighborhoods due to lower profit margins. A move to value-based reimbursement should improve this perception, and there are some signs that clinical practices and health care systems are now becoming more incentivized to address social determinants and improve health equity. The International Statistical Classification of Diseases and Related Health Problems (ICD-10) now includes Z codes that capture social determinants.[132] In emerging value-based models, risk adjustment related to care for disparate populations often considers medical comorbidities but does not always adjust for social determinants (e.g., poverty, homelessness). Neither the Medicare Medical Spending per Beneficiary measure nor MACRA's outpatient Merit-based Incentive Payment System are adjusted for social determinants. The Affordable Care Act's reimbursement policies do reward population health management, care coordination, and value-based purchasing—all domains that require attention to social determinants of health to be successful.[133] Until these factors are included in measures of medical spending, health plans and clinicians who serve populations made vulnerable by social injustice risk being penalized.[134] This argues for the need for physicians to serve as advocates.

See Appendix 12.1 of this chapter for a collection of screening tools for social determinants.

APPENDIX 12.1

Screening Tools

Examples of screening tools to assess social and economic circumstances are described here.

Adverse childhood experiences (ACEs)

Measured by the 10-item ACE Questionnaire, each affirmative answer is assigned 1 point. The points are totaled for a score out of 10, which is known as the ACE score.

While you were growing up, during your first 18 years of life:		
1. Did a parent or other adult in the household often... Swear at you, insult you, put you down, or humiliate you? Or act in a way that made you afraid that you might be physically hurt?	Yes	No
2. Did a parent or other adult in the household often... Push, grab, slap, or throw something at you? Or ever hit you so hard that you had marks or were injured?	Yes	No
3. Did an adult or person at least 5 years older than you ever... Touch or fondle you or have you touch their body in a sexual way? Or try to or actually have oral, anal, or vaginal sex with you?	Yes	No
4. Did you often feel that... No one in your family loved you or thought you were important or special? Or your family didn't look out for each other, feel close to each other, or support each other?	Yes	No
5. Did you often feel that... You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you? Or Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?	Yes	No
6. Were your parents ever separated or divorced?	Yes	No
7. Was your mother or stepmother...Often pushed, grabbed, slapped, or had something thrown at her? Or sometimes or often kicked, bitten, hit with a fist, or hit with something hard? Or ever repeatedly hit over at least a few minutes or threatened with a gun or knife?	Yes	No
8. Did you live with anyone who was a problem drinker or alcoholic or who used street drugs?	Yes	No
9. Was a household member depressed or mentally ill or did a household member attempt suicide?	Yes	No
10. Did a household member go to prison?	Yes	No
Total (out of 10)		

Modified from *Got Your ACE Score?* https://acestoohigh.com/got-your-ace-score/. Accessed October 28, 2019.

Nearly two-thirds (64%) of adults report an ACE score of at least 1.[161] Adults with an ACE score of 6 or more die nearly 20 years earlier on average than those without ACEs. Notably, other sources of childhood trauma (e.g., food insecurity or community violence) are not included in the ACE Questionnaire but likely impact health and wellness. The ACE score also does not tally positive experiences that can help build resilience and protect a child from the effects of trauma.

Food insecurity

An 18-item Household Food Security Scale has been developed and validated as an effective way to assess food insecurity. It is generally used for research purposes.

In the clinical setting, a single question can be a powerful and effective screening tool: "In the past month, was there any day when you or anyone in your family went

hungry because you did not have enough money for food?" Of the patients in a pediatric clinic whose caregivers were administered this question, 78% of those who responded "yes" also reported being food insecure by the Household Food Security Scale, and 84% of those who responded "no" reported being food secure using the 18-item scale.[162]

Knowledge of a patient's food insecurity gives rise to insight about barriers he or she may face in managing chronic disease. Those with food insecurity are more likely to postpone needed medical care and to postpone medications (likely due to costs), and are more likely to require emergency department visits and hospitalizations.[163] Patients with insulin-dependent diabetes should be educated about how to adjust their insulin doses for days when food access is limited or unpredictable in order to avoid dangerous hypoglycemic reactions.

General screening

1. **The EveryONE Project:** The American Academy of Family Physicians offers a social determinants of health screening tool, available in short and long form in English and Spanish, as part of The EveryONE Project. The short form includes 11 questions about housing, food, transportation, utilities, personal safety, and the need for assistance. The long form includes additional questions on child care, finances, and education, plus guidance on action planning. Both forms can be self-administered or administered by clinical or nonclinical staff.[164]
    - EveryONE Project screening tool: https://www.aafp.org/patient-care/social-determinants-of-health/everyone-project/eop-tools/assessment-action.html
2. **Protocol for Responding to and Assessing Patient Assets, Risks, and Experiences (PRAPARE) Action Toolkit:** As part of a national effort to develop a standardized approach for assessing, documenting, and addressing social determinants, the National Association of Community Health Centers developed a free Action Toolkit that contains resources, best practices, and lessons learned. Information is included in the electronic health record for incorporation into care decisions and referrals for additional services. In sites that piloted the tool, 97% to 99% of patients screened had one or more social determinants identified.[129]
    - PRAPARE toolkit: http://www.nachc.org/research-and-data/prapare/toolkit/
3. **CMS Health-Related Social Needs:** As part of the Accountable Health Communities Model (AHCM) project, the Centers for Medicare & Medicaid Services (CMS) developed a 10-question Health-Related Social Needs screening tool. Intended to be self-administered, this tool addresses food insecurity, housing instability, transportation and utility needs, and interpersonal safety.[166]
    - AHCM website: https://innovation.cms.gov/initiatives/ahcm/
    - AHCM screening tool (pdf): https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf
4. **HelpSteps:** Boston Children's Hospital developed the HelpSteps tool to be administered in the office via Internet-based technology (e.g., a kiosk in the waiting room, an iPad in the examination room, etc.). Studies on HelpSteps

reveal that information disclosure about psychosocial and socioeconomic questions is enhanced using computer technology, identifying more social needs than face-to-face interviewing, especially for highly sensitive issues such as household violence and substance abuse.[167]
    - HelpSteps website: https://www.helpsteps.com
5. **Poverty Intervention Tool:** Developed by the Ontario College of Family Physicians' Poverty Committee, the Poverty Intervention Tool begins with the single screening question "Do you have difficulty making ends meet at the end of the month?" which has a sensitivity of 98% and a specificity of 40% for living below the poverty line. The tool is tailored to provinces and territories in Canada but could be modified for any practice region.[124]
    - Poverty Intervention Tool website: https://cep.health/clinical-products/poverty-a-clinical-tool-for-primary-care-providers/

B. Community

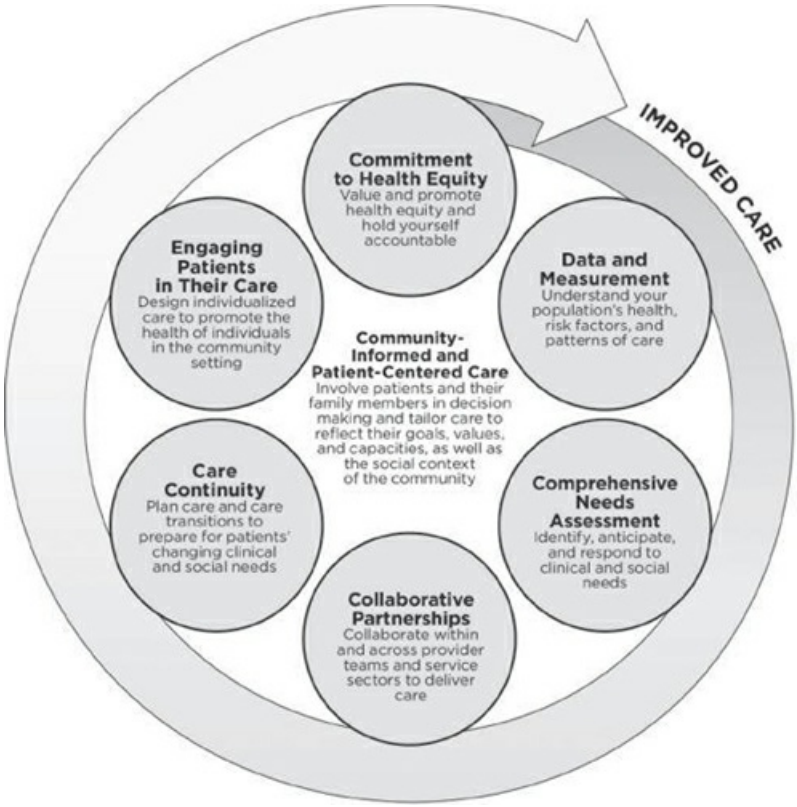
Medical practitioners must know social and economic data regarding the communities in which they practice. Most practices lack integration with community-based services to facilitate ease of referral. Equitable practice designs allow for linkage with community programs and services, to facilitate individual interventions and enable the use of this information to advocate for both patient and community-level improvements impacting health. An important first step is to ask; community groups and leaders are in the best position to identify common needs and advise practitioners on appropriate interventions.

1. Equitable practice design

The National Academies of Science, Engineering, and Medicine published a consensus statement that identified six community-informed and patient-centered systems practices that health care systems and clinical practices can adopt to improve care for socially at-risk populations[135]:

1. Commitment to health equity: Value and promote health equity and hold yourself accountable
2. Data and measurement: Understand your population's health, risk factors, and patterns of care
3. Comprehensive needs assessment: Identify, anticipate, and respond to clinical and social needs
4. Collaborative partnerships: Collaborate within and across provider teams and service sectors to deliver care
5. Care continuity: Plan care and care transitions to prepare for patients' changing clinical and social needs
6. Engaging patients in their care: Design individualized care to promote the health of individuals in the community setting

These practices are ideal when they work in concert with each other, centered around community-informed and patient-centered care where patients and their families are involved in decision making and care is tailored to their goals, values, and capacities and the social context of the community (Fig. 12.4).



• FIG. 12.4 Systems Practices to Improve Care for Socially At-Risk Populations. *Source:* (From National Academies of Sciences, Engineering, and Medicine. *Systems Practices for the Care of Socially At-Risk Populations.* Washington, DC: National Academies Press; 2016.)

In order for health care to become more inclusive, it is important to explicitly consider how the practice environment presents itself to all members of the community (e.g., patients of immigrant and refugee status, patients with low incomes, individuals who identify as LGBT, individuals with disabilities, etc.) and seek ways to be more inclusive. Waiting rooms and other patient spaces within a clinical practice or health care facility can be intentionally designed to be welcoming to a more diverse patient population and enhance collaboration between the staff and the patients they serve. Language on intake forms can be modified to be more inclusive. Training for frontline staff members is critical, as they are often the first to identify social needs and can be invaluable assets in referring patients and families to community resources. Several innovative approaches provide enhanced access to community resource information, including co-location of health and social services (e.g., behavioral health, Medicaid, and the Special Supplemental Nutrition Program for Women, Infants, and Children). Practices may also consider including services not often considered part of traditional medical care, such as

emergency food boxes and on-site medical-legal partnerships.

One of the national leaders in the creation of LGBT-affirming practice settings is The Fenway Institute. The National LGBT Health Education Center, which is part of The Fenway Institute, provides educational programs, publications, online resources, and consultation to health care organizations with the goal of optimizing quality, cost-effective health care for LGBT people. They have also published a comprehensive guide to LGBT health that is available in print and digitally that can serve as a resource for those interested in providing effective care for sexual and gender minorities, who face significant health disparities.[136]

Clinicians and staff are more likely to ask social questions when there are clear opportunities to assist patients and families in getting the resources they need.[137] Web-based programs with an updated database of community service agencies loaded on laptops or tablets in the waiting room can maximize referrals without disrupting the actual visit. For example, a database of nutrition resources might include not only information on healthy eating, but also links to local food pantries and farmers' markets and referral to a nutritionist. Utilizing such tools can reduce or eliminate the need for a practice or health system to develop its own resource guides. Care managers or other trained staff can access the resources of primary care, public health, social services, and other sectors to meet a range of patient needs. Additionally, prepopulated letter templates or referral pathways within the EHR improve the ease of referral and result in more appropriate transfer of information to a community specialist. In one example of a medical-legal partnership, a letter to help patients with low incomes and chronic medical conditions retain heat and electricity services was integrated into the EHR, resulting in a 300% increase in the number of completed utility protection letters.[138]

Emerging models of care, such as patient-centered medical homes, use multidisciplinary team members to expand the reach of the physician, enhance the comprehensiveness of care, and reduce health inequities. In addition to the additive impact that a team of health care professionals can have above and beyond that of a single physician, newer care models also facilitate greater access to care by expanding clinic access and availability of physicians and health care professionals; providing alternatives such as phone, email, or virtual care; and being located in areas where patients live and work, such as in or near schools or churches. Locating within a community and being more available to those who reside there can also increase the likelihood of providing culturally appropriate care that reflects an understanding of the social determinants. Dedicated medical home support staff, such as community health workers, patient navigators, and case managers, as well as trained college students and electronic referrals made directly to community agencies, may facilitate linkage with community programs.

2. Moving care out of clinics

Community health workers are becoming more prominent partners in addressing social determinants of health. These individuals are members of the communities they serve, and thus possess intimate knowledge of community needs and resources. They are considered leaders among their peers. They can be trained to initiate discussions about

underlying social conditions and environment-related factors that impact health. They increase access to services, identify solutions to improve neighborhood conditions, and create community opportunities.

Providing care for individuals who are homeless, among those who face the biggest barriers to health care access, is another critical step in reducing disparities in health. The Street Medicine Institute (SMI) facilitates and enhances the direct provision of health care to the unsheltered homeless where they live. SMI provides health and social services specifically focused on addressing the unique needs and circumstances of people experiencing homelessness, exactly where they are and on their own terms, to maximally reduce or eliminate barriers to care access and follow-through. SMI does this by providing communities and clinicians with expert training, guidance, and support to develop and grow their own Street Medicine programs. Now a global leader in developing the field and practice of care of the homeless, SMI has helped cultivate or improve similar programs in over 85 cities in 15 countries across 5 continents.

3. Using practice data to support community-based change

Including data on social determinants of health in the EHR supports the potential to assess the overall health and needs of a practice's panel of patients. This potentiates the ability to address systemic issues without adding to the administrative burden on providers.[118] For example, identifying a group of patients with uncontrolled asthma in a concentrated geography may signal substandard housing and a need for legal and other community services to help address this underlying issue. The EHR could be used to identify all patients served by a clinical practice or health system who live in a healthy-food desert and advocate for access to fresh produce in identified areas. Such information could also help care teams and community partners target disease prevention and healthy living initiatives, such as developing safe and free opportunities for exercise. These data can be derived from practice-entered or health care system-entered screening tools or can be identified through publicly available community-level geocoded data (e.g., Aunt Bertha, *Health*Landscape, Health Resources and Services Administration).[127]

Ongoing quality improvement efforts that assess the outcomes of screening and intervention initiatives to reduce the impact of social determinants can help ensure that interventions are effectively reaching those they are intended to help. The health care system needs to more effectively utilize measures to understand the impact of income, education, and related issues on health and health care utilization. Data-driven economic arguments can help payers of health care services recognize the important role that reducing the impact of social determinants of health can play in sustaining and improving health, lowering costs, and reducing disparities. Savings realized from lower health care costs can help ensure financial support for those organizations that provide vital social services.

Health care systems could see greater improvements in patient outcomes if they become involved in addressing social determinants in the communities they serve. Failing to address social determinants at the most fundamental level impedes the opportunity to effect widespread, sustainable change in population health.[34]

Developing a community-based coalition of partners aids in defining key components of a health-promoting system.[141] A shared vision among stakeholders and bidirectional understanding of perspectives and contributions form the foundation of a high-functioning coalition. Communication is key, especially with the public sector, and requires using language that facilitates understanding about the impact of social and economic factors on health and health care. Talking about reversing inequity in opportunities to improve health and reducing expensive health care utilization may be most effective.[142]

A variety of health care professionals and other community partners may be considered in developing coalitions to address social determinants of health. An example of this is found in Health Share of Oregon, a nonprofit, state-designated coordinated care organization that established a Community Advisory Council composed of strategically recruited members who reflect the diversity of the community across race, ethnicity, age, gender, sexual orientation, and geographic location. The council conducts community health assessments to identify community needs and develops community health improvement plans to address health disparities. It also advises organizational governance regarding Health Share's strategic plan, quality improvement plan, innovative interventions and care redesign, and opportunities to improve population health at the community level.[143] Council members can include community-based organizations, government agencies, and private sector partners who collaborate to advance social accountability and participate in collective action to create systems that protect health.[144]

Health professions can play many important roles beyond the provision of direct patient care. Practice-based or health system–based health care professionals can contribute their expertise and influence as health advocates within communities, speaking alongside and on behalf of others to support the mobilization of resources to effect change. Such activities could range from providing volunteer clinical services to serving on the advisory boards of advocacy or social service organizations.

Medical-legal partnerships are another promising clinical-community collaboration that addresses problems with housing, public benefits, and education.[145,146] Attorneys can help improve health by holding schools, agencies, and landlords accountable for addressing patient and family needs. The National Center for Medical-Legal Partnership has a mission to improve the health and well-being of people and communities by leading health, public health, and legal sectors in an integrated, upstream approach by combating health-harming social conditions.[147] They provide a toolkit to guide practices, health care systems, and legal institutions through the process of coordinating care and developing a medical-legal partnership.

Outreach workers are also potential members of a community-based health care team. For example, the family empowerment program is an interdisciplinary approach to working with multistressed urban families. This model has been used to provide services to disengage youth from gangs and street activity and to connect them with resources for housing, job training, health care, and education.[148]

Coalition building requires a phased approach, beginning with joining or creating an organization to advocate both within and on behalf of communities. Adaptation and

utilization of available tools can save time and limited resources when working with community partners, as in these examples:

- The WHO's Health Impact Assessment can be used to provide a better understanding of the potential impacts of a proposed policy, regulation, or project while it is being developed.[149]
- The Prevention Institute's Tool for Health and Resilience in Vulnerable Environments (THRIVE) can be used to help community members shift from focusing on a discrete health problem to focusing on the factors that underlie the problem. THRIVE provides a structured flow and process that is easily accessed by all involved partners and is organized so that community members with little experience can understand the role that physical, social, and economic environments play in shaping the health and safety of their community and can identify potential solutions.[150]
- The Community Tool Box is a free, online resource with tools for learning and assessing community needs and resources, addressing social determinants of health, engaging stakeholders, action planning, building leadership, improving cultural competency, planning an evaluation, and sustaining efforts over time.

See Appendix 12.2 of this chapter for a collection of tools to support referrals and resources.

APPENDIX 12.2

Tools to Support Referrals and Resources

Clinicians should be able to refer patients to special services that address their economic, environmental, and psychosocial needs in the same fashion as they would refer for physical therapy or specialty care.[169] Many clinical practices and health care systems have developed local resource guides with referral information based on specific needs. Additionally, national search engines are available that can provide specific information to help match patients' resource needs with their geography.

1. **Aunt Bertha:** A free online social services search engine, Aunt Bertha connects people in need to programs in their community. The site lists available social services, including food, housing, transportation, health care, finances, education, employment, legal aid, and goods/supplies (e.g., baby supplies, clothing). The services are based on zip code and allow for electronic referrals.
    - Aunt Bertha website: https://www.auntbertha.com
2. **Neighborhood Navigator:** The American Academy of Family Physicians developed the Neighborhood Navigator to address social determinants at the point of care. The interactive tool can be used to connect patients to social services in their area that can provide help with food, housing, transportation, employment, legal, or financial issues. Results can be filtered by category, patient eligibility, and demographics. Neighborhood Navigator can accommodate more than 100 languages and is integrated with Google Maps to provide step-by-step

directions to community resources. Care teams also can refer patients to a patient-facing version of the tool (https://navigator.familydoctor.org) to enable them to independently locate services that meet their social needs.
    - Neighborhood Navigator website: https://www.aafp.org/patient-care/social-determinants-of-health/everyone-project/neighborhood-navigator.html
3. **HealthLandscape Community Vital Signs Population Health Profiler:** Also developed by the American Academy of Physicians, *Health*Landscape has a Community Vital Signs Population Health Profiler tool, which lets users create zip code–level maps of their service area and key community measures, including the distribution of age, ethnicity, social deprivation, inequities, access to health care, and chronic conditions.[170] The tool is intended to provide practices with the ability to easily upload a list of zip codes and counts of their patients in those zip codes to see the health and social characteristics of the areas that they serve. Using this tool, clinicians can map the percentage of the population with hypertension compared to their patient distribution or map the percentage below poverty level or who have health insurance, all using small area estimates.
    - *Health*Landscape Community Vital Signs website: https://www.healthlandscape.org/PopHealthProfiler
4. **Health Leads:** Developed at Boston Medical Center with support from the Robert Wood Johnson Foundation, Health Leads uses trained college students as referral specialists to address basic resource needs at the root causes of poor health.[171] Sample screening questions include "Are you running out of food at the end of the month?" and "Do you have heat in your home this winter?" The program then enables physicians and other health care professionals to prescribe basic resources such as food and heat, just as they do medication, and refer patients to needed community resources, just as they do any other specialty. Health Leads–trained students work side by side with patients to connect them with the basic resources they need to be healthy (e.g., applying for nutrition assistance program benefits, locating shelters, aiding in housing searches, or locating child care services). Use of a resource database and case management system enables these advocates to search for community resources and benefits that best match the needs of the patients they serve.
    - Health Leads website: https://www.healthleadsusa.org

C. Public policy and advocacy

The contributions physicians can make do not always have to occur in direct clinical services to patients. Physicians can work collectively with colleagues and other agencies in support of or in opposition to public policies and use their voices to educate the public to the social and political causes of health inequity.

Public policy can play a central role in advancing (or hindering) public health. Public policies addressing vaccine-preventable illness, tobacco control, newborn screening, and motor vehicle safety, just to name a few, have contributed to major improvements in public health over the past century. This section reviews possible directions for policy

change to address health inequalities and makes some recommendations to the health professions student aspiring to get involved in advocacy.

Addressing social determinants of health and health inequity will require change across a wide range of policy areas. In 2016, multiple evidence-based areas of policy reform in the United States were proposed in a discussion paper published by the National Academy of Medicine[151]:

1. Address root causes of social determinants of health in areas such as redlining and mortgage foreclosure by banks, dispossession by real estate developers, locating toxic waste and landfills in communities of color, workplace exploitation, and segregation.
2. Increase resources and invest in environments to foster healthy behaviors throughout the life course. Policy interventions include nutrition assistance at all stages of life, high-quality child care and early education, healthy behavior incentives, and firearm safety.
3. Extend the reach and transform the financing of health care services. Improve clinical health care services, including improving health care access, cost, and quality. Include alternative payment models, broader health insurance coverage, and greater investment in chronic disease and oral health.

As the authors stated, "The best available evidence suggests that a health policy framework addressing social and behavioral determinants of health would achieve better population health, less inequality, and lower costs than our current policies."[151] Furthermore, they pointed out that "drivers of health lie outside the conventional medical care delivery system, so we should not equate investment in clinical care with investment in health."[151]

In England, the Secretary of State for Health commissioned a task force in 2008 to identify policy objectives to address health inequalities. The Marmot Review put forth six policy objectives: expand investment in early child development and maternity services and parenting programs; expand the role of schools in support of families and children; reduce long-term unemployment and increase access to high-quality jobs; establish a minimum income for healthy living; improve access to open and green spaces and integrate planning of transportation, housing, environment, and health systems to address social determinants of health; and strengthen clinical health care delivery and disease prevention across the social gradient.[1]

Public policy goals that address social determinants of health cannot be accomplished without focused, strategic advocacy work. Busy health professions students or working professionals may feel they have limited time to get involved in advocacy. However, health care professionals can carry a great deal of influence with legislators and voters. Their voices can play a crucial role in advocacy for policy and sociocultural change. Here are some considerations for those interested in getting involved.

There are a different modes and types of advocacy work. There tends to be a focus exclusively on elected officials and the process of lobbying and legislation. One should also consider grassroots organizing and the role of mass media and communications.

Grassroots community organizing and coalition building can increase the ability of local and regional communities to effect change that is rooted in the needs of everyday people. In a society dominated by social media and mass media, there is a central role for strategic communications and cultural leadership in influencing the cultural narratives that often determine the shape and outcome of public policy efforts.

There are countless organizations at multiple levels that continually invite involvement. As just one example, consider the extensive reach of engagement of the American Medical Association, with national, state, regional, and institutional organizations. Every medical specialty has professional associations at multiple levels, and other health professions have similar organizations. Furthermore, policy think tanks and research groups can have a significant influence on public policy development.

Ideally, advocacy includes and prioritizes the voices and leadership of those most impacted by health inequalities. Community-based and foundation-funded collaboratives can play key roles in advocating for health policy change. An example is Building Healthy Communities, a 10-year, $1 billion initiative launched by The California Endowment to promote health equity. As they say, "Where you live shouldn't determine how long you live, but it does." Through this initiative, 14 local communities in California have been funded over 10 years to build power, advance local and statewide policy, and change the narrative about community health. These collaboratives, involving community residents, grassroots organizations, youth, and government leaders, have had significant influence on public health and health policy outcomes across the state. They have focused on educational policy and improvements in schools, neighborhood and community development, and improved health care access and delivery.[152]

Health professions students interested in advocacy may consider the following:

- Geographic scope: Opportunities for advocacy abound at the institutional, local/regional, state, and national levels.
- Issue area: Think about specific issues that are personally meaningful and motivating. The umbrella of "social determinants of health" is broad and, as outlined previously, cuts across many areas of policy and social change.
- Advocacy skills: Many skills are important to successful and strategic advocacy work, including knowledge of the issue and of pertinent governance structures, communication (mass media, social media), organizing (grassroots neighborhood-based, online/digital), policy (think tank and position paper development), lobbying and coalition building, event planning (collective action, events and rallies), electoral campaigning (ballot measures and initiatives), fundraising, and organizational development. Those interested in advocacy may consider which skills they already have and can contribute in order to begin and build on those strengths.

The best time and place to get involved in advocacy is here and now. With this in mind, the interested student, in order to identify the opportunity of the moment, may

methodically seek the greatest "overlap" of:

- Interest: What is personally meaningful to the student?
- Opportunity: Where does organizational or group momentum already exist, and where can health professions students make an impact?
- Need: What is important and needed in society?

D. Global considerations

Structural and social disparities are pervasive across the globe. Worldwide increases in global migration have highlighted the connections in health across continents. Many health professions students seek experiences in global health, and it is important to structure these programs in a manner that promotes equity by empowering partner communities and generating sustainable support structures. One does not have to travel the globe, however, to encounter patients with health concerns related to the following issues. The impact of these global trends is felt by communities throughout the United States.

1. Climate change

Climate change is a global structural determinant of increasing magnitude. In 2019, over 70 American health organizations (including the American Medical Association) joined together to issue the "U.S. Call to Action on Climate, Health, and Equity: A Policy Action Agenda."[153] The coalition represents physicians, nurses, health care and public health professionals, health care workers, hospitals, health care systems, health education institutions, and public, environmental, mental, and community-based health agencies and organizations.

> Climate change is one of the greatest threats to health America has ever faced—it is a true public health emergency. The health, safety and wellbeing of millions of people in the U.S. have already been harmed by human-caused climate change, and health risks in the future are dire without urgent action to fight climate change.[153]

The report explicitly addresses the disproportionate impact of climate-related health risks on vulnerable populations and its potential to exacerbate health inequities. The group maintains an optimistic outlook, stating that immediate action can mitigate planetary health consequences: "the health crisis caused by climate change also presents a major health opportunity. Building healthy energy, transportation, land use, and agriculture systems now will deliver immediate and sustained health benefits to all and reduce future health risks from climate change."[153] In the meantime, physicians and other health care professionals must be attuned to the health impacts of environmental stressors, extending beyond extreme events to include vectorborne, foodborne, and waterborne infectious diseases; changes in the quality and safety of air, food, and water; and stresses to mental health and well-being.

2. Immigration

Evolving political, social, and economic policies and inequalities fuel immigration, and US physicians and other health care professionals must be prepared to attend to the health of immigrant communities. Immigration impacts health outcomes[154] via the conditions that individuals and families endure during the process. Additionally, there is increasing evidence that allostatic load associated with immigration status can determine health, as illustrated by the finding that preterm births for Mexican women rose after the 2016 election.

According to the Pew Research Center, there were 43.7 million foreign-born people in the United States in 2016, including 11 million undocumented immigrants. Immigration affects health through many mechanisms, including access to resources, experiences of violence, discrimination, fear, stress, and access to safe work and housing. The Personal Responsibility and Work Opportunity Reconciliation Act—the 1996 Welfare Reform Act—made most legal immigrants ineligible for publicly funded services (i.e., Medicaid) for the first 5 years of residence in the United States; undocumented immigrants are ineligible for all publicly funded services. While the Affordable Care Act expanded access to care for many immigrants, undocumented immigrants remain ineligible.

Recently, the United States has heightened immigration enforcement, increased family separations at the border, and increased deportations. Fear of deportation increases emotional distress and decreases self-reported quality of life.[155] As detailed earlier, the impact of chronic stress on health outcomes has been well documented. The Urban Institute studied the health impact of raids and deportation on children.[156] After deportations, children and family members left behind experience difficulty coping with the economic and psychological stress (feelings of abandonment, symptoms of emotional trauma). Family separations increase symptoms of depression, anxiety, and posttraumatic stress disorder, and worsen post-resettlement stress.[157] Physician and health care professional awareness of these impacts is necessary to provide appropriate care to families and communities impacted by family separation throughout the country.

Fear of deportation and retaliation prevents some immigrants from seeking fair housing and labor protections. This fear puts them at increased risk of work-related injuries and illness[157,158] and makes them more likely to tolerate poor housing and unsafe neighborhoods. People of immigrant status are more likely to have limited formal education, to work in low-paying service occupations, and to live in poverty. Although there are variations based on country of origin and circumstances surrounding emigration, these conditions are especially true for immigrants from Mexico and Central America. Immigrants and refugees are also less likely to have had basic preventive care in their country of origin, such as immunizations, age-appropriate screenings, and care for chronic illnesses such as diabetes and hypertension.[159]

Recent troubling human rights abuses, family separations, and medical neglect are well documented occurrences in migrant detention centers operated by the US Department of Homeland Security (DHS).[159a,159b]

Institutions of organized medicine have spoken out against these policies; many have

called for an end to family separation and a reinstatement of the Flores Settlement Agreement.[159c-159g] Physicians for Human Rights has organized an Asylum Network of physicians trained to provide forensic medical and psychiatric evaluations of migrants seeking asylum.[159h] A national network of physicians called Doctors for Camp Closure has issued a five-part position statement calling for an end to the use of detention, an end to family separation, immediate implementation of independent medical oversight of detention centers operated by DHS, cessation of medically dangerous deportations, and termination of the federal Migrant Protection Protocol policy (also known as "Remain In Mexico").[159i] US physicians may see patients who have been directly or indirectly affected by these policies and should be aware of these policies and their health impacts.

Policies regarding expanded access to health care, strengthened access to safety net programs, and increased funding for community clinics and other community-based resources could support improved health outcomes for these vulnerable immigrant populations.

VII. Case study conclusions

Case study 1 conclusion

You inform G.C. that you will work to meet his care needs, and you acknowledge the drivers behind his distrust of the health care system. You prescribe hormone therapy for gender-affirming care. You discuss the labs that are needed prior to prescribing and for monitoring. You also spend time reviewing some of G.C.'s high-risk sexual behavior, recommended immunizations, and preventive care. After assessing his risk for suicide and harm to self, you decide to see how his mood changes with starting testosterone. G.C. is interested in supportive counseling, so you do a warm handoff (transfer of care between two members of the health care team, where the handoff occurs in front of the patient and family)[160] with the counselor. Your encounter with G.C. reminds you to review the clinic's intake forms and signage to assess for inclusivity.

Case study 2 conclusion

After you assess M.K.'s cardiovascular risk, you address his mood. You talk with M.K. about his family situation; you acknowledge the burden of this stress and how it is negatively affecting his well-being. M.K. completes the Patient Health Questionnaire-9 and Generalized Anxiety Disorder-7 surveys and screens positive for moderate depression and anxiety. With further questions, you confirm a diagnosis of depression with anxiety. Together you develop a follow-up plan and agree to continue to discuss his mental health, his tobacco use, and his ongoing primary care needs. He accepts your suggestion to be referred to counseling. Assuming other community members share similar fears about profiling, you make a note to reach out to community partners to discuss potential opportunities to provide guidance to youth and their families regarding these concerns.

Case study 3 conclusion

Your clinic routinely asks patients to complete the American Academy of Family Physicians EveryONE Project Social Needs Survey. R.L. identifies food insecurity, housing insecurity, and safety concerns in the survey. You both use the EveryONE Project Neighborhood Navigator to search for resources for housing, utilities, legal aid, and social services that are available in her zip code. Together, you complete the Patient Action Plan and commit to a follow-up plan. Your team helps her to enroll in a federally qualified health center and apply for SNAP and WIC benefits. You also introduce her to a colleague from the clinic's medical-legal partnership office.

VIII. Chapter summary

This chapter addresses the role of the social and economic conditions in which people live, work, and play as prime determinants of health and health disparities in populations. Although most people in the United States tend to think of population health largely as a function of access to health care services, strong evidence shows that such access is a relatively minor determinant of health. The root causes of ill health are powerfully correlated with conditions such as socioeconomic position, educational attainment, housing, and exposures to racism and discrimination. Evidence-based models give compelling rationales for believing that the connections between social determinants and health outcomes are causally related. To address social determinants of health, it is imperative to recognize and address the underlying structural determinants driving health inequity.

The chapter details exemplar programs that facilitate health care professionals' ability to screen for the ways in which social and economic conditions contribute to health outcomes for their patients. Beyond screening, the chapter also details how practice support resources and professionals outside the traditional boundaries of health systems can help address the social determinants of health. Crafting more equitable practice designs and using practice data to drive broader structural changes may also assist in alleviating the inequitable toll that adverse social conditions take on health. All of these approaches should incorporate community organization, participation, and advocacy, and the chapter details a variety of programs that do so effectively.

Special emphasis must be placed on the cultivation of cultural humility within health care professional practice. Professional attitudes toward disadvantaged groups have a great impact on quality of care, and thus lifelong learning is essential to action on the social determinants of health.

Questions for further thought

1. Beyond the examples given in the chapter, describe one additional example of a social determinant of health and how it might influence health equity for a population.
2. From your own experience, describe an example of intersectionality and how the individual factors may have compounded to impact an individual's health outcomes.
3. What are some examples of the impact of race on disparities in morbidity and mortality rates?
4. Why are differences in educational attainment correlated with health disparities?
5. How can you, as a health care professional, impact social determinants in your community?

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This volume is a collection of papers by a multidisciplinary group of scholars, the MacArthur Research Network on Socioeconomic Status and Health, written at the conclusion of their decade-long collaboration. This group developed understanding of social disadvantage and its consequences, and, crucially, the mechanisms by which socioeconomic factors affect the health of individuals and their communities.

Bazemore AW, Cottrell EK, Gold R. et al. *Community vital signs* incorporating geocoded social determinants into electronic records to promote patient and population health J Am Med Inform Assoc 2, 2016;23: 407-412.

Given the proliferation of big data, geospatial technologies, and democratization of data, the time has come to integrate "Community Vital Signs" into the electronic health record (EHR). This article describes (i) historical precedent for the concept of Community Vital Signs, (ii) opportunities to expand upon these historical foundations, and (iii) a novel approach to EHR integration.

Centers for Disease Control and Prevention. The Adverse Childhood Experiences Study Last reviewed April 2, 2019. Available at https://www.cdc.gov/violenceprevention/acestudy/index.html 2019; Accessed October 28.

Adverse childhood experiences (ACEs) have a tremendous impact on future violence victimization and perpetration and lifelong health and opportunity. This Centers for Disease Control and Prevention (CDC) website portal provides an overview of ACEs, plus sections on the original CDC-Kaiser study, resources, literature, and the Behavioral Risk Factor Surveillance System survey, in which 32+ states are participating in collecting more data.

Daniel H, Butkus R. *Health and Public Policy Committee of American College of Physicians. Lesbian, gay, bisexual, and transgender health disparities* executive summary of a policy position paper from the American College of Physicians Ann Intern Med 2, 2015;163: 135-137.

In this position paper; the American College of Physicians examines

the health disparities experienced by the lesbian, gay, bisexual, and transgender (LGBT) community and makes a series of recommendations to achieve equity for LGBT individuals in the health care system. These recommendations include enhancing physician understanding of how to provide culturally and clinically competent care for LGBT individuals, addressing environmental and social factors that can affect their mental and physical well-being, and supporting further research into understanding their health needs.

Gold R, Bunce A, Cowburn S. et al. *Adoption of social determinants of health EHR tools by community health centers* Ann Fam Med 5, 2018;16: 399-407.

This pilot study assessed the feasibility of implementing electronic health record (EHR) tools for collecting, reviewing, and acting on patient-reported social determinants of health (SDH) data in community health centers. The authors found that adoption of systematic EHR-based SDH documentation may be feasible, but substantial barriers to adoption exist. Lessons from this study may inform primary care providers seeking to implement SDH-related efforts, as well as related health policies.

Gottlieb I, Sandel M, Adler NE. *Collecting and applying data on social determinants of health in health care settings* JAMA Intern Med 11, 2013;173: 1017-1020.

Current approaches to social determinants generally focus on population-level and policy interventions; these overlook individual and clinical innovations within health care that can address patients' social circumstances. This article proposes a framework for how social determinants interventions in the health care system can be construed across three tiers—patient, institution, and broader population—and describes ways to collect data and target interventions at these levels.

Siegel J, Coleman DL, James T. *Integrating social determinants of health into graduate medical education* a call for action Acad Med 2, 2018;93: 159-162.

The authors assert that competency in recognizing and mitigating social determinants of health (SDH) should become a vital component of graduate medical education in all specialties. Although the most effective approaches to educating trainees about SDH are uncertain, in this invited commentary the authors offer

several key principles for implementing curricula focusing on SDH. These include universalization of the material, integration into clinical education, identification of space for trainee introspection, clarification of specific competencies in identification and mitigation of SDH, and creation of robust faculty development programming.

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Health law and ethics

William M. Sage, MD, JD, I. Glenn Cohen, JD, Allison K. Hoffman, JD

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In this chapter

Both law and ethics are essential attributes of a high-functioning health care system and powerful explainers of why the existing system is so difficult to improve. US health law is not seamless; rather, it derives from multiple sources and is based on various theories that may be in tension with one another. There are state laws and federal laws, laws setting standards and laws providing funding, laws reinforcing professional prerogatives, laws furthering social goals, and laws promoting market competition. Complying with the law is important, but health care professionals also should understand that the legal and ethical constraints under which health systems operate must themselves adapt if health systems science is to advance.

Learning Objectives

1. Explain the relationship between law and ethics in the design and operation of US health care.
2. List several areas of health system governance that depend heavily on law and identify the principal health laws in each area.
3. Describe a few ways in which the transition from a dyadic approach to care based on one patient and one doctor to a systems approach based on teams, organizations, and populations presents challenges for health law and ethics.

"A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."

—American Medical Association Principles of Medical Ethics[1]

I. Introduction: Law and ethics in health systems change

A systems approach to health care is replete with legal issues. State laws govern the provision of health care (such as licensing health professionals and facilities) and many aspects of health insurance. Federal laws determine how hundreds of billions of dollars flow through the health care system each year (especially Medicare and Medicaid), and both fund biomedical innovation (the National Institutes of Health, among others) and regulate it (the Food and Drug Administration [FDA]). Underlying both sets of laws is a strong commitment to professional self-regulation, which continues to entrust physicians with authority over many aspects of medical practice even as corporate control grows and expenditures rise. The pursuit of value-based health care may be impeded by existing laws or by fear of legal liability under conditions of uncertainty. Moreover, interest groups opposed to value-improving reforms may lobby to preserve or even increase legal barriers.

The relationship between health law and medical ethics remains unsettled, although the rapid growth of the regulatory state has undoubtedly pushed law to the forefront.[2,3] However, ethics must continue to be the main driver guiding behavior for the benefit of the patient. The ethics of personhood is a crucial aspect of health system governance, as is the related ethics of technological change. The ethics of privacy has become particularly important as more information—including genetic information—is collected, exchanged, and analyzed electronically.

A. From rationing to justice

Fortunately, the ethical challenge most often associated with efforts to reduce health care expenditures—explicit or bedside rationing of lifesaving services—should become less of a concern in the current era of value-based health care design than in the decades that preceded it. Rationing seemed inescapable when society believed that nearly all care that physicians recommended or rendered was scientifically required, precisely delivered, and fairly priced. Under those assumptions, spending more on health care meant spending less on other needs, and spending less on health care meant sacrificing quality or compromising access.[4,5]

By contrast, the pursuit of value today is motivated by the recognition that health care delivery can frequently be inefficient.[6] Wasteful spending reduces quality rather than enhancing it, which implies that the pursuit of value can boost the health care system's accessibility and therefore its fairness without requiring tragic choices. That is why the three prongs of the Triple Aim are framed as iterative, decentralized improvements rather than as competing characteristics of a system in ethically perilous equipoise.[7] In addition, value-based care might create its own ethical challenges, such as what constitutes value or whose views determine how much value is worth paying for.

At the same time, other ethical challenges have intensified. Many aspects of the health

care system increasingly appear unjust, such as substantial barriers to receiving necessary services and demonstrable racial and ethnic disparities in both access and outcomes.[8,9] Moreover, profound inequalities at the community level in wealth and education, endemic violence, concentrated environmental hazards, and other social determinants exert negative effects on health that cannot be overcome by medical care alone.[10]

B. Big ethical questions and enforceable legal obligations

Other core issues in ethics and associated law respond to new medical technologies and changing social values. By the 1980s, the nascent field of bioethics had crystallized around a few topics: reproductive technologies (such as in vitro fertilization) and the regulation of reproduction (abortion, contraception, sterilization, maternal-fetal conflicts); end-of-life decision making, assisted suicide, and the definition of death; organ transplantation (procurement and allocation); and research ethics. In the late 1990s, genetics and genetic information became a central concern, along with HIV/AIDS and pandemic disease/bioterrorism. Behavioral health, drug development and pricing, population health, and global health also present persistent ethical-legal challenges.

When one teaches pure bioethics, deeply normative arguments are always on the table. Questions might include: What criteria help us determine when legal personhood should begin or when individuals are dead? How should we understand coercion or exploitation in deciding whether organs or women's eggs should be sellable? What claims can we make to health as a human right, and what do we owe one another as social solidarity?

Translating bioethics into law, by contrast, requires a kind of double vision. With very few exceptions, normative and conceptual arguments must be introduced through formal procedures and translated into enforceable obligations with associated remedies.

Bioethics has very likely inspired legislatures to pass statutes and administrative agencies to adopt regulations, as well as motivating various groups to support or challenge those enactments. There may also be an upside of legal analysis: the dry vernacular of the courts sometimes "takes the political charge out of contentious issues and deflects expressive contention away from [them]."[11] This, of course, raises an even harder "meta-question" about whether the American civic ideal of the rule of law can withstand too much engagement with comprehensive moral views.

C. Ethics of organizations and groups

The development of systems of care has challenged both medical ethics and health law. Historically, medical ethics focused on individual duties and rights arising from the intimate, dyadic relationship between a single physician and his or her patient. As Paul Starr documented in his Pulitzer prize-winning book *The Social Transformation of American Medicine,* legal doctrines arose that reinforced these ethical obligations by insulating the physician-patient relationship from both governmental and corporate control.[12] A crucial task for health systems science, therefore, is to identify and rethink

the ethical and legal interdependencies among health care professionals, health care institutions, patients, and the public.

The rapid expansion of health maintenance organization (HMO)–based coverage in the early 1990s ("managed care") precipitated a vigorous debate over two ethical issues: whether individual physicians might ethically consider group as well as individual patient interests and whether health systems might articulate and embrace a nascent "organizational ethics." These controversial changes, which would be reinforced by law, reflect several underlying assumptions. First, that established "fiduciary" duties (see the following section) would need to be supplemented by more complex corporate obligations, including those associated with physician employment. Second, that protecting public funds from corporate exploitation could no longer rely on certifications of necessity from individual health professionals but would need to be done more directly. Third, that substantial self-regulation would need to occur through firm-specific processes with government oversight of corporate compliance, rather than exclusively through licensed professions. And fourth, that corporate entities should be subjected to stronger expectations of market competition than has been the case for individual professionals, raising the question of whether "professionalism" can be maintained without allowing some degree of economic protectionism ("market power").

In the last two decades, the ethics of groups has expanded dramatically beyond HMO coverage to communities and populations more generally. In contrast to many European countries, which have a public law that imposes collective, constitutional obligations ("positive rights") based on ideals of social solidarity, Anglo-American political philosophy has emphasized individual freedom from government coercion or restriction ("negative rights"). As a result, there is neither an enforceable right to health care in the United States nor a collective national commitment to providing it affordably. Both bioethics and health law are therefore entering unfamiliar territory as they confront a variety of population-based challenges: the optimal balance of individual and societal responsibility for health, emergency humanitarian interventions, health and human rights more broadly, setting priorities for health and health care investment, relating health to economic development, safeguarding vulnerable populations, environmental justice, population genetics, balancing health and civil liberties, global health equity, and social determinants of population health.

Exercise

Think of the law related to some aspect of medical care. Does the law answer all the questions of professional ethics or bioethics that occur to you in connection with that aspect of medical care? Why do you think some bioethical questions have many associated laws and regulations, while others do not? When you need to make an ethical decision, do you expect to look up an answer, to ask a supervisor, to consult a colleague (if so, of what sort), to confide in family or friends, or to rely on your personal experiences and moral judgment? Write a paragraph about an ethical challenge you personally faced or witnessed during medical or health professions school, describing how it was resolved (or not) and whether or not its resolution depended (or should

have depended) on law.

II. Fiduciary duty and conflict of interest

The power long granted the US medical profession to self-regulate, rather than being subject to governmental or corporate control, has carried with it a strong presumption of ethical conduct. Whereas a physician's competence and skill in a particular case might be questioned later in court (e.g., in a malpractice suit), that physician's commitment to act for the patient's benefit has seldom been subject to direct legal oversight. This stands in contrast to the legal framework for policing the fiduciary obligations to shareholders of corporate directors and executives: bad outcomes (alleged violations of the fiduciary duty of care) are generally excused under the "business judgment rule," but acts of self-dealing or prioritizing the interests of third parties (alleged violations of the fiduciary duty of loyalty) are closely scrutinized.

In recent years, much greater attention has been paid to physicians' ethical obligations beyond clinical competence, with areas of potential compromise often labeled "conflicts of interest."[13] Conflict of interest has entered the health policy vernacular because of a growing recognition that each physician-patient relationship is subject to institutional complexities and financial entanglements, both of which are intensified by the uncertain yet lucrative process of biomedical innovation. These pressures call into question three layers of public trust in medicine and increase the perceived need for legal regulation: trust in physicians to serve their patients, trust in researchers to serve the interests of society, and trust in professions to ensure ethical conduct by their members.

One can expect issues of loyalty and faithfulness to become even more important as care responsibilities are shared between individual professionals and health care organizations, as health care converges with health-related activities of private industry and public social service agencies, and as more data flow among (and are analyzed by) all these actors, including using "deep learning" to anticipate and modify human behavior. Both law and ethics will need to evolve as well, going beyond the direct disclosure that has been the traditional response to conflict of interest and meeting public expectations by developing transparent processes and rules of conduct.

Case Study 1

You are a noted physician-researcher who is a salaried full professor at an internationally known nonprofit academic cancer center. You run a large research laboratory there that studies the biology of cancer. You do not care for patients directly; rather, your laboratory conducts research trials that make promising therapies available to physicians and their patients at the cancer center and elsewhere. Over the course of your career, you have pioneered new treatments for several deadly cancers. Some of these treatments were patented and licensed to a large pharmaceutical company, which has developed drugs and biologics approved by the FDA that pay you substantial royalties. You also have a lucrative consulting contract with the pharmaceutical company.

1. Are these payments "conflicts of interest"? Should you continue to accept them?

Should you disclose them to the cancer center? To the federal government under the Affordable Care Act's "Sunshine Act" provisions?

2. You also learned recently that the senior leadership of the cancer center and several members of its board of trustees have sizable investments in a start-up company that has signed a contract with the cancer center to digitize its patient records and imaging results in connection with applying "big data" analytics to cancer care. Are these arrangements legally and ethically permissible?

A. Self-dealing in ethics and law

Payments to physicians by pharmaceutical companies are the clearest example of conduct that can distort care, skew research, and reveal weaknesses in professional self-governance.[14,15] Constructing a health care system around costly services certified as necessary through individual physicians' orders, referrals, or prescriptions creates a potential risk of kickbacks or the equivalent. The pharmaceutical industry dedicates fewer resources to research and development than to marketing and for many years spent the largest sums on face-to-face "drug detailing" by sales representatives who routinely offered gifts—ranging from trivial to lavish—to physicians likely to prescribe their products. During this period, the professional ethical response to the tension between physicians' self-interest and their fiduciary obligations to patients was muted.

Early ethical rules either merely echoed the legal prohibitions that were being adopted by Medicare to discourage unnecessary referrals (see the section on Fraud and Abuse later) or drew strained distinctions between prohibited gratuities and permitted payments for services rendered, such as speaking or consulting—even though the latter may sway physicians to overprescribe company products. It took a series of scandals, as well as generational change among physician leaders, to overcome this ethical complacency. In 2010, Congress passed the Physician Payments Sunshine Act as part of the Affordable Care Act (ACA), requiring all medical product manufacturers to disclose payments made to physicians or teaching hospitals to the Centers for Medicare & Medicaid Services, which makes that information publicly available through a searchable online database.[16]

B. Ambiguities in understanding conflict of interest

Important questions remain unsettled regarding the legal and ethical response to physicians' conflicts of interest. One question is whether the "primary interests" that take priority over "secondary interests" should be defined in terms of generally desirable attributes and broad social goals (e.g., professional altruism, scientific progress, the health of society) as opposed to specific obligations to identifiable parties (e.g., clinical decisions made to benefit patients).[17] A treating physician has a specific obligation of loyalty to a patient; a biomedical researcher does not have such an obligation.[18] Perhaps because individual physicians have only rarely faced situations where one patient's interests directly conflict with another's, such as those of a seriously injured potential organ donor and a transplant recipient, medicine has been less focused

on specific obligations than, say, the legal profession—which is detailed regarding whether and how to represent clients who are competitors or adversaries.

Labeling general motives and conduct as "conflicted" in the absence of specific duties can become a vehicle for professions to resist change, much as the medical profession historically declaring unethical any physician who accepted corporate employment. It can also breed tunnel vision regarding available ethical or legal responses. Specific conflicts of interest between agents or fiduciaries (physicians, attorneys, etc.) and the principal parties usually present a policy choice between requiring direct disclosure and informed consent, which enables a patient or client to assess the professional's likely fidelity given the conflict, and outright prohibition, which is justified when no amount of information given to the principal party would be sufficient to assure loyalty. Larger social goals, by contrast, may be better served by regulatory approaches to misconduct that take account of the broader causes and consequences of new organizational forms and financial arrangements, as well as by corresponding changes to health professions education that seek to reset professional norms.

C. Payment reforms and nonfinancial motivators

A second unresolved question concerns overall incentive structures for medical professionals. Ethical and legal agonizing over how physicians are paid if not on a fee-for-service basis demonstrates the limitations of the conflict-of-interest frame.[19] Throughout the 1990s, attempts by managed care organizations to modify financial incentives associated with patient care to health plan enrollees (e.g., capitation, withheld fees, bonus pools) were met with accusations of conflict and demands for disclosure or prohibition.[20,21] This faded as physician practice structures became too diverse and payments too intricate to bless or prohibit based on whether physicians were being paid to do more or do less, but was never replaced by a cohesive public policy regarding medical pricing and payment within health care organizations.

Similarly, university-based physicians have been criticized not only for receiving external payments from industry but also for failing to confront their nonfinancial conflicts of interest—such as winning government research grants, achieving institutional advancement, or gaining professional eminence.[22] This is particularly challenging when those considerations are alleged to compromise character. Human motivation is complex, and attempting to distinguish selfless from selfish conduct in the absence of a specific obligation and an identifiable external threat to fulfillment may prove fruitless.

D. Institutional conflicts of interest

A third unresolved question involves conflicts of interest at the institutional level, particularly within academic health care organizations that pursue mixed missions of patient care and biomedical research. Case Study 1 is based on conduct revealed in 2018 that both prompted institutional soul-searching and created potential legal liability at a renowned cancer center.[23] The ethical challenges of shifting professional services into

corporate entities are not limited to medicine. Defining the ethical obligations of law firms as opposed to individual lawyers is also a work in progress.

Many health care organizations require routine internal disclosure of conflicts by individual faculty and staff, which is reviewed and if necessary addressed by the organization. One real-world trend making this process more tractable is to emphasize each employee's obligation to the organization rather than to general professional ideals such as scientific progress and to monitor and address conflicts of interest within health systems on that basis.

While common in the corporate world, this approach departs from the traditional treatment of academic departments and individual faculty members as autonomous professional actors. Nonetheless, it has become a practical necessity to assure compliance with each organization's various legal responsibilities (see the section on Privacy and Confidentiality later).

When considering institutional conflicts, many health care organizations focus mainly on the personal conflicts of individuals in leadership positions whose outside interests could influence the direction of the overall organization. What remains to be thoroughly examined are the obligations of large health care organizations themselves given potentially conflicting commitments to patient care, funded research, and training—which may need as-yet undeveloped ethical and legal solutions. This is especially true for academic organizations that, in their own operations and in their agreements with commercial partners, promote discovery for the benefit of future generations as they care for those currently afflicted. As Case Study 1 suggests, ethical conduct, even by prominent organizations, can no longer be taken for granted.

When it seemed in the 1990s that physician groups, hospitals anchoring organized systems of care, and HMOs would be responsible for managing cost and quality at the group level, there was a surge of interest in organizational ethics, which many physicians resisted as contrary to the traditional primacy of individual patient interests.[24] Although the value-based care models of today seem less likely than managed care a generation ago to raise the specter of profit-motivated rationing, more work needs to be done on the ethics of organizations such as accountable care organizations that care for defined populations.

III. Professional self-regulation and market competition

Many ethical challenges for value-based health care relate to long-standing but inefficient professional practices. The medical profession's privilege to self-regulate carries with it a significant potential risk of economically self-interested conduct that could raise prices, reduces access to care, and discourages innovations in delivering health care or promoting health. Sometimes, such conduct violates federal and state antitrust laws that protect market competition in the private economy. However, self-regulation also promotes many desirable attributes of medical professionalism: expertise, diligence, loyalty, good character, altruism, charity, and collegiality. In an article describing lawyers rather than physicians, Professor Ronald Gilson asked a key question: "Is market power a precondition to professionalism?"[25] Economists have been divided on the answer. When health care costs began to rise in the 1960s, Milton Friedman argued that eliminating professional licensing would lower prices yet maintain ethics, while Kenneth Arrow claimed that professional ethics helps fill information gaps between physician and patients, thereby improving efficiency.[26,27] Each of them eventually won a Nobel Prize in economics.

Case Study 2

You are a practicing physician appointed by the governor to serve on the state medical board. Part of the state's Medical Practice Act provides that a physician may not prescribe medication in the absence of an established physician-patient relationship. This was enacted mainly because of concern over controlled substances. A for-profit company recently started operating in your state. The company signs contracts with large employers giving their workers telephone access to licensed physicians for medical consultations. You and the other physicians on the medical board, who have a voting majority, agree to adopt an emergency rule stating that a physician-patient relationship may not be established by telephone, and you notify the company that its physicians therefore may not prescribe medication over the phone. You adopt the rule knowing that the company's physicians never prescribe controlled substances and that many physicians in the state prescribe medication by telephone when on call for other physicians' patients, which the medical board regards as acceptable.

1. How do you justify the new rule?
2. How would you respond to a lawsuit alleging that the medical board violated the federal antitrust laws by acting anticompetitively?

A. The federal antitrust laws

The Sherman Antitrust Act (passed in 1890) declares "contracts, combinations, and conspiracies in restraint of trade" to be illegal and empowers both the government and private parties to bring suit.[28] Nonetheless, medical associations have routinely denied

membership and the business connections and resources associated with it to physicians who deviated from professional norms regarding the economics of medical practice. In the 1940s, the US Department of Justice (DOJ) brought criminal charges against the American Medical Association (AMA) for organizing a physician boycott of a group health plan.[29] By 1980, the US Supreme Court had firmly applied the antitrust laws to the "learned professions."[30]

B. Physician-hospital relations

The unusual relationship between US physicians and hospitals accounts for much of the confusion over antitrust law and medical practice. Most American hospitals are nonprofit organizations with a "voluntary, self-governing" medical staff composed mainly of economically independent, private practice specialists from the community who admit patients and use the hospital's resources to care for those patients. In other countries, family physicians typically have private offices, but specialist physicians are hospital employees. The American approach is the product of a complex history. Contributing factors include the conditions of federal funding for hospital construction after World War II, state laws that prohibit direct employment of physicians as the "corporate practice of medicine," private (Joint Commission) accreditation standards on which Medicare payment is based that view hospitals as under professional control, and the practicalities of generating hospital revenues from physician referrals in a nonuniversal health care system.

Because the medical staff model of hospital operations puts independent physicians in the position of collectively monitoring one another and judging new applicants, physicians who are disciplined or excluded can allege an economic "conspiracy" against them. Antitrust lawsuits in connection with hospital privileges became frequent enough that Congress passed a special law (the Health Care Quality Improvement Act of 1986) conferring legal immunity on bona fide peer review activities—protection that physicians demanded in order to continue serving on medical staff committees.[31,32] After Medicare changed its payment policies in the 1980s to encourage hospital cost containment, physicians accustomed to "open" medical staffs also sued hospitals and organized medical groups for excluding them from contracts to provide services in hospital-based departments such as anesthesiology, radiology, and emergency medicine. These suits were usually unsuccessful, as courts concluded that competition between hospitals was more significant than competition within hospitals—foreshadowing a more organization-based approach to hospital care.

C. Health care consolidation

In recent years, the industrialization of the health care system has altered the pattern of antitrust litigation. Individual physicians are less often involved as plaintiffs or defendants, in part because many physicians are now employees of hospitals and other organizations, and employees cannot be sued as conspirators with one another or with their employers. Most legal disputes over competition today involve preventing

anticompetitive mergers and acquisitions between hospitals, between health insurers (sometimes including pharmacy benefit managers), or between hospitals and large physician group practices.

These cases are usually brought by government antitrust enforcers such as the DOJ, the Federal Trade Commission, and state attorneys general.[33] Mergers are analyzed by defining the geographic market (e.g., Chicago) and the product market (e.g., acute care hospital services), estimating the economic effects (e.g., higher prices) of reducing the number of competitors, and determining whether any competitive benefits (e.g., reducing production costs, upgrading quality control systems) outweigh the likely harms from the challenged transaction.[34] Recent antitrust litigation has focused as well on contract terms imposed on other parties by dominant hospitals or health insurers that have the effect of preventing new competitors from entering the market.[35] Still, the hospital and health insurance sectors have become much more consolidated over the past two decades, putting into question the effectiveness of antitrust law in protecting competition in the health care sector.[36,36a,37] Of particular concern is that US antitrust laws are not well suited to undoing (as opposed to preventing) excessive consolidation or to keeping price and output at competitive levels in consolidated markets.

D. The competitive effects of regulation and self-regulation

Some of the most interesting disputes under antitrust law concern the relationship between market competition in health care and other health-related laws. Litigation involving pharmaceutical companies, for example, often relates to the anticompetitive effects of using FDA rules (e.g., those created by the Hatch-Waxman Act of 1984) to delay market entry of low-cost generic drugs.[38] For physicians and other professionals, the US Supreme Court ruled in 2015 that state licensing boards controlled by members of the regulated profession can be sued for federal antitrust violations if their regulatory actions are not supervised by actual state government.[39,40] This decision limiting "state action immunity" has important implications for the structure and operation of self-regulatory bodies in many professions, which often control entry of potential competitors by setting rules that favor established practice styles or asserting that services are being delivered by unauthorized individuals. Echoing Case Study 2, for example, after the Texas Medical Board acted repeatedly to discourage telemedicine, an antitrust suit led the Texas legislature to enact new rules that permit greater flexibility, promoting both competition and innovation.[41,42] Antitrust law can even reach situations that seem mainly bioethical in nature but that have commercial implications, such as collectively agreed limitations promulgated by a professional specialty society on the money that fertility clinics may pay to young women for egg donation.[43]

IV. Fraud and abuse

Imagine the following three scenarios, loosely based on the facts of actual legal cases:

- A medical device company pays a physician a small fee for every patient he refers to use the company's heart-monitoring device.
- Dr. Brown is a 25% investor in an imaging facility. He sends all his patients to this facility for imaging services, and, at the end of the year, Dr. Brown earns a share of the facility's profits.
- Mercy Hospital bills the Medicare program thousands of dollars for a full multiuse vial of Herceptin for each breast cancer patient treated, but the hospital can—and often does—use the same vial of Herceptin for multiple patients.

Each of these situations raises legal and ethical challenges. How should the law interject to regulate or eliminate them, if at all?

Estimates suggest that 10% or more of health care spending may be due to fraud and abuse,[44] ranging from providing unnecessary services (abuse) on one end to upcoding for care provided or billing for care that was not provided at all (fraud) on the other. Since the inception of Medicare, laws have increasingly attempted to root out fraud and abuse, although with limited success. Increased enforcement efforts during the Obama administration identified and prosecuted especially egregious offenders, yet it is a problem that will only be solved with structural and cultural changes. Physicians and other individual practitioners can play an important role by resisting incentives to bill more and do more.

Prior to the ACA, the Centers for Medicare & Medicaid Services paid claims with minimal investigation, after which the DOJ attempted to recoup illegal payments, an approach known as "pay and chase." The ACA introduced a more proactive strategy, using algorithms to identify fraudulent claims before payment. Although more successful, it still captures only a small percentage of cases of fraud and abuse.

A. False claims, kickbacks, and self-referral

Fraud and abuse laws aim to identify illegal practices that unnecessarily drive up the cost of health care, to recoup some of the unwarranted spending, and to target and punish wrongdoers. These laws are defined in federal and state statutes, as well as in guidance issued by the Department of Health and Human Services Office of the Inspector General.

The oldest federal antifraud law is the 1863 Civil False Claims Act (FCA), which broadly prohibits defrauding the government.[45] In health care, the FCA prohibits knowing submission of any false claim to the federal government, such as seeking payment for services not provided or provided in a way that does not meet program standards on, for example, quality and reporting. The FCA is notable for "qui tam," or

whistleblower, provisions, which allow anyone who knows of a violation to file an action on behalf of the government and to receive a percentage of recovered damages. A majority of successful FCA cases are brought in this way by employees who become frustrated with corporate practices, by competitors, or by patients. Violators face civil penalties up to $11,000 per claim plus three times wrongfully billed amounts and, in the most severe cases, exclusion from participation in Medicare and Medicaid.

The federal anti-kickback statute (AKS) is narrower and prohibits bribes or kickbacks, whether in cash or kind, for referrals or generation of business that is payable by a federal health care program.[46] Because it is a criminal law, it includes an intent requirement—that a violation be knowing and willful—but that standard is met if one purpose of an arrangement is unlawful, even if there are also legitimate purposes.[47] For example, waiving copayments for Medicare patients can be a violation of this law if one purpose is to induce patients to use more care, which can drive up Medicare spending. Physicians and others should be concerned about the AKS because violations are punishable by up to 5 years in prison, as well as by other criminal and civil penalties. Possible sanctions include steep fines and exclusion from Medicare and Medicaid.

When the Medicare inpatient Prospective Payment System was introduced in the 1980s, capping payment for hospital stays, various services moved from hospitals to outpatient settings. Many physicians invested in these ancillary care facilities, including clinical laboratories, imaging centers, and ambulatory surgery centers. In 1989, Congress passed the Ethics in Patient Referrals Act,[48] which prohibits financial relationships that can lead to overutilization. It and its successors, called the "Stark laws" after their strongest proponent, former Rep. Pete Stark, prohibit referrals for "designated health services" to facilities in which a physician or physician's family member has a financial interest, unless an exception applies. The Stark laws have no intent requirement, which means merely acting outside the permitted bounds triggers civil (but not criminal) penalties. The penalties are substantial, however, and may include exclusion from Medicare and Medicaid. Bills for services that violate the AKS or Stark laws are considered false claims, and therefore are actionable under the FCA as well. Both the AKS and Stark laws have carve-outs by statute or regulation, which explicitly make some activity permissible. For example, AKS "safe harbors" and Stark laws exceptions allow many arm's-length transactions that do not reward patient referral, such as salaried employment and various payments at fair market value.

B. Structural causes of fraud and abuse

Structural forces exacerbate fraud and abuse. The most important is how the United States pays for health care. Any payment system creates incentives and opportunities for abuse or fraud.[49] A fee-for-service system creates strong incentives for using more care, particularly when the recipient relies on professional advice regarding its necessity and the bill is mainly paid by third parties. When a physician gets paid once for an office visit, again for a laboratory test, and a third time for imaging—if he or she has an ownership interest in the laboratory and imaging facility—he or she has an incentive to do more, even if just to rule out a low-probability event. This physician also has an

incentive to charge, or at least refrain from questioning, a high price.

Private insurance companies have weaker incentives to combat health care fraud than one might expect and may even compound it. A physician told one of the authors a story of providing a routine service for a patient with diabetes. When he submitted a bill to the Medicare managed care plan, he got a warning reminding him that the patient had diabetes and asking if he wanted to add a modifier to the claim indicating the complexity of the service. This modifier would help the insurance company maximize its revenue because Medicare "risk-adjusts" its payment to health plans based on the health status of its covered population. The physician changed the bill as he feared the company would stop sending him patients if he refused.

Although the evidence is mixed regarding associations between corporate form and fraud, the United States is an extreme outlier among nations in how for-profit entities permeate its health care system. Even if nonprofit organizations often behave no better than their for-profit peers, profit potential leads to abuses, a fact illustrated by the proliferation of high-profile and high-dollar fraud prosecutions. Fraud and abuse claims against pharmaceutical companies are not the most common but are some of the biggest. The DOJ settled with GlaxoSmithKline in 2012 for $3 billion in civil and criminal penalties and with Pfizer in 2018 for $2.3 billion, including a $1.3 billion criminal penalty for off-label promotions and kickbacks. DaVita Healthcare Partners paid $350 million in 2014 to settle claims of illegal kickbacks and soon after set aside an additional $495 million in case ongoing fraud litigation went badly for the company. These companies were fined for systemic patterns of fraud and abuse.

Laws themselves may exacerbate fraud and abuse. Compounding the piecemeal payment structure is the separation between provider and facility payments, which is a relic of state laws. Yet this separation complicates billing and referral patterns, which can create opportunities for and obfuscate overuse and fraud.

C. Seeking cultural as well as structural change

Real solutions to fraud and abuse are more complex than passing and enforcing laws, even though monitoring and enforcement will always be needed. Simpler payment and delivery systems can make opportunities for abuse fewer and can make fraud easier to detect. Physicians are increasingly being employed by hospitals and large group practices, which might reduce various parties' incentives to boost referrals. Violations could be easier to identify by auditing contracts and imposing compliance obligations on provider organizations. Good hospital-based compliance programs might significantly reduce egregious offenses.

Changing professional culture is an indispensable part of combating fraud and abuse and should be integrated into physician education and training. A recent article highlighted the continued use of medical interventions after research disproves their value, focusing on stents for stable cardiac patients.[50] The article describes Grand Rounds at Barnes Jewish Hospital in St. Louis, where an expert first discussed his individual patient who fared well without a stent and then presented randomized clinical trials showing stents to be no more effective than less-invasive treatments in

stable patients. He then asked how many doctors in the room would stent the patient he first described, and half still raised their hands. Such instincts reflect a deep culture of adopting new forms of promising technology but not backing off when evidence refutes the promise.

Health care will always be ripe for profit making. Physicians are uniquely positioned to—and have a responsibility to—resist incentives to overuse care or reap unearned profits and report those who are doing otherwise.

V. Privacy and confidentiality

The physician-patient relationship requires trust and the free flow of information within, but not outside, the health care setting. Twenty-five years ago, patients' informational privacy was protected by a set of loosely defined professional commitments, and seldom-enforced state laws generally conferring on physicians rather than patients the ownership of the paper charts in which sensitive information had been recorded. Today, protecting digital information that can be remotely appropriated, aggregated, and misused is not only an ethical requirement but also a legal one for physicians, nurses, and hospitals—an obligation primarily met through compliance with detailed federal regulations. At the same time, under certain circumstances these principals have a legal duty to report information regarding patients and others, including to law enforcement and public health authorities.

Four trends in patient and physician attitudes toward health privacy are worth highlighting. First, patients are demanding autonomy to direct their own care, and doing so requires them to have greater access to and control of their personal information. Second, new information and communication technologies such as telemedicine and artificial intelligence-based predictive analytics promise greater clinical efficiency and effectiveness. Third, there is increasing interest in genetic information. More individuals are using commercial gene analysis to learn their ancestry and their medical predispositions, information that also has important ramifications for genetically related family members.

Finally, the collateral consequences of leaked health information are increasingly serious. Many purveyors of non–health care services are "data hungry," and public disclosure of health information can be devastating. Moreover, law enforcement is making increasing use of databases connected to genetic testing in ways that may result in police interactions or even criminal charges for patients and their family members.

Case Study 3

You are a physician treating a young MSM (man who has sex with men) patient. After reviewing blood tests taken as part of his annual physical, you determine he has seroconverted to being HIV+. You know he has previously attempted suicide, and you are worried about how he will take the news. There are a number of things you would like to know to help you provide better care, but the patient has been reticent about sharing details of his personal life. Does he have a primary partner or multiple partners? Does he engage in significant drug use? Does he currently engage in sex work?

1. Can you search for him online to uncover relevant nonhealth information? Read the public content of his Facebook profile? Look at police records available from public databases? Or would those kinds of searches violate his privacy rights?
2. You also consider your obligations to public health authorities or his prior partners to provide information regarding his seroconversion.

A. The duty to protect information under HIPAA

The main laws that govern the privacy obligations of physicians and other care providers are the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[51] regulations issued under HIPAA by the Department of Health and Human Services, and the amendments contained in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.[52] Collectively, we can refer to these sources as "the HIPAA regime." In broad strokes, the HIPAA regime requires "covered entities" to maintain the confidentiality of "protected health information" (PHI), using or disclosing PHI only in permitted ways.

The HIPAA privacy rule defines PHI as "individually identifiable health information" regardless of the medium, electronic or otherwise, in which it is held.[53] Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, that:

1. is created or received by a covered entity or employer; and
2. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
3. that identifies the individual; or
4. with respect to which there is a reasonable basis to believe the information can be used to identify the individual.[53]

Health care providers are covered entities, as are health plans and health care clearinghouse organizations. Covered entities are required to[54]:

1. adopt internal procedures to protect the privacy of PHI;
2. train employees regarding privacy procedures;
3. designate a privacy officer;
4. secure patient records that contain protected information; and
5. establish and enforce agreements with "business associates" that are not themselves covered entities to ensure privacy protection for any PHI those organizations have access to.

The definition of "business associates" is expansive and includes anyone who "creates, receives, maintains, or transmits protected health information" for claims processing, administration, or in connection with accounting, legal, management, or other services.[53]

The HIPAA regime creates a default rule that no PHI can be used or disclosed unless one of the recognized exceptions apply. One of the leading health law textbooks summarized these exceptions[54]:

- PHI can be disclosed to the individual or the individual's personal representative (with special rules if there are concerns about abuse or neglect).

- PHI can be disclosed for "treatment, payment, or health care operations" with the patient's general consent. Disclosure for payment or health care operations must be the "minimum necessary" for the permitted use (a standard that also applies to authorized disclosures). Disclosure for treatment is not subject to that limitation, reflecting long-standing professional preferences and the perceived exigencies of medical care.
- PHI can be disclosed where the entity receives a more specific "valid authorization" from the patient, typically via a signed document that may vary depending on whether it is a general authorization or one that complies with special rules governing psychotherapy notes, marketing uses, or the sale of information.
- A subset of PHI can be disclosed without written authorization in certain situations after giving the patient an opportunity to object. For example, basic information about an individual's identity and condition can be added to the hospital directory and made available to callers if the individual does not object. It can even be provided in emergency circumstances if doing so is consistent with any known patient preferences and is in the best interests of the patient.
- PHI can be disclosed without authorization or agreement in roughly a dozen categories of special circumstances (e.g., where the disclosure is required by law).
- A "limited data set" that excludes most identifying information can be disclosed for use in public health, research, and operations. Limited types of PHI may also be disclosed in carefully circumscribed circumstances for institutional fundraising and by health plans involved in underwriting decisions.
- Covered entities are also permitted to disclose PHI "incident to use[s] or disclosures otherwise permitted or required" so long as the covered entity has followed the standards governing the minimum necessary disclosure of information and has put in place proper administrative, physical, and technical safeguards.

Two points are worth highlighting. First, many health care providers and hospitals use the "valid authorization" pathway—including when patients first join a medical practice—to comply with the law. Second, when it comes to research use of patient data, the HIPAA regime allows data to be shared by removing a set of 18 specified identifiers such as names and e-mail addresses, in which case the data will be treated as not being PHI under the law.[57]

B. Other medical privacy and mandatory reporting laws

Beyond HIPAA, other laws protect patient privacy as to specific kinds of information. At the federal level, these include the Genetic Information Nondiscrimination Act of 2008 (GINA)[58] and the Privacy Act of 1974[59] (governing the use of information collected by federal agencies).[60] Many states have their own statutes governing the confidentiality of patient data,[54,62] which may be stricter than HIPAA. Private lawsuits

are not available under the HIPAA regime, but breaches of patient confidentiality can give rise to substantial liability under state laws governing breach of contract, malpractice, general negligence, breach of fiduciary duty, and fraud/misrepresentation.[54,64]

In some instances, the law requires physicians to break confidentiality and reveal information to relevant parties. Most states require physicians and others to report abuse of children or vulnerable adults. For example, Florida law requires that a physician "who knows, or has reasonable cause to suspect, that a vulnerable adult has been or is being abused, neglected, or exploited shall immediately report such knowledge or suspicion to the central abuse hotline."[65] Under state law, physicians also typically must report knife or gunshot wounds to the police.[66] A third common category pertains to certain contagious or transmissible diseases, including sexually transmitted diseases, which statutes typically require to be reported to public health authorities. Beyond these statutory examples, judicial decisions have imposed on physicians a duty to warn others who may be at risk; these include cases involving contagious diseases,[67] patients with mental illness who threaten identified persons,[68] and the offspring of patients who carry a hereditary disorder.[69] These legal duties to disclose vary by state and often turn on the specific facts at issue.[54]

C. Privacy and system-based practice

While this discussion has focused on individual physicians, health care institutions also have a major role to play in patient privacy. They must educate their staff about HIPAA and other privacy laws, put policies in place that ensure compliance, provide a high level of corporate data security, and respond effectively to any data breaches that may occur. It is important for health care institutions to honor HIPAA's respect for patient rights, rather than citing it inappropriately as a "bogeyman" or "conversation ender" when, for example, patients request access to their own health records. Institutional culture is equally valuable for preventing quotidian violations of patient privacy that usually go uncorrected—for example, discussing a patient in an elevator where other patients may be in earshot,[71] or posting a radiograph or an image from a particularly challenging surgery on Facebook. As health care systems come to rely on sophisticated outsiders to augment services that were traditionally offered in-house, it is essential that the vendors selected and the flow of information among them reflect the highest standards of data security and privacy protection. These include e-prescribing practices, secure communications methods, ransomware response plans, and policies for dealing with inadvertent disclosure.[72]

Many academic medical centers also collect, store, and conduct research on biospecimens obtained from patients. Recent changes to the federal "Common Rule" governing research ethics in the United States (still not in effect, as of this writing) provide new methods for patient consent relating to biospecimens. In the past, a researcher could remove identifiers from the data, seek study-specific consent, or follow institutional procedures for waiver of consent.[73] The revised regulations permit

"storage and maintenance of identifiable biospecimens for potential secondary research if sources give their broad consent and the organization's Institutional Review Board (IRB) determines that such consent was properly obtained and that storage provisions to protect confidentiality are adequate." The regulations permit secondary research on properly stored biospecimens without additional consent if the IRB, again conducting only a limited review, "finds that the research is within the scope of that consent, provisions to protect confidentiality are adequate, and the study plan does not include returning individual research results."[73] It remains to be seen how many researchers make use of these new opportunities and how they play out in practice.

Going beyond the existing law, a systems-level approach presses forcefully on several questions: First, to what extent do attempts to rein in health care costs in the United States require more access to patient data? Second, should the legal system focus not just on protecting patient health care data, but also on the broader category of patient health data or even data relevant to health?[74-76] In a world that takes seriously the social determinants of health, the physicians of tomorrow may want to use data generated from social media, wearable activity trackers, shopping habits, and the like in formulating the best treatment for their patients. At what point does the collection and sharing of such data become problematic? Do we need to move away from the current US health privacy approach, which operates differently by sector and custodian, to a more European approach that applies uniform protection to personal data regardless of who generates or transmits it?[77] In determining when to breach confidentiality to protect other patients or the public's health, should potential stigma or possible threats to members of vulnerable minority groups (e.g., the patient in Case Study 3) outweigh the duty to disclose? What should patients be told when forming a clinical relationship about the circumstances under which their private information might be disclosed?

VI. Health insurance

Imagine that you are a patient arriving for scheduled surgery at a hospital that is in your insurance network. You studied your health insurance policy and understood that you would pay a $250 deductible and 10% of the rate your insurer had negotiated for the surgery, which you estimated to be about $1000 in all. When the bill arrives, it is for $5273, including a charge for an out-of-network anesthesiologist that your insurance will not pay.

Or imagine you are a doctor treating a patient with cancer. You would like to prescribe a treatment regimen that you know works well for this type of patient and cancer, but the patient's insurance might not pay for it. Even if the insurer confirms coverage, the patient's share of the cost might still make treatment unaffordable.

These scenarios occur and persist uniquely in the United States because of its idiosyncratic system for financing health care. A century ago, people who needed medical care simply paid for it. Medical advances and industrial growth have made services so expensive that good insurance is necessary to access good medical care.[78] For most doctors and hospitals, insurance is also the key to being paid. Laws that influence the structure of insurance are therefore important for physicians to understand, both for their patients and for themselves.

Financing health care in the United States is more complicated than in peer nations because most countries have a universal, or near-universal, public system that pays for baseline medical care. This is often referred to as "single payer," even though most countries also have a secondary system of private insurance. The United States, in contrast, relies on a patchwork of public and private financing with gaps that leave 10% of the population uninsured, even after the ACA's coverage gains.

This convoluted system of financing profoundly affects the practice of medicine. A patient's resources—financial and intellectual—can have a significant impact on access to medical care even for people with decent insurance coverage. Can the patient afford his or her health plan's cost-sharing obligations? Can the patient navigate the complexity of his or her insurance benefits and find the care he or she needs within the health plan's provider network? Can the patient take time off work for appointments, especially if a limited provider network requires him or her to travel farther for care?

Similarly, physicians must decide where in the system to practice and then negotiate various agreements to do so. Once practicing, they will treat patients with different types, levels, and terms of coverage. Even though most doctors—quite understandably—would rather not have to think about how their patients will pay for medically indicated care, health insurance can influence a patient's ability to get well as much as any other factor. Physicians have no choice but to take note.

A. Insurance coverage in the United States

Just over one-third of the US population has public health insurance, mostly Medicare and Medicaid.[79] For select populations, the government provides care directly through

the Indian Health Service, Veterans Health Administration, and federally qualified community health centers. Medicare, a federal program, covers 57 million older Americans and some people with disabilities. Medicaid, which is funded primarily by the federal government but administered differently by each state, has become the largest insurer in the United States.[80] It began as a program to cover poor people receiving cash welfare. Over time, it expanded to include pregnant women and children whose families earned just above the welfare income thresholds.[81] In 1997, in turn, the Children's Health Insurance Program was created for children above Medicaid's income thresholds.

In the ACA, Congress attempted to make Medicaid a more nationally uniform program for the poor by extending eligibility to all nonelderly poor earning up to 138% of the federal poverty level (just under $35,000 US dollars for a family of four in 2018). This expansion was challenged legally. In *NFIB v. Sebelius,* the US Supreme Court held that it was unconstitutionally "coercive" for Congress to force states to expand their programs on pain of losing all federal Medicaid funding, rather than just the incremental funding associated with the additional beneficiaries.[82] The effect of this decision was to make expansion optional for the states. As of March 2019, 36 states and Washington, DC, have embraced the Medicaid expansion, while 14 states have not yet done so.[83]

Private financing includes employer-sponsored health insurance (ESI), individual health insurance, charity care, and out-of-pocket payments. Without insurance, most people cannot afford more than very basic services, and some hospitals will not admit someone for care without proof that he or she can pay. Annual per-person medical spending in the United States is over $10,000, while median household income before taxes is approximately $55,000.[84] The average bill for uncomplicated childbirth in the United States is over $10,000, while coronary artery bypass surgery costs on average over $78,000.[85] Consequently, over half of Americans have private health insurance, mostly ESI, but with individual coverage increasing because of nondiscrimination rules and tax subsidies for working-class enrollees under the ACA.[79] In some cases, people pay for care out-of-pocket. Charity care for the uninsured is sometimes available from free clinics, providers, hospitals' charity care programs, or drug assistance programs, but it is contingent and may be extremely limited in scope.

B. Accepting patients with different insurance coverage

Physicians and hospitals have significant discretion over which patients they treat, especially for nonemergency care. Private insurance generally pays ("reimburses") health care providers the highest amount for a given service, but Medicare covers the elderly and disabled patients on whom most hospitals rely to fill beds and who represent a substantial portion of many physicians' practices. Choosing to accept patients covered by Medicare or Medicaid comes with regulatory obligations. For example, billing a federal health insurance program makes a physician subject to federal fraud and abuse laws, described elsewhere in this chapter, and both Medicare and Medicaid impose on health facilities detailed conditions of participation, which derive

from state licensure, survey, and certification as well as Joint Commission accreditation requirements.

Most hospitals and a majority of doctors accept both private and public health insurance, but some accept only private insurance, and an increasing number, especially physicians in high-demand practice areas in urban centers, do not accept insurance at all or charge retainer fees to join their practice. A recent study showed that rates of provider participation are highest in ESI, followed by private ACA marketplace plans, and lowest in Medicaid.[87] The Mayo Clinic recently announced that it will prioritize privately insured patients over those with Medicare or Medicaid.[88] Providers and facilities are more likely to accept Medicare than Medicaid because its reimbursement rates are higher.

Although a physician, especially one who has already built a strong reputation, can make more money by accepting only privately insured or cash-pay ("concierge") patients, a decision to do so exacerbates problems that lower-income and elderly people have in accessing health care. In the study referenced previously, physician appointments were most available for patients with ESI and lowest for Medicaid patients.[87] Although no law requires it, many physicians consider it an ethical obligation to accept public health insurance for at least a part of their patient population.

C. Insurance benefits and cost-sharing

Health plans differ in the benefits they cover and what share of the costs patients must pay. Medicaid and Medicare coverage is governed by federal law, and benefits are consistent across states and plans. Private insurance varies more because it is primarily subject to state rather than federal regulation. Employers have wide discretion over benefit design, and even though ESI is usually comprehensive, few legal requirements apply to it.

The ACA imposed federal law on individual insurance, requiring all plans to cover 10 categories of essential health benefits, including outpatient care, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, and prescription drugs.[89] The ACA, however, gave states discretion in deciding exactly which services fall into these categories. Even ACA marketplace plans may differ considerably from state to state.

A few of the ACA's rules do extend to all private health plans, including ESI and individual coverage. These include coverage of certain preventive care without cost-sharing, limits on annual out-of-pocket spending, and an end to annual and lifetime dollar limits on coverage (e.g., no more than $1 million in benefits over the life of a beneficiary). Some ACA requirements have been contentious. For example, preventive care under the ACA includes all FDA-approved methods of contraception. Although the ACA and related federal regulations exempted houses of worship and offered accommodations to religious nonprofits, private companies successfully challenged the contraception mandate as a violation of their religious liberty and prevailed in the US Supreme Court.[90] The Trump administration issued new regulations that are now,

themselves, facing legal challenges. While these cases work their way through the courts, some patients will have plans that fully cover contraception, while others might not.

D. Provider network regulations

Another effect of health insurance on medical practice is through network structure. Outside of a few well-established HMOs such as the Kaiser Permanente system, for many years health insurers did not limit enrollees to certain health care providers or even make it financially more attractive to receive care in some settings than others. This changed in the 1980s, when laws were passed to allow state Medicaid programs and then private insurers to "selectively contract" with hospitals and physicians—negotiating lower fees in exchange for channeling more patients to these "preferred" providers.

Although Medicare and most Medicaid programs accept all qualifying providers and suppliers, private insurers have significant discretion on how to compose their provider networks. In California, for example, the ACA health insurance exchange has opted not to contract with the largest, most expensive hospital systems, such as Cedars-Sinai and UCLA Medical Center in Los Angeles. Instead, they have contracted with smaller hospitals that are willing to offer lower prices.

For patients, the shift to network-based coverage typically resulted in more favorable financing of "in-network" than "out-of-network" providers (e.g., 90% rather than 50% coverage), creating a strong incentive for them to seek in-network care. It also occasionally exposed them to shockingly high "surprise medical bills" from nonnetwork providers who had not agreed to specific fees by contract with their insurer but unexpectedly became involved in their care.

Initially, individual physicians applied to networks that insurers assembled and managed. Over time, physicians joined together in larger groups and associations, both for delivering care and for contracting with insurers. Today, over 40% of physicians are employees of hospitals, compared to 25% as recently as 2012.[91] In all these circumstances, physicians should carefully examine proposed contract terms and consult an attorney if any seem objectionable.

Some laws regulate provider networks. Several states apply legal standards for "network adequacy" to assure an appropriate geographic distribution of physician specialists. Some states prohibit or cap "surprise medical bills." States also may restrict particular contracting practices between insurers and providers, such as "most-favored nations" clauses. These provisions, which require a provider to give the contracting insurer the lowest rate that provider offers to any payer, have been challenged under the antitrust laws because they discourage new insurers from entering the market. Another example is the "any willing provider" law, which requires an insurer to allow any provider into its network who is willing to sign the insurer's standard contract. As of 2014, 27 states had these laws, sometimes limited to pharmacies and pharmacists.[92] These laws make it easier for providers to remain in practice or enter new markets but reduce insurers' ability to bargain for lower fees in exchange for assured patient

volume.

E. The cost of complexity

Although the details of health insurance may seem outside of the treatment relationship or secondary when time with patients is short, they likely are as important determinants of health outcomes as a good diagnosis and treatment regimen. In 2016, 50% of employer plans had a deductible of $1000 or more for individual coverage, five times more than a decade prior.[93] If health care costs continue to rise and more individuals join health plans with high deductibles or narrow networks, these challenges will only become more acute as fewer patients are able to afford their assigned share of treatment costs.

VII. Informed consent to treatment

Informed consent is one of the most important obligations of health professionals. Ethically, the process of engaging a patient and eliciting that person's informed consent to medical treatment has several benefits. It enables a desirable exchange of information regarding therapeutic objectives and the means available to achieve them, builds understanding and trust between the patient and the care team, aligns the expectations of both physician and patient regarding the course of care, and promotes collaboration that likely improves medical outcomes.

Case Study 4

You are a young attending neurosurgeon at a major urban medical center with a well-regarded brain and spine institute. A 40-year-old woman with a recurrent pituitary tumor, originally treated elsewhere, consults you about additional surgery. She is having significant symptoms and is very concerned that she will not live to raise her children to adulthood. You have only operated on a few recurrent brain tumors. You explain to her that it is a complex operation and outline the risks and benefits of being more or less aggressive in attempting to remove tumor regrowth. The institute where you work uses an interdisciplinary team approach, so you refer her for team-based preoperative evaluation and counseling, which includes interactive, computer-based decision aids. At the end of that evaluation, the physician assistant presents her with a surgical consent form, reviews it carefully with her, and obtains her written agreement to remove as much of the tumor as possible in the judgment of the operating surgeon. On the morning of the surgery, you speak briefly with her, and she reiterates her confidence in your ability. Unfortunately, the surgery leaves her with significant neurologic deficits, which she claims were not a risk she had wanted to take.

1. Should she be able to sue you for failure to obtain her informed consent? Should it matter that most of the information she received was provided by others on your team?
2. Should you have been required to disclose your relative inexperience? What if part of the operation was done by a senior surgical resident under your supervision?
3. What if you have a consulting agreement with a surgical instrument company?

A. The ethical consensus on consent

As an ethical matter, informed consent is firmly embedded in physicians' professional expectations of themselves.[94] Broad acceptance of patient autonomy as a goal and obligation of medical practice is even carrying over to domains beyond consent to treatment. For example, the AMA and many other physician professional associations now recognize an ethical obligation of transparency and engagement following unexpected outcomes of care (see the section on Medical Malpractice and Redressing Error later). Consent to participation in biomedical research—including threats to

privacy—is also evolving as society acknowledges the therapeutic misconception often associated with biomedical research settings: that participants in research studies may incorrectly assume that the white-coated, medically trained researchers they encounter are always acting as "doctors" would toward their "patients."

Whether informed consent truly shifts authority over treatment decisions from physician to patient, and whether that is always desirable, is a closer question. American physicians' ethical embrace of honesty with patients is relatively recent; in 1960, physicians routinely withheld a cancer diagnosis from the patient (sharing it only with family members), arguing that shielding patients from despair was medically beneficial. Such paternalism would be unthinkable in modern medical practice, although a very limited "therapeutic privilege" not to disclose risks to emotionally fragile patients remains part of the law. Still, inherent tension exists between the patient role and the hoped-for autonomy expressed in the idea of informed consent. It is unrealistic to expect that merely sharing information can overcome those limitations. Particularly in cases of serious, unexpected illness that imposes both a physical and an emotional burden, patients remain dependent on (and may strongly desire) physician guidance, which physicians are ethically obligated to provide.[95]

B. The weaknesses of consent in the law

The robust ethical grounding for informed consent is not matched in the law.[96] American informed consent law typically applies only to surgery or other physically invasive procedures, and generally requires only the disclosure (without verifying comprehension) of risks, benefits, and treatment alternatives. Recognizing patient dependence, some countries require physicians to recommend a course of treatment; US law does not. Moreover, inadequate information only supports a lawsuit seeking damages for lack of informed consent in a narrow range of circumstances, although additional legal remedies exist where a physician blatantly disregards a patient's right to information or engages in outright deception.[97]

Informed consent law is not established as a nationally uniform standard by Congress but varies from state to state, usually as the result of judges deciding cases, though sometimes in the form of statutes enacted by state legislatures. Except for egregious cases of medical procedures (or worse) done to patients without either knowledge or permission—which can lead to civil claims as well as criminal charges of battery—informed consent is considered part of the law of professional negligence (see the section on Medical Malpractice and Redressing Error later). Informed consent law requires patients seeking redress in court to demonstrate that the failure to disclose information both breached a legal duty and caused injury.

State laws divide as to whether the sufficiency of disclosure should be set by professional custom as a "standard of care" (which seems contrary to the notion of informed consent being patient oriented) or based on what a reasonable patient would consider material to a decision (which seems more consistent with goals of patient autonomy).[98] Texas takes a unique approach, empowering a public commission with physician leadership and attorney participation to distinguish between procedures that

require specified disclosures and procedures that do not.[99]

Even in states that apply a standard of disclosure highly favorable to patients, legal claims for lack of informed consent typically fail on the issue of causation. The undisclosed risk must be the risk that materializes and causes injury: if a patient is not told about a substantial risk of infection, but the postsurgical complication is something other than infection, there is no legal claim for recovery. In nearly all states, moreover, the plaintiff must prove that a reasonable patient would not have undergone the treatment had sufficient disclosure been made.[100] This means that even though an undisclosed risk materialized with horrific effects, a patient generally has no legal remedy if treatment was medically indicated and was performed nonnegligently because a reasonable person would have elected to undergo the procedure even if fully informed. An injured patient's lawyer still may argue lack of informed consent to a jury as part of a broader malpractice suit in order to portray the physician as uncaring and potentially less attentive—and therefore more likely to have botched the procedure. In states that do not require expensive expert testimony to establish what should have been disclosed, moreover, plaintiffs' lawyers may routinely allege lack of consent to pressure a malpractice insurer to settle and avoid the expense and uncertainty of trial. Standing alone, however, lack of informed consent is a weak legal claim.

C. Consent involving systems of care

The organizational role in informed consent has been mainly administrative: providing a physical venue for presurgical consultation and ensuring that forms are completed and signed as required. Particularly for surgery, hospitals have been regulated (and self-regulated through the Joint Commission) as staffed, equipped environments for physicians' professional work rather than as clinical service providers in their own right. Unfortunately, combining time pressure with paperwork in health facilities has set a poor example for physicians and other health professionals by making "consenting" a patient into a procedural hurdle to be overcome in a short clinical encounter rather than a deliberate process of extended information exchange and shared decision making. Recently, some professional organizations, physician practices, and hospitals have reversed this trend and implemented systems of patient education with audiovisual, often Internet-based aids that can be used iteratively to convey information, verify comprehension, and promote informed consent.[101]

The growth of managed care and health systems has caused courts to rethink several aspects of informed consent law, as Case Study 4 illustrates. Established law focused on disclosing characteristics of the disease and possible treatments rather than of the physician or system of care. By contrast, physician-specific disclosure requirements have been imposed in several situations, obligating physicians to convey information about their clinical experience and measurable outcomes, financial incentives, and direct participation in the patient's surgery (versus care by a physician in training or other assistant).[102,103] This remains a work in progress, reflecting the growing pains associated with embedding physicians in a larger system and distinguishing among them, rather than assuming that all physicians are equally qualified and that treatment

in different settings has the same risk-benefit profile.

There are likely to be further pressures on informed consent as health care systems implement value-based care models. Eliciting patients' goals for treatment, measuring outcomes that patients report, and incorporating a variety of organizational structures and contractual relationships that depart from the traditional one physician–one patient norm all increase potential liability. For example, attaching disclosure obligations to cross-cutting aspects of care (e.g., physicians' financial incentives, conflicts of interest, or reliance on interprofessional teams) removes the materialized risk constraint that has limited legal recovery to a small subset of bad outcomes. Similarly, segmenting care into a number of tactical alternatives (e.g., the choice of surgical approach, the extent of resection) among which patients select may persuade courts to find that inadequate disclosure caused harm even when some course of care was clearly necessary and the treatment administered was performed properly.

Another question raised in Case Study 4 that is being actively debated by courts and professional associations is whether the treating physician or surgeon must personally obtain a patient's informed consent. Within organized systems of care, a process that involves multiple members of the clinical team and takes advantage of institutional resources seems more likely than a single conversation with a hurried physician to educate patients effectively about their choices, offer time for reflection and questioning, and enable patients to take an active role in decision making. Exclusive control by a physician over the site and terms of the consent conversation may build trust and reinforce a physician's sense of moral responsibility. At least one court has ruled informed consent to be "non-delegable" by the attending surgeon, though the decision failed to distinguish between delegating the task and delegating the legal liability associated with doing the task poorly, confusion that may intensify as more physicians become hospital employees and the hospital thereby becomes legally accountable for physician negligence.[104]

VIII. Medical malpractice and redressing error

Physicians are trained, skilled, hard-working, and committed professionals who fervently hope never to cause harm to their patients. Yet millions of patients suffer avoidable injuries from medical care each year, and thousands die as the result.[105] As other chapters in this book have explained, poorly designed safety systems that fail to account for predictable human behaviors are largely responsible for medical errors, particularly in hospitals. Considering this state of affairs, it is both shocking that so many adverse outcomes happen unnecessarily and heartening that so many more are prevented by the personal dedication of physicians, nurses, and other members of health care teams.

When care does go badly, physicians can be held ethically and legally responsible for violating the duty of care they owe to their patients. As with the duty of loyalty (see the section on Institutional Conflicts of Interest earlier), the fiduciary duty of care requires physicians to act affirmatively for their patients' benefit, faulting them as much for failure to diagnose or treat as for treatment done badly. Poor care—particularly if egregious or repeated—can subject physicians to professional discipline (including license suspension or revocation) by state medical boards. It can cause physicians to lose admitting or treatment privileges following peer review procedures undertaken by a hospital's self-governing medical staff. In addition to these professional self-regulatory responses, poor care can lead to private litigation by patients against physicians—medical malpractice lawsuits.

Case Study 5

You are a general surgeon in private practice. Your patient, a young man, has significant symptoms of right-side inguinal hernia and has agreed to surgery at the hospital where you typically operate. He signs a consent form for right inguinal hernia repair at his preoperative visit and again when he arrives at the hospital for surgery. However, neither form makes it into the electronic health record. He is brought into the operating room (OR) and anesthetized. You and the other OR personnel "huddle" and agree to a plan for right-sided surgery. Unfortunately, an emergency takes you out of the OR for half an hour. When you return, you quickly examine the patient and, noting a likely left-sided hernia, you proceed to repair that side, failing to operate on the right. When the patient wakes up in the recovery area, he is upset to find that the wrong hernia has been repaired. You immediately apologize and arrange for him to return to the OR for additional surgery, which goes well. The following day, the hospital administrator visits the patient's room and assures him that he will not be charged for his care. Several months later, he files a malpractice lawsuit against you and the hospital.

1. The hospital settles and reports the payment to the state medical board and to the National Practitioner Data Bank. Do you feel this is justified?
2. The state medical board investigates and decides to sanction you and assess a fine, which will be visible for 10 years on the medical board's public website and which you will have to disclose to hospitals where you seek privileges for the

remainder of your career. Do you feel this is justified?

A. The unusual salience of medical malpractice

Medical malpractice differs in several ways from other issues in health law and policy. It is almost entirely governed by state rather than federal law. Judges are more important than legislatures to how malpractice law develops, and no regulatory agencies play significant roles. The politics of altering malpractice law and associated procedures—called "tort reform"—involves well-funded constituencies outside of health care who exploit medical care to serve larger agendas involving the effect of private lawsuits (the "civil justice system") on America's economy and social fabric.

Medical malpractice has unique emotional resonance with physicians. Many allegations of malpractice are felt as assaults on character and reputation and as betrayals of the intimate bond between physician and patient. Malpractice law is part of tort law, which provides recourse for harms that do not fall within other legal regimes governing criminal conduct or contractual agreements. The purpose of a tort claim is simple: to recover compensation for wrongful injury, typically from an insurance company (e.g., automobile, property, or malpractice coverage). Yet most physicians consider a malpractice lawsuit tantamount to a criminal accusation, describing it using terms such as "charge," "verdict," and "guilt" (the usual corresponding tort terms are "claim," "judgment," and "liability"). Moreover, although much of the patient-physician relationship is defined by contract, most aspects of malpractice liability may not be modified by agreement between a physician and his or her patients (except perhaps to settle claims through private arbitration rather than in court).

B. Malpractice litigation

To prevail in a medical malpractice suit, a lawyer representing a patient as plaintiff must establish several elements of the case by a preponderance of the evidence. This means "more likely than not" and is a much easier standard to meet than in a true criminal case, which must be proved "beyond a reasonable doubt." First, the defendant physician must owe a legal duty to the plaintiff in the form of a physician-patient relationship. Second, the defendant must have violated that duty by failing to meet the standard of care customary among physicians in the defendant's field and circumstances, which the law terms "professional negligence." Third, the plaintiff must have suffered injury, which can take the form of money expended (additional medical expenses) or unearned (lost wages from death or disability), harm not usually measured in dollars (pain and suffering), or both. Fourth, the defendant must have caused the plaintiff's injury, both in the narrow sense of the injury not occurring but for the physician's negligence and in the broader sense of it seeming reasonable to hold the physician and therefore the physician's liability insurer financially responsible.

Because physicians collectively determine the standards of practice to which they will be held in court, malpractice liability is to a large degree just another method of professional self-regulation. The vast majority of malpractice claims are abandoned by the claimant or settled out of court (often without a formal lawsuit) with money paid by

a liability insurance company. Still, physicians tend to regard a claim against them as an external and arbitrary threat. One reason is that a binding decision can be rendered by a jury or judge with no medical training. Another reason is that both sides in a lawsuit hire physicians to serve as expert witnesses, and the plaintiff's expert will report that the defendant was negligent. A third reason is that plaintiffs' lawyers are paid a hefty percentage (around 40%) of any money they recover for their clients, which enables poor people to afford representation but which physicians see as an incentive to distort the facts. But the biggest reason may be that malpractice claims can be incredibly slow to resolve, with major claims often dragging out for 5 years or more. These years can be filled with stress, uncertainty, inconvenience, and even self-doubt for physicians. This can be compounded for those in traditional small practices who fear sudden, sharp increases in the cost of their malpractice insurance coverage or, as has occasionally happened, coverage becoming unavailable—putting their professional livelihoods at risk.

C. Situating the malpractice system in system-based care

The medical malpractice system is seriously flawed as a method of either compensation or quality improvement. Several studies have established a two-sided mismatch between unsafe care and malpractice claims: many lawsuits do not reflect poor care, while the vast majority of injuries caused by medical errors are never redressed in court. The administrative costs (insurance adjusters, lawyers, expert witnesses, etc.) of compensating harm through malpractice claims consume roughly half of the available funds. Few opportunities exist in litigation to understand the causes of errors or improve safety for future patients. Fear of malpractice liability may lead physicians to make clinical decisions that do little to benefit patients but increase health care spending ("defensive medicine"). The litigation process is convoluted, confrontational, and inhumane for nearly everyone involved. Yet most efforts to reform medical malpractice have tended to focus on only one piece of the problem—so-called frivolous suits and excessive awards—with the result being (perhaps) less of a bad system but certainly not a good system.

Medical malpractice law has adapted in decentralized, state-by-state fashion to the expansion of corporate structures and systems of care. In the early 20th century, laws in most states shielded hospitals from liability by virtue of their status as charitable organizations, while holding physicians (usually surgeons) responsible for poor care by nurses and others under the "captain of the ship" doctrine. In recent decades, however, hospitals have been held "vicariously liable" for the negligence of health professionals whom they employ or hold out to the public as their agents (e.g., an emergency physician or radiologist). Hospitals may also be directly liable for negligence in granting medical staff privileges to physicians, for inadequately supervising physicians, and for failing to maintain a safe environment for patient care. Similar theories of liability have been applied to HMOs and other health plans, particularly in the 1990s when managed care seemed to be taking a more aggressive approach to costs by denying coverage for expensive treatments or obligating patients to receive care from particular hospitals and physicians. When individuals who have ESI bring lawsuits, however, the Employee

Retirement Income Security Act of 1974 (ERISA), a federal statute governing pensions and fringe benefits, may prevent them from recovering damages under either malpractice law or state insurance law.

Malpractice insurance has also changed dramatically. Malpractice suits became more frequent and the damages awarded more generous in the 1970s, which was largely a consequence of rising public expectations from improvements in medical technology and expertise along with expanded health insurance coverage. Commercial insurers therefore pulled back from an increasingly uncertain market, while companies owned by physicians (and hospitals) stepped in to fill the void. These companies dominated medical liability coverage for the next 3 decades, leveraging relationships with state and local medical societies to lobby for tort reform that had as its dominant objective keeping liability insurance available and affordable for individual physicians (and opposing system-based malpractice changes such as "enterprise liability" that would have assigned primary responsibility for errors to organizations rather than isolated professionals).

As malpractice markets stabilized in the mid-2000s, more physicians became employees of hospitals and large medical practices. Liability insurance diversified to encompass new approaches to risk bearing, such as captive insurers, risk-retention groups, and institutional self-funding backstopped by excess coverage. There is undoubtedly some tension between physician control over medical care and corporate accountability; physicians who are employees may find it hard to speak up unless corporate culture encourages it. Moreover, corporate defendants are more likely than individual physicians to incur (and perhaps deserve) judgments against them that include substantial punitive damages. On the plus side, however, institutional coverage for medical liability is less vulnerable than individual coverage to periodic malpractice "insurance crises," which tend to selectively burden a few high-risk specialties in states without tort reform. Institutional coverage also is better aligned with systems-based safety improvement strategies and is more likely to have personnel and processes in place to support both affected professionals and injured patients. For example, physicians working in health systems can expect assistance in the event of serious error from dedicated patient safety officers, patient grievance counselors, and quality improvement support staff. These resources reflect not only greater financial capacity at the institutional level, but also more detailed and demanding accreditation and regulatory requirements than apply to individual health professionals.

D. Communicating and resolving patient harm

Insights from health systems science are enabling new generations of physicians to release malpractice policy from its unique professional and political history and integrate it with other aspects of health law and professional ethics.[106] This trend is illustrated by the growth of communication and resolution programs (CRPs). CRPs are organized responses to medical error that prioritize transparency, immediate assistance to patients and families, timely compensation for unreasonable care, safety improvement, and caregiver support. In roughly 20 years, CRPs have moved from a

few public and academic institutions such as the Veterans Administration hospital in Lexington, Kentucky, and the University of Michigan into the medical mainstream, earning endorsement from the AMA, the American College of Surgeons, and other professional groups.

Although CRPs are sometimes described as a form of "alternative dispute resolution" that substitutes for malpractice litigation, an ethical commitment to good patient care, respect, and teamwork lies at the heart of the CRP approach. Over a 50-year period, physicians' fear of being sued, adversarial tactics by plaintiffs' lawyers, and a "deny and defend" mentality among liability insurers normalized the concealment of errors and the refusal to engage patients and families when care went poorly. This is finally changing, as younger physicians who fully embrace shared decision making and who tend to practice in more organized, less financially exposed environments apply lessons from patient safety science to their own workflow. Younger professionals would never question the ethical obligation to tell patients honestly what might happen during medical care (see section on Informed Consent to Treatment earlier). Unlike some of their predecessors, telling patients honestly what did happen during medical care is equally intuitive to these emerging professional leaders. Still, as Case Study 5 implies, doing the right thing ethically will not always protect physicians from legal accountability.

IX. Withholding and withdrawing care

In situations involving withholding or withdrawing care, the law sometimes envisions an ideal world that is very different from what physicians see on the front lines. Advance directives often fail to capture what patients would actually want and are sometimes disregarded by physicians.[107-109] The most recent approach to these decisions in some US states, termed Physician Orders for Life-Sustaining Treatment (POLST), integrates patients, family members, and physicians in end-of-life care planning and has proven more successful at translating patients' wishes into medical actions.[110] Even POLST, however, may rely on assumptions about available physician time and training that are not always realistic.

The situation presented in Case Study 6 is similar to ones that many clinicians encounter regularly across America.[111] The "black-letter law"—meaning the law on the books—for these kinds of cases is relatively well established, though it differs to some extent by state. However, the law "in action" is much fuzzier. Many states adopt standard-like approaches to the legal questions, leaving open difficult fact and value judgments and problems of application. Moreover, for every case litigated in this area there are tens or more that are resolved without a court ever considering the matter. Hospitals, care teams, patients, and their families are all "bargaining in the shadow of law," in the sense that they are engaged in the private resolution of disputes under assumptions about what might happen if they went to court.[112] Their perceptions of the law may be very different from its actuality.

Case Study 6

Mrs. C., 84, was admitted to the hospital with signs of dementia, including periodic confusion. She was not eating adequately; eventually, the care team inserted a nasogastric tube. She was no longer ambulatory and was confined to bed, unable to move from a semifetal position. She suffered from arteriosclerotic heart disease, hypertension, and diabetes mellitus; her left leg was gangrenous to her knee; she had several necrotic decubitus ulcers (bedsores) on her left foot, leg, and hip; she had an eye problem that required irrigation; she had a urinary catheter in place and could not control her bowels; she could not speak; and her ability to swallow was very limited. However, she interacted with her environment in limited ways. She could move her head, neck, hands, and arms to a minor extent; she was able to scratch herself and had pulled at her bandages, tube, and catheter; she moaned occasionally when moved or fed through the tube or when her bandages were changed; her eyes sometimes followed individuals in the room; her facial expressions were different when she was awake than when she was asleep; and she smiled on occasion when her hair was combed or when she received a comforting rub. After determining she was not capable of directing her own care, the court named her nephew as her legal guardian. The nephew petitioned to discontinue her feeding tube, which would lead to her death. Mrs. C.'s guardian ad litem—the individual appointed by the court to protect her interests—opposed the move.

1. How should their disagreement be resolved?
2. What does the law permit?

A. Legal distinctions based on competency

At one time, both in law and in ethics, the difference between withdrawing and withholding treatment was seen as important. It was argued that "it was permissible to withhold life-sustaining treatment but not to withdraw such treatment, just as there is no obligation to come to someone's rescue, but there is an obligation not to abandon a rescue."[54] Over time, though, both law and ethics have revisited this conclusion. Indeed, some now argue that it is worse to withhold than to withdraw because without trying a treatment, the opportunity to see if the treatment works is lost. Moreover, as Justice William J. Brennan, Jr., observed in his dissenting opinion in the Cruzan case, "If we did not recognize a right to have treatment withdrawn, many people might not seek care in the first place because they would be afraid of not being able to stop treatment once it was started."[114] While many physicians may still feel more uncomfortable withdrawing than withholding treatment, the law no longer imposes a distinction.[115,116]

Instead, the law divides its analysis of both withdrawing and withholding care according to whether the patient is competent or incompetent, as those terms are used by the legal system. The law as to competent patients is today relatively straightforward. The US Supreme Court's decision in *Cruzan v. Director, Missouri Dept of Health*[117] is typically read as confirming the constitutional right of a competent patient to refuse medical treatment regardless of his or her medical condition.[54,119] The case law typically grounds this right in conceptions of bodily autonomy and, according to the US Supreme Court, can be seen as a "logical corollary of the doctrine of informed consent [in] that the patient generally possesses the right not to consent, that is, to refuse treatment."[120]

The law as to patients not deemed competent is more complicated. As Rebecca Dresser has ably summarized, courts and legislatures in US states have adopted three different approaches.[121] First, under the subjective standard (also called the advance directive approach), the treatment (or nontreatment) of the incompetent patient should reflect that patient's previously expressed wishes. When there is a clear and applicable advance directive or a proxy directive designating someone else to make decisions should the patient become incompetent, things run relatively smoothly. That said, even well-written advance directives may fail to provide for particular situations or ambiguities. Without a detailed specification in writing, some states have accepted evidence about a patient's general or specific remarks about life-sustaining treatment to help guide decisions, but others have found such evidence too informal.[121]

A second approach is the substituted judgment standard (also called the "limited-objective" standard). As the New Jersey Supreme Court described this approach in the Conroy case, decision makers should permit an incompetent patient to forgo life-sustaining treatment "when there is some trustworthy evidence that the patient would have refused the treatment" and "it is clear that the burdens of the patient's continued

life with the treatment outweigh the benefits of that life for him."[121] This standard allows refusal of care despite relatively weak evidence of what the patient would have wanted (the subjective element) as long as objective judgments about the patient's quality of life with and without treatment accord with the available subjective evidence.

A final approach is the "best interests" standard (also called the "objective standard"). This standard requires "decision-makers to assess and then balance different features of the individual incompetent patient's medical situation, such as prognosis and quality of life with and without treatment. Judges and other decision-makers consider the burdens and benefits the individual patient would experience if life-sustaining interventions were provided, or conversely, forgone."[121]

This determination does not turn on what a particular patient actually wanted, but on what is judged to be in the patient's best interests from an objective point of view. The best-interests standard is most often used in cases where there is no evidence of what the patient would have wanted, which usually involve profoundly disabled patients who have never been competent.

B. Revisiting end-of-life practices in health care systems

Existing law faces several new pressures that highlight institutional and systems-based issues. First, to what extent does it make sense to resolve disputes over withholding or withdrawing care in courtroom proceedings, as opposed to relying on hospital ethics committees or other forms of dispute resolution? The prevailing practice has changed over time.[122-124] Second, choices to pursue treatment impose significant costs on patients' families and the health care system. To what extent can cost legitimately be considered in setting rules about care, or is it antithetical to medical ethics even to pose that question? Third, many physicians have strong beliefs about end-of-life care. To what extent should hospital systems make efforts to accommodate physicians whose religious or conscientious beliefs prohibit withholding or withdrawing care?[125]

Moreover, discussions about medical care at the end of life tend to quickly become politicized, which often erases any hope of maintaining privacy for the individuals involved, while also exposing health care systems to unwelcome if arguably necessary publicity. Consider the saga of Terri Schiavo, who spent 15 years in a persistent vegetative state while her family, the courts, and Congress very publicly fought over what should be done.[126] Or consider how a proposed provision in an early draft of the ACA to authorize Medicare reimbursement for physicians who engage patients in end-of-life care planning was distorted by partisanship into an accusation that the Obama administration was seeking to institute "death panels."[127] Finally, to what extent is dementia a challenge to the legal distinction between competence and incompetence in refusing care?[128,129] What about a pre-dementia patient who asks for care to be withheld if dementia develops, but who after developing dementia seems to be happy and enjoying life? Are the pre-dementia individual and that individual's later self with dementia the same person from a moral perspective? From a legal perspective?

In Case Study 6, Mrs. C.'s situation involves withdrawing care that has already started as opposed to withholding care that has not yet been initiated. Has this chapter

helped you decide her case? The chapter has not discussed a third category, "physician-assisted suicide" (sometimes called "medical aid in dying" by those who resist the "suicide" characterization), where the physician actively works to hasten death. It also has put aside special legal questions concerning withdrawing and withholding care for infants and other minors, where special rules and other bodies of law (e.g., family law, child abuse and endangerment law) come into play.[130-136] These are legally, medically, ethically, and socially contentious issues.

X. Chapter summary

Law is a common feature of life, especially in important economic sectors that affect public health and safety. Unsurprisingly, law is a constant presence in the US health care system. In other parts of this book, various health law issues are presented largely in terms of compliance with legal duties and obligations, as well as respect for the legal rights of others. In everyday practice, most such issues have reasonably clear answers. As long as physicians and health care professionals are able to recognize the probability of legal considerations being relevant to a situation, some research and perhaps a brief consultation with a lawyer or compliance professional will generally reveal an advisable course of action. The relationship between health law and medical ethics remains unsettled. However, ethics must remain the main driver guiding behavior for the benefit of patients.

This chapter has gone beyond pursuing that limited albeit important objective. The more deeply students explore health law, the more they realize that "it's complicated." Experienced lawyers often answer questions with "it depends" for good reason. In many situations, sound legal judgment requires an ability to match subtle distinctions in fact to complex legal precedents. These problems may be magnified in health law, whose sources are particularly multifarious—constitutional, statutory, regulatory, and common law, along with custom and practice—and whose subjects of regulation (physicians, nurses, hospitals, insurers, patients, families, pharmaceutical companies, etc.) interact with one another in complex patterns.

For students of health systems science, moreover, health law is key to understanding why the health care system operates as it does and why it has been so challenging to improve. Legal standards, and the substantial financial subsidies that are based on them, can act as either barriers to, or facilitators of, health system change. Health law also has a profound relationship to medical ethics, a relationship derived from its grounding (for better or for worse) in the professional ethics of physicians, as well as its connection to the bioethics of adapting technological advances in biomedical science and informatics to the needs and concerns of patients and society. Considered from a broader vantage point, studying health law raises at least as many questions as it provides answers. The chapter embraces this duality across a number of legal domains from conflict of interest to end-of-life care.

Questions for further thought

1. How much of a say should the medical profession have in what health laws are enacted? Should it depend on the subject matter of the law in question? Should physicians help draft or enforce laws defining or protecting the quality of care? Laws limiting who can practice medicine? Laws determining what services health insurance must cover? Laws establishing the methods of payment for those services? Laws setting fees?
2. Fair procedures are at the heart of legal governance. For adjudicating a claim or charge, these consist of notice to the defendant, a structured opportunity to gather evidence and hear from witnesses, adversarial advocacy by legal counsel for each side, an impartial decision maker, and a public, usually reasoned decision. Legislation and administrative regulation have similar features designed to promote transparency, public input, accountability, rationality, and evenhanded enforcement. In what ways are these procedures compatible or incompatible with medical professionalism?
3. Which laws governing the system for financing health care in the United States would you change and why? Would you expand public funding for health insurance for the poor or direct public funding for health care services instead? Would you alter the rules for how and how much physicians and hospitals are paid by Medicare and Medicaid? How would you revise health care financing to do a better job of addressing health disparities and improving population health?
4. Do you agree or disagree with the following statement: "When it comes to end-of-life decision making, physicians defer too much to patients' family members"? To what extent are family members good proxies for what patients would want? Are judges and courts well suited to mediate between family members and the patient care team? Or should judicial processes be largely irrelevant to the daily operations of health care systems?

THE CODE OF MEDICAL ETHICS

Elliott J. Crigger, PhD

Since its adoption at the founding meeting of the American Medical Association (AMA) in 1847, the AMA *Code of Medical Ethics* has articulated the values to which physicians commit themselves as members of the medical profession. The profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of the profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self.

The *Principles of Medical Ethics* and the *Opinions* of the AMA Council on Ethical and Judicial Affairs that interpret them are not laws but standards of conduct defining the essentials of honorable behavior for the physician. The relationship between ethics and

law is complex. Ethical values and legal requirements are usually closely related, but ethical responsibilities usually exceed legal duties. Conduct that is legally permissible may be ethically unacceptable. Conversely, the fact that a physician who has been charged with allegedly illegal conduct has been acquitted or exonerated in criminal or civil proceedings does not necessarily mean the physician acted ethically. In some cases, the law mandates conduct that is ethically unacceptable. When physicians believe a law violates ethical values or is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal duties.

The practice of medicine is fundamentally a moral activity, founded in a "covenant of trust" between patient and physician. Patients are dependent on the medical expertise of the physicians to treat what ails them, and often physicians quite literally have the patient's life in their hands. The patient must trust that the physician will rely on appropriate and complete medical knowledge and deploy the care with compassion. Patients should be confident that they are receiving the best medical care their physicians can provide, uncompromised by external factors; the physician must hold the interests of the patient as paramount. Once a patient-physician relationship has been established, the physician has an obligation not to abandon the patient.

Among their core responsibilities, physicians have the obligation to respect and support patients as autonomous decision makers. Patients generally reserve the right to have ultimate say over their bodies and what treatments they agree to. In turn, physicians are expected to provide all information relevant to a medical decision to enable the patient to make an informed, considered decision to accept or decline treatment.

Physicians have a further, fundamental responsibility to protect patients' privacy. To receive the care they need, patients must be willing to submit to examinations that can be physically intrusive and to share highly personal and often sensitive information. Patients must be able to trust that their physicians and others who participate in care will protect their dignity and safeguard the confidences they have shared. Physicians have corresponding obligations to ensure that trust is warranted. Thus physicians have a responsibility to provide an environment in which intrusions on patients' physical privacy are minimized and to ensure that patients' confidential information is shared only with appropriate health care personnel or others to whom the patient has authorized disclosure, an obligation that extends to protecting the security and integrity of medical records.

In exchange for medicine's promise to be trustworthy, society grants the profession considerable authority to set the ethical and professional standards of practice and the privilege to self-regulate.

As a self-regulating profession, medicine accepts responsibility for articulating and holding its members and members in training to core ethical values in their interactions with patients, the public, one another, and the organizations and institutions in which they practice. The duty of self-regulation thus ranges widely over the many settings and relationships in which physicians engage professionally.

As clinical practitioners, physicians promise to respect patients and patients'

intimates and to avoid exploiting the power differential inherent in patient-physician relationships. They likewise commit themselves to lifelong learning in the service of their patients.

As educators, physicians promise to instill the ethical precepts of the profession and to be fair and respectful in their conduct toward trainees.

As custodians of professional values and conduct, physicians promise to identify lapses in their own behavior or that of colleagues and to address fairly and compassionately conduct that puts patients, the reputation of the profession, or public trust at risk.

These issues and more are explored in the AMA *Code of Medical Ethics.*

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Health care policy and economics

Matthew Davis, MD, MAPP, Elizabeth Tobin-Tyler, JD, MA, Mark D. Schwartz, MD

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In this chapter

Health policies both reflect and shape historical and contemporary political philosophies and priorities. The overarching objective of this chapter is to demystify the health policy process—to help readers understand the interplay among multiple stakeholders, why these individuals and organizations behave the way they do, and how their decisions interact to become the form and function of the US health care system. A second major emphasis of this chapter

is health care economics, because concerns about the affordability and high costs of health care continue to motivate policymaking at the federal and state levels. The chapter includes an examination of major health care reform efforts in the United States over the past century, with a focus on the Affordable Care Act (ACA) to provide readers with a helpful rubric for understanding the core elements of this complex major reform effort. Major challenges and changes in the implementation of the ACA are also summarized. This chapter enables a level of awareness and understanding of principles of policy and economics that will permit readers to make sense of the differential impacts of health care policies on multiple different stakeholders.

Learning Objectives

1. Identify the core principles of the formation and implementation of health care policy and health care economics in the United States.
2. Explain how the economic aspects of the US health care system dominate health care policy and reform efforts and how health care professionals, health plans, and patients affect health care spending.
3. Describe central themes of health care reform and related health care economics principles in the United States over the last century and how they relate to the main components of the Affordable Care Act.

I. Introduction

For many, US health care policy and the related economic complexities appear to be a bewildering array of overlapping programs, chronically acrimonious political debates, and conflicting special interests. The often arcane nature of health care policy is further complicated by the fact that policy can occur at many different levels. Examples include requirements to use electronic health records to document encounters between patients and physicians; immunization requirements affecting nursing staff within hospitals; decisions about which medications will be included in a formulary in a state Medicaid program; and how much tax will be levied on American workers in order to finance the federal Medicare program. The aggregate effect of these characteristics of health care policy and economics leads many patients, physicians, other health care professionals, and other stakeholders to feel bewildered. They may have the sense that policy is something done *to* them, rather than *for* them or *with* them.

The first overarching objective of this chapter is to demystify the policy process—to help current and future health care professionals understand the interplay of multiple stakeholders, why these individuals and organizations behave the way they do, and how their decisions interact to shape the form, function, and economic dynamics of the US health care system. The key starting point is to understand that policy (from the Greek word *polis,* meaning city) is made anytime there is a decision that affects more than one person. Policies are a necessary part of any system in order to create efficiencies, establish and deliver on expectations, and specify consequences for failure to behave in acceptable ways. Policies also provide mechanisms through which failings and inequities in a system can be addressed.

These positive aspects of policies are counterbalanced, however, by two key caveats. The first is the so-called law of unintended consequences—that health care policies, no matter how well intentioned, have unforeseen effects on stakeholders. While some unintended consequences are minor, others may lead to circumstances that are worse than the situations they were intended to address. For example, a childhood vaccine against a disease called pertussis (whooping cough) was found to cause too many serious side effects, so a new vaccine against pertussis was developed and substituted for the older version in the 1990s. While the new vaccine caused fewer side effects, it failed to sustain immunity as long, thereby leading to the unintended consequence of more frequent outbreaks (i.e., less effective prevention) of pertussis in children and adults.[1] When unintended policy consequences occur, recognizing them and addressing them promptly and comprehensively can help achieve the original goals with minimal long-term impact to the stakeholders whose interests were adversely affected.

The second caveat, particularly relevant in the US health care system, is that policies can run contrary to the paradigmatic American focus on the individual. A policy that advantages one individual may well inconvenience or disadvantage another. Effects at the individual level tend to be emphasized more in the media and public narrative than the possibility that a policy may have accomplished the utilitarian goal of "the greatest good for the greatest number." The tension between benefits—whether health,

economic, or otherwise—for individuals versus benefits for the population is a frequent, highly visible challenge in health care policymaking in the United States. For example, legislators in Congress often lament how many taxpayer dollars are spent on the federal Medicare program, while individual Medicare-covered patients' pleas for expensive therapies with questionable benefit and value often appear on the home page of media outlets.

These caveats notwithstanding, health care policy is a dominant force for change in the US health care system. This chapter presents the fundamental principles that undergird health care policymaking and presents central stakeholders and themes that strongly influence the direction of policies related to health and health care. In this chapter readers will also find many examples of health care policies that have shaped the health care system in the United States as it functions today and will inform what reforms are attempted in the future. To examine every major health care policy would require many books; instead, this chapter highlights instructive, influential policies across many aspects of the system.

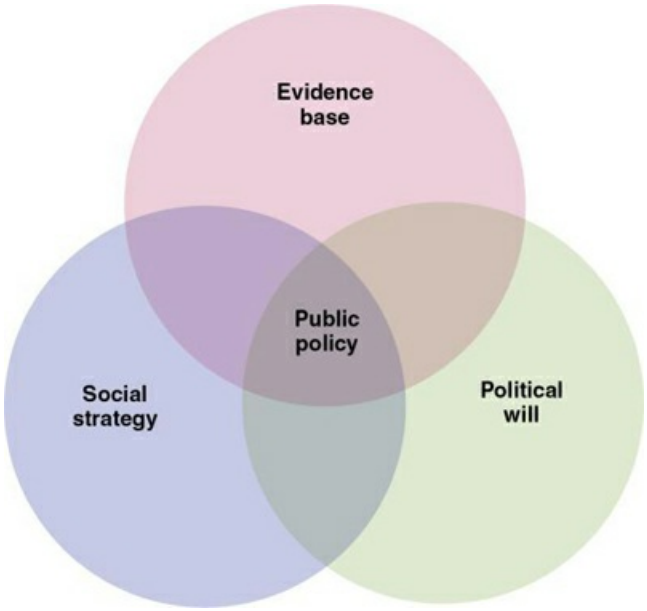
To complement the descriptions of major policy decisions and dilemmas, this chapter also emphasizes principles of health care economics, because common questions such as, "Who pays for health care?" and "What can a person do if he or she cannot afford health care?" continue to motivate health care policymaking at federal and state levels in the United States. While it is possible to understand US health care policy at a basic level without fully grasping economics, this chapter enables a level of awareness and understanding of economic principles and phenomena in the US health care system that will permit readers to make sense of the differential impacts of policies on multiple different stakeholders.

II. Core principles of health policy

Health policy is a nexus of policy, politics, procedure, and science. It is a dynamic blend of social strategies, laws, regulations, and funding decisions, most often embodied in constitutions, legislative actions, rules, and judicial decisions. It reflects and shapes historical and prevalent philosophies and priorities and drives governmental actions.[2] If health policy is chess, then health politics is chess while playing rugby on a speeding train.[3]

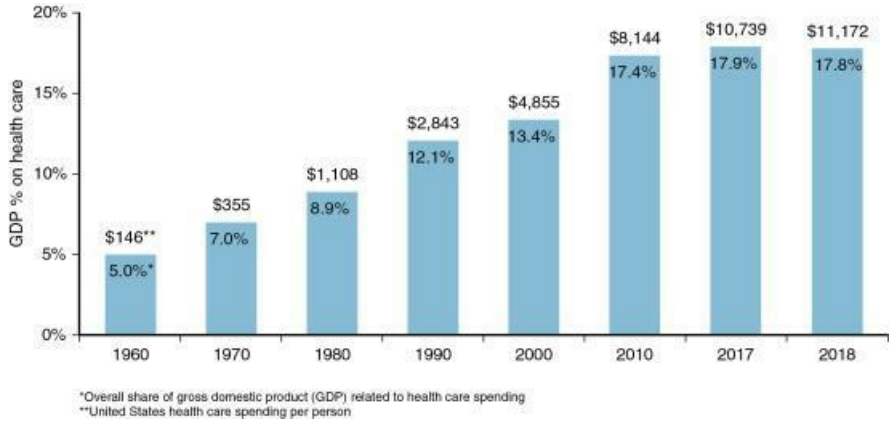
A. Political will

Health policy can be made or changed when three forces align: the scientific evidence base, social strategy, and political will (Fig. 14.1).[4] Scientific evidence refers to data regarding the nature of the problem to be addressed by policy. Social strategy is the actual detailed policy plan or approach to address a problem along with the social infrastructure (systems) in place to support the strategy. Political will is the public support for the resources needed to implement the strategy and achieve the solution. *Public* in this context refers to both government leadership and the broader community of constituents that the policy will affect.[5] In political terms, will is manifested as how decision makers vote on particular policies. In health policy, evidence and strategies abound, but unified political will is increasingly precious. Yet no policy change happens without it.



• **FIG. 14.1** Model of Public Policy. *Source:* (Adapted from Richmond JB, Kotelchuck M. Political influences: rethinking national health policy. In: Mcquire C, Foley R, Gorr A, Richards R, eds. *Handbook of Health Professions Education.* San Francisco, CA: Jossey-Bass Publishers; 1993:386-404.)

In the example of the Affordable Care Act (ACA, signed into law in 2010),[6] there had been broad agreement for a long time on the nature of the problem: economically unsustainable growth in the cost of health care at individual and national levels, with diminishing and disparate returns in health outcomes. As a proportion of the US gross domestic product (the sum of all goods and services produced annually), national health care expenditures in the United States more than tripled from 5% ($27.4 billion) in 1960 to 17.4% ($2.6 trillion) in 2010 (Fig. 14.2).[7]



• FIG. 14.2 Trend in National Health Expenditures in 2018 Dollars per Capita and as a Proportion of Gross Domestic Product in the United States, 1960–2018. *Source:* (From National Health Expenditure Data, Centers for Medicare & Medicaid Services, US Government. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical. html. Modified December 17, 2019. Accessed March 3, 2020.)

In 2018, US health care spending leveled off at 17.8% of gross domestic product, still faster than the rate of general inflation over the last few years. Aggregate national spending on health care grew 4.6 percent in 2018 to reach $3.6 trillion ($11,172 per person). The rate of growth in health care spending since the passage of the ACA was slower than in previous decades. While the United States spends far more per capita on health care than all other Organization for Economic Cooperation and Development countries, which averaged $3992 per capita in 2017,[8] it still lags behind in health outcomes, access, efficiency, and equity, ranking last among 11 comparison countries in an annual assessment by The Commonwealth Fund.[9] There is no shortage of evidence and agreement that something must be done to improve this "value equation" in the US health care system: the care that is provided, at the cost incurred, must provide better health outcomes than it currently does.

Over recent decades, many policy approaches to addressing this problem have been proposed from across the political spectrum. In fact, many of the core provisions in the ACA had been developed, argued, and refined over the years by both political parties, including insurance marketplaces, mandates to purchase insurance, standardized benefits, and a ban on denying coverage based on a preexisting medical condition.

One of the major reasons that the majority of US presidents over the last century tried

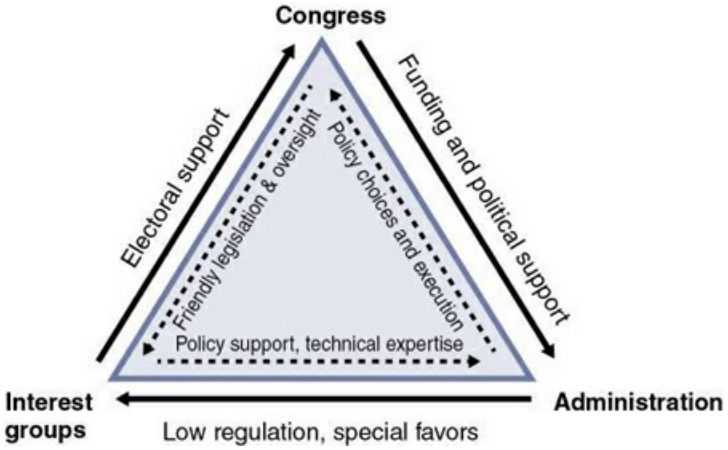
and failed to reform the country's health care system was not for lack of evidence or good ideas, but rather for lack of political will. Political will has been called "the slipperiest concept in the policy lexicon" and "the sine qua non of policy success which is never defined except by its absence."[10] A reasonable definition is that political will is "the extent of committed support among key decision makers for a particular policy solution to a particular problem,"[11] and it is a complex, multifaceted construct that must be understood in its context.

In more pragmatic terms, there are five principal stakeholders in health policy that can influence political will: patients, providers, payers, public entities, and the press (the "5 Ps"). Patients are the ultimate beneficiaries and consumers of health policy and health care. However, individual citizens usually lack the political clout of larger constituencies to influence health policy decision makers. Providers are often divided between two key players: physicians (and other health care professionals) and hospitals. Although aligned in their core mission to provide health care services to patients to reduce suffering and prolong healthy lives, physicians and hospitals are often in conflict in their respective business models and self-interests.[12] Payers of health care include insurance companies, employers, federal and state governments, and consumers themselves. Health care is ultimately financed by consumers through premiums, taxes, and salary offsets via insurance companies (private and public) and employers that offer health insurance. Public entities (e.g., government and public health agencies) are increasingly important players that regulate and provide health insurance and direct health care services through Medicare, Medicaid, and public clinics and hospitals. Public health officials at local, state, and national levels also contribute their expertise and efforts regarding surveillance for acute and chronic diseases, as well as outreach to promote preventive health practices. Finally, the press (i.e., ideas, perspectives, and opinions disseminated via traditional media) has a broad and pervasive impact on how the public and policymakers understand and react to health policy.[13,14] While social media also is an increasingly popular medium for communication, including for policy debates, the "voices" in social media accounts amplify the views of stakeholders rather than being an additional stakeholder themselves.

B. The Iron Triangle

While the "5 Ps" described previously are key stakeholders in health policy, the so-called *Iron Triangle* of US health care drives the federal policymaking apparatus (Fig. 14.3). The Iron Triangle describes the tightly interdependent relationships among three major forces in shaping political decision making: the administration (executive branch), Congress (legislative branch), and interest groups (constituencies). Small groups dominate the three sides of the Iron Triangle: government bureaucrats in executive positions, legislative committees with jurisdiction and authority on the issue, and a corporate or professional interest group or coalition of groups. This "sub-government" is quite stable and often impenetrable. The actors organize into mutually reinforcing relationships between regulated interests and regulators. In the United States, legislative power is exercised in Congress and particularly in its committees and

subcommittees. By aligning themselves with selected constituencies, interest groups and administrative agencies may be able to affect policy outcomes directly in legislative committees.



• **FIG. 14.3** The Iron Triangle of Health Policy.

The classic example is the triangle formed by the US House and Senate Committees on Armed Services, the Department of Defense, and the defense contractors, often called the *military-industrial complex*.[15] An example in health care is the triangle formed by the House Ways and Means Subcommittee on Health, the Office of the National Coordinator on Health Information Technology in the US Department of Health and Human Services (HHS), and the electronic health record vendors—represented by their trade association, the Electronic Health Record Association. These relationships are echoed at state and local levels as well. For many years, the sophisticated tobacco lobby successfully worked with state legislatures and health agencies to limit restrictions on tobacco sales, often by shifting the debate from public health to economics and freedom of choice concerns.[16] One of the prevailing economic features of perennial national debates about health care policy is the frequent focus on "pocketbook" concerns for consumers. Economic arguments can play a role at the individual level, where the public is concerned about the increasing costs of health care that they face. Economic arguments also play out at the state and federal levels, where taxpayer dollars are increasingly used to support the costs of health care through government programs. In general terms, more generous government programs to pay for health care for individuals in the United States mitigate the economic burden at the individual level. On the other hand, governments can only afford more generous programs if taxes are increased or other programs are funded less to compensate for greater spending on health care.

In the daily work of health policy decision making, interest group constituencies are valued and powerfully influential partners of the congressional committees that authorize and fund policy and of the federal agencies that operationalize and regulate the law. As political bodies, congressional committees and federal agencies seek to develop their power base to maximize their influence and impact. They typically work

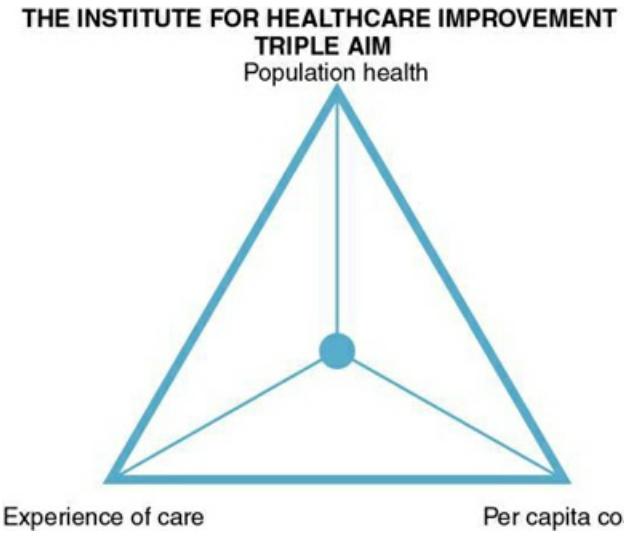
with interest group constituencies that will provide the most political clout in a policy arena. As a result, committees and agencies tend to ally themselves with the powerful interest groups more often than with the citizens who are the target of a particular policy or service.

"Constituents" are politically active groups who share a common interest or goal. Interest groups are the stakeholders and core constituencies of the federal committees and agencies. They include the major health industries and their lobbying groups, such as trade associations, voluntary health associations, professional societies, academia, think tanks, unions, and other stakeholders. These groups are wealthy, well organized, and well connected. They can move money and votes, exerting their influence through direct lobbying, making campaign contributions, and providing valued technical expertise for the applicable policy.

These alliances provide efficient and manageable access by Congress and the administration to expertise and political clout. In contrast, consumer-citizens are usually loosely organized, have divergent views, and lack political and financial muscle. Thus most consumers, even those organized into small groups, have limited influence on policymakers. This tends to produce policies that often do not adequately reflect the priorities of the ultimate beneficiaries.

C. Health policy trifecta—the Triple Aim

There is relatively broad agreement about the core aims of health reform. This is embodied in the Triple Aim,[17] initially described by the Institute for Healthcare Improvement: improving the experience of care, improving the health of populations, and reducing per capita costs of health care (Fig. 14.4). A high-value health care system requires attention to all three of these interdependent and sometimes conflicting aims. Most health policy initiatives seek to address one or more of these aims. Federal policy to fund recommended vaccinations for children is a rare example of the trifecta, improving access and quality outcomes while reducing the cost of preventable illnesses. Some have also expanded the Triple Aim to the Quadruple Aim, which includes health care worker wellness.[18] This is supported by the American Medical Association and many medical societies.[19]



• **FIG. 14.4** The Triple Aim of Health Care Reform. The IHI Triple Aim framework was developed by the Institute for Healthcare Improvement in Boston, Massachusetts (www.ihi.org).

III. Core principles of health care economics

When it comes to paying for health care, the bottom line is that the patient (often called the *consumer*) pays—if not always individually, then certainly collectively as a nation. While there may be health insurance plans that help to pay for health care, consumers pay premiums that finance the plans; insurance plans pay for health care principally from the premium dollars already paid to them. While there may be government-sponsored health programs such as Medicare and Medicaid, consumers pay the taxes that finance those programs. Increasingly, patients who seek health care are asked to "cost-share" with their insurance plans and government programs, thereby emphasizing consumers' central role in paying for care.

A. Why health insurance?

A common question is "What is the need for so many different ways to pay for health care in the United States, if consumers are the ultimate payers?" The answer is that health care in the United States is more expensive than the average consumer can afford, especially when it comes to a sudden need for complex health care in the highest-cost settings (e.g., hospitals).

Insurance as a financial mechanism is designed to help dampen the economic shock of an unexpected, costly event for an individual and his or her family—whether that event is a house fire, a car wreck, or a fractured hip. The central premise of insurance is that a company, by pooling the risks of various unexpected events over a large enough group of consumers (policyholders) and asking those consumers to pay regularly (premiums) into a central account, will have enough money to help the consumers pay the large bills that come due for unexpected, expensive events that actually occur (claims).

Given that US consumers depend on health insurance plans for financial help at some of their most vulnerable times, the financial well-being of health insurance companies (also called *carriers*) is a key issue in the functioning of the US health care system. Carriers' financial status depends greatly on their abilities to anticipate the types of health problems that consumers will experience and the corresponding amount of health care that consumers will seek. If the insurance company charges an amount for its premiums that is acceptable to consumers and has fewer claims to pay than it expected, then the company will do well. If the insurance company faces more claims than it anticipated for the premiums it charged, then the company will struggle. Furthermore, if the insurance company charges too much for its premiums in an effort to do well, it will likely lose customers to another company with similar benefits in its plan that is charging lower premiums.

In this example, the financial pressures on insurance carriers are clearly evident. The challenge for patients is that health insurance carriers, as businesses, often find ways to share those financial pressures with their policyholders and thereby optimize their business model and achieve revenues that exceed expenses. The authors discuss these

strategies next.

B. Key concepts in health insurance

Health insurance is often described as a "benefit" accessible to employees of companies in the United States that make health plans available as part of benefit packages (i.e., as part of a compensation package, other than wages). In another sense, each health insurance plan is itself a package of benefits—the specific events of health care (e.g., a doctor's visit, a prescription for a pharmaceutical) that, if sought by the policyholder, will be recognized by the insurance carrier as part of the plan and for which the carrier is prepared to pay some share of the costs.

Benefits in health plans have many facets, often described as what a plan "covers." One aspect of benefits is the type of setting in which health care is received. For example, a plan may cover visits to the hospital, emergency department, or primary care office, but may not cover visits to a dental health professional. Another facet of benefits may be quantity based, such as a limit on the number of visits to a mental health professional that will be covered in a given year. A third facet of benefits is network based, in which the plan contracts with a limited set of health care professionals with whom it has a preferred relationship. These professionals are within the "network" of the plan, and care sought from other health care professionals (whether intentionally or accidentally) is "out-of-network" and not covered in the same way by the insurance carrier. Insurance carriers are increasingly arranging "narrow networks" of a limited number of health care professionals and hospitals, with which they have negotiated very competitive reimbursement rates in order to control costs. A fourth aspect of benefits is based on preferred lists related to specific prescription drugs, diagnostic tests, and durable medical equipment that a plan will cover.

Without a benefit specified as part of a health insurance plan policy, a consumer will find it exceedingly difficult to receive help from an insurance carrier in paying for care. Yet even when a benefit is specified as being covered by a plan, the interaction of a policyholder with a health plan revolves around the interaction of benefits with the cost-sharing structure. The cost-sharing structure involves a set of specific components:

- *Premium:* The price paid by the consumer to hold the insurance plan, usually for 1 year at a time, and commonly paid in monthly installments. The premium must be paid regardless of whether the policyholder uses any health care.
- *Deductible:* The amount of a health care bill from a health care professional or institution (e.g., hospital) that a patient must pay before the health insurance plan begins to help. In other words, this is the amount deducted from what the carrier pays.
- *Co-insurance:* The share of a health care bill remaining to be paid after the deductible has been applied for which the policyholder is responsible.
- *Copay:* The flat fee for health care use that is applied at the location where care is received (e.g., primary care office, pharmacy).

To ensure their financial well-being, insurance carriers apply these components of

cost-sharing as an interwoven set to attract potential policyholders and influence the health care-seeking behavior of consumers. For instance, lower premiums are paired with higher deductibles in order to attract consumers with more modest incomes, who find the premiums more affordable and who may be willing to tolerate higher deductibles for the relatively infrequent health care they seek. On the other hand, patients who anticipate frequent health care use often opt for the most affordable higher-premium plan they can find, which typically has lower "user fees"—that is, the deductible, co-insurance, copays, or a combination of these are more modest than in the lower-premium plans.

By packaging benefits and cost-sharing in ways that attract groups of consumers with particular shared concerns and circumstances, health insurance carriers try to optimize their financial outcomes in ways that may also benefit consumers. The better that an insurance carrier can anticipate the costs of costly, unexpected events in a group of insured individuals (also called *covered lives*) who have access to a plan with certain benefits, the better that the carrier can set a premium and cost-sharing for that plan that will be closer to the real cost of the health care sought by the policyholders. Theory holds that a financial model closer to the real cost will be advantageous to consumers in terms of yielding a fairer price. In contrast, when a carrier has a plan with a more heterogeneous group of policyholders, it is typically more difficult for the carrier to anticipate the costs it will face. As a consequence, the carrier will likely build a cost-structure cushion into the plan to account for uncertainty; the consumers typically experience the cushion as greater cost-sharing and the plan as consequently less affordable.

Importantly, one of the most common forms of health insurance in the United States today is private health insurance sponsored by employers. Employees are able to pay premiums for such plans with their pretax workplace earnings, thereby reducing their taxable income. Moreover, employers commonly pay for a portion of the annual premiums as part of employees' compensation. So-called *group health insurance* of this type has the advantage of making insurance plans more widely available to consumers who may have had difficulty finding a similar plan that was affordable to them in the individual insurance plan market.

C. Rising health care costs—everyone's concern?

An additional concern for health insurance carriers, over which they have less control, is the cost of health care incurred by policyholders. A fundamental equation in economics is

$$\text{Cost} = \text{Price} \times \text{Quantity}$$

In other words, health care costs rise when prices are higher or when the quantity of health care sought by consumers increases, or both. Cost-sharing arrangements involving higher deductibles and co-insurance are known to discourage consumers' use of health care services (although consumers may avoid using necessary as well as

unnecessary services) and thereby mitigate increases in quantity. However, the aging population in the United States and the ability of modern medical therapies to help patients live with reasonable quality of life, despite one or more chronic health conditions, has meant that the frequencies of health care encounters has been increasing over time. As costs of health care increase, carriers pass on their higher spending to their consumers in order to sustain their corporate earnings, whether they are for-profit or not-for-profit.

Another core principle of economics is that prices are driven by the costs of goods and the costs of labor. In the health care context, the costs of goods include the prices of widely used pharmaceuticals and diagnostic tests, which continue to advance in their sophistication and their prices. Some experts have estimated that advances in medical technology such as diagnostic tests and pharmaceuticals have been responsible for as much as 50% of the increase in medical spending in the United States over the last several decades. While some of this increased spending is related to broader use (e.g., more patients are undergoing magnetic resonance imaging than in the past), a large component of higher spending is related to the higher price per unit good as well (e.g., costs of biologic pharmaceuticals now used to treat many inflammatory conditions such as rheumatoid arthritis, psoriasis, and eczema).

In the health care environment, the costs of labor are a major concern. Physicians in the United States are the best paid physicians in the world, but they also face major educational debt liabilities that may constrain their realized incomes. The ratio of subspecialty-trained physicians to primary care physicians in the United States is essentially the mirror image of other industrialized nations, which also increases the costs of labor as a per-encounter average. Advanced practice nurses and physician assistants are increasingly involved in primary and subspecialty care settings in the United States and are able to provide high-quality care at lower per-employee costs than physicians. While there are evolving interprofessional models of practice involving teams of physicians and other health care professionals that demonstrate many efficiencies, especially in pediatric care and some surgical subspecialties, these models have not yet been widely adopted.

As a result, health insurance carriers have turned to various approaches to limit their exposure to higher prices related to the costs of labor. One such approach—**network-based benefits design**—was mentioned earlier. Another approach is related to how health insurance carriers pay health care professionals for services that they provide. In the United States, the original form of payment by insurers is called **fee-for-service**, in which insurance carriers pay health care professionals for services as charged—for example, by the visit and by the procedure. Fee-for-service arrangements are simple, but they may encourage health care professionals to provide unnecessary care because they will be paid more for doing more.

In contrast, in **managed care arrangements**, a health insurance carrier contracts with health care professionals on a per-patient (also called *capitated*) basis, in order to set a fee that will be paid from the carrier to the professional regardless of the amount of health care sought by the patient. From the patient perspective, managed care plans are advantageous because they encourage health care professionals to anticipate health care

needs and adopt a preventive approach to care (e.g., by administering influenza vaccinations), in order to minimize the need for future unexpected visits (e.g., hospitalization for influenza) to manage acute health needs or exacerbations of chronic conditions. From the insurance carrier's perspective, managed care arrangements can work well because they provide more certainty for the carrier about how much it will pay health care professionals in a given month.

From the health care professionals' perspective, however, managed care arrangements are sometimes criticized as restricting autonomy and clinical decision making. Health care professionals who provide care that is more expensive than the capitated payment they received from the carrier are left at a financial disadvantage. Anticipating unfavorable financial outcomes can sometimes lead to adversarial, rather than collaborative, relationships between health care professionals and their patients. Frustration with capitation-related limits on care, such as limits on tests that can be performed and medications that can be prescribed, may lead patients and health care professionals alike to place blame on health insurance carriers, while insurance carriers are often working to keep costs within reach of average patients. In addition, the administrative costs borne by health care professionals and hospitals to contract with, and file claims with, insurance carriers are substantial. Consumers also bear the time costs of dealing with insurance carriers and health care professionals and hospitals in order to pay bills for care they have received.

In summary, in health insurance plans, consumers and health care professionals are increasingly aware that while health plans make it possible for patients to get access to expensive health care, the increasing costs of health care related to increasing prices for goods and labor are threatening the very fabric of health care today. That is why measures of health care quality are so important, to help ensure that patients and their health care professionals are working toward the same goals of improving care and outcomes. (See Chapters 6 and 7 for more on health care quality and safety.)

D. Government-sponsored coverage for health care

When the market for private insurance does not provide an affordable option for an individual, that consumer may seek access to care, coverage, or both through a government-sponsored program. Government-sponsored programs such as Medicare, Medicaid, the Veterans Health Administration (VHA), the TRICARE system for active-duty military personnel and their dependents, and the Indian Health Service are not health insurance, although they are often referred to that way in the media and general conversation. Rather, these are programs that provide direct benefits for health care to the program enrollees, called *beneficiaries.* Just as a privately insured person has coverage for health care expenses through a private health insurance plan, a person enrolled in Medicare also has coverage but through a different mechanism. Stated another way: All health insurance is a form of health care coverage, but not all health care coverage is health insurance.

As described in detail later in this chapter, government-sponsored programs grew out of a need for health care coverage for certain populations (e.g., seniors, poor children, veterans, native populations) who were perceived to have particular medical

needs that were not being served through the private health insurance market. Such programs are funded by taxpayers and therefore have a fundamentally different responsibility to the public in their financial management than do private insurance plans.

As a result, programs such as the VHA and Medicare have led the way in implementing cost-control efforts. For example, the VHA contracts with pharmaceutical companies for a limited formulary of prescription drugs for its entire beneficiary population (over 8 million veterans), thereby keeping its acquisition costs low and passing those savings on to the veterans. While the veterans' health care professionals must prescribe within a narrower formulary than many other health care professionals, the superior health outcomes of veterans versus same-age Medicare beneficiaries with regard to heart disease and diabetes suggest that such formulary limits are not limiting appropriate care.

Medicare has supported the concept of the accountable care organization (ACO) across the United States in an effort to encourage health care professionals and health care organizations to work together across multiple different settings (emergency department, hospital, primary care, rehabilitation care) to optimize patient outcomes while controlling growth in costs. There is a common misconception that "ACOs are the new HMOs," referring to health maintenance organizations that emerged in the late 20th century and were formed by health insurance carriers to emphasize disease prevention, limited access to subspecialists, and cost control. It is essential to understand that while health insurance companies were the organizers of HMOs, health care organizations and clinicians are the organizers of ACOs; therefore the perspectives and interests of the organizing entities for HMOs and ACOs are distinct from each other.

ACOs are groups of physicians, hospitals, and other providers who agree to take accountability for the cost and quality of all of the health care services received by a large group of patients. In most of these programs, the ACO providers are paid standard fees for their services, but they can earn bonuses or pay penalties based on whether Medicare spending on their patients is higher or lower than targets set by Medicare. Although the goals of improved quality and controlled cost growth were somewhat challenging for many institutions in the early years of Medicare ACOs, there is some evidence of the promise of this model.[20] As the concept of ACOs has been more broadly adopted (including in private insurance arrangements and for nonelderly adults and children as well), different structures have been established: about one-third include larger integrated systems, while nearly one-half are smaller and physician led, and the remainder are hybrid forms of the other structures.[21]

While these are positive examples of economic innovations in care financing and corresponding structure by government-sponsored programs in the United States, there are also negative examples. For instance, in 2015 the VHA was widely criticized for long wait times for its patients that had been exacerbated by tight budgets for staff. In Medicare, efforts to control hospital-related spending by declaring brief hospital admissions as "observation" stays had the consequence of shifting the majority of costs of hospital care to the beneficiaries, whose Medicare benefits would have otherwise

covered the bulk of costs if the brief admissions were designated as routine hospitalizations.

The proportion of the US population with government-sponsored coverage continues to grow steadily, as a result of three phenomena. First, there are demographic shifts. The share of the US population age 65 and older has grown, and the proportion of the US population covered by Medicare has increased. The same is true for the number of military veterans in the United States. Second, there are changes in government program eligibility related to persistent poverty and near-poverty in the population. As the income eligibility requirements for Medicaid have become more generous, because of reforms such as the ACA, more poor and low-income individuals have qualified for Medicaid. Third, fewer employers are offering group health insurance plans to their employees. Over time, those affected have had to seek coverage through government sources (as eligibility permits) or become uninsured.

The shift of individuals to Medicaid coverage has implications for health care professionals and hospitals, because reimbursement from Medicaid is substantially lower than from Medicare and from private health plans for the same clinical services. Medicaid has structural limitations because it is funded through federal and state taxes, and states set reimbursement levels lower than those for Medicare in order to mitigate the strain of Medicaid payments on state budgets, which in the vast majority of states must be balanced annually. For example, in a recent study of physician payments for vascular surgery, the mean Medicaid payment was 60% of Medicare payment for the same procedure, and there was up to threefold variation in payment across states for a given procedure.[22] Lower reimbursement by Medicaid for surgical and medical care leads some health care professionals and institutions to decide not to accept patients who have Medicaid coverage. Consequently, individuals with Medicaid must seek care in practices and health care systems with broader service missions and tolerance for providing care even when reimbursement is less than cost. Given these market dynamics, access to health care is more limited for patients with Medicaid than for patients with Medicare and private health insurance.

IV. Theories and history of health care reform

Much of American economic and political ideology is grounded in the market theory first espoused by Adam Smith in the late 1700s: Markets unfettered by government interference are most efficient, producing the appropriate amount of goods or services demanded by consumers through a price mechanism.[23] In the context of the delivery of health care services, however, the producer-to-consumer relationship is not so neatly defined. Is health care a commodity that is sold to consumers like other market commodities? If so, do the usual economic theories that govern the market apply to health care?

Another core component of Smith's theory is that producers and consumers must have symmetrical information for a market to function well. In other words, consumers can act in their best interests when they know the true costs of goods and labor that producers face in making a product or delivering a service. Consumers in the US health care system have imperfect information; because they do not know the actual costs of the medical services they receive at the time they receive them, they cannot bargain for a better price.[23] Furthermore, consumers with health insurance do not have as much incentive as an uninsured patient to know the costs of health care because most insurance plans shield them from experiencing the full costs of a typical encounter. Another major challenge is that consumers also have imperfect information in choosing their health insurance plans; consumers who are insufficiently informed about the costs of health care cannot make optimal decisions in the choice of insurance plans with different payment structures and benefits. The asymmetry in information among the physician, insurer, and patient leads to what economists call *market failure.* So far, attempts to develop health care cost transparency tools have shown little efficacy in providing consumers with meaningful information in order to inform their decision making.[24]

A. How much government regulation is best for US health care?

Some government regulation of health insurance therefore is needed to maintain a competitive insurance market, protect against monopolies, and provide consumers with information so that they can make informed decisions.[25] The question for health policymakers and reformers interested in improving the health care market is: How much and what types of government regulation can ensure an efficient market? As is described further in this chapter, many of the provisions of the ACA are focused on regulation of the health insurance market to improve competition and create more transparency for consumers.

However, government regulation of the health insurance market is clearly not the only consideration in the debate about the role of government in health care. What about individuals who are outside of the health care market because they have

difficulty accessing health insurance and health care in the first place? What is the role of government in ensuring that its citizens have access to health care? These pivotal questions are at the heart of major efforts to reform the US health care system over the last half-century. There are many competing values and principles involved in health system reform efforts. While discussion of all of these topics is beyond the scope of this chapter, Table 14.1 provides a list of important considerations.

TABLE 14.1

Objectives and Corresponding Benchmarks of Fairness in Health Care

Equity	Efficiency	Accountability
Intersectoral public health	Efficacy, efficiency, and quality improvement	Democratic accountability
Financial barriers to equitable access	Administrative efficiency	Patient and physician autonomy
Nonfinancial barriers to access		
Comprehensiveness of benefits and tiering		
Equitable financing		

Adapted from Daniels N. *Just Health: Meeting Health Needs Fairly.* New York: Cambridge University Press; 2008:246.

Proponents of a strong role for government in health care take issue with the idea that health care services should even be considered a market commodity. Instead, they argue that health care should be considered a right that must be distributed equitably across the population. Some theorists argue that health care is special and different from other social goods because of its impact on equality of opportunity; the government therefore has an obligation to ensure fair access to health care in order to enable its people to participate in political, social, and economic systems.[26] Under this theory, health care reform efforts should include considerations of equitable distribution of health care resources.

The principle of equitable distribution of health care resources undergirds the health care systems of many peer nations of the United States that have more socialized systems that depend much more than does the United States on government payment for health care for their citizens and much less than does the United States on private health insurance. In such systems (such as in Canada), citizens pay higher tax rates than in the United States in order to support government expenditures on social programs in general, of which health care is a major component. In turn, the government often imposes cost controls on markets such as pharmaceuticals, creates waiting lists for elective procedures (e.g., joint replacements for arthritis) to manage the quantity of elective procedures per year, and exerts downward pressure on physician earnings in order to mitigate natural increases over time in these expenditures. Socialized systems also tend to place a stronger emphasis on prevention (e.g., vaccinations) and on high-value services based on evidence. For example, patients over a certain age may not be eligible for hemodialysis or an organ transplant because the procedure is not likely to

lead to sufficient benefit in the length and quality of life for affected patients at the population level. Collectively, such value-focused efforts lead to slower growth in health care expenditures for the government programs and lower health care spending at the overall population level, which help sustain the tax burden at a manageable level. Importantly, the emphasis on prevention and high-value services in many cases yields better measures of overall population health (e.g., lower infant mortality rates, higher life expectancy) in industrialized countries with socialized medicine than in the United States without socialized medicine. Expressed in economic terms, many European countries can make the argument that their socialized medicine programs are yielding an efficient return on investment while also costing less per capita than health care in the United States.

Despite this economic argument rooted in improved health outcomes, the strong cultural emphasis in the United States on individual rights and aversion to higher taxation rates have made socialized medicine a challenging political proposition. Politicians and interest groups who promote "Medicare for all" and call for "single-payer" systems are tapping into the appeal of more socialized systems to mitigate the economic burden for individuals and families. This appeal, however, conflicts fundamentally with deeply held expectations among many Americans about the role of government in their lives and has fueled major political debates about health care over the last several decades, addressed in the next section.

B. The politics of health care reform

A lack of shared values and goals has made health care reform difficult in the United States. A slight majority of Americans (56%) believe that it is the responsibility of government to ensure that all citizens have health insurance.[27] Slightly more than half (54%) of Americans rate the quality of health care in the United States as excellent or good, while 77% rate their own health care as excellent or good. Yet nearly three-quarters (71%) believe the health care system has major problems, with one in five believing that it is in a state of crisis.[28]

In addition to the lack of consensus among policymakers and the American public about the values and goals for health care reform, or even the need for it, the current "system" is a "patchwork of public and private insurance plans; federal, state, and local governments; and institutions and individual providers who are often unconnected to one another."[29] In structuring reform efforts, policymakers have had to determine which aspects of the system may be influenced by government regulation, what level of government (federal, state, local) should be charged with administering policy changes, and how much to intervene in the core relationships among health care institutions, clinicians, and patients in order to improve the system. Furthermore, while there is a great deal of fragmentation in the delivery of health care across multiple settings such as hospitals and primary care, reforms that address one aspect of the system (e.g., cost containment) inevitably affect other aspects (e.g., access to and quality of care).

C. A brief history of health care reform in the United

States

Perhaps the best way to trace the ways in which reform theories, public opinion, and politics have influenced health care policy in the United States is to explore the history of reform successes and failures. Understanding this history is fundamental to providing appropriate historical context for the passage of the most significant recent change to health policy, the ACA in 2010.

1. Proposals for universal coverage

For more than 100 years, health care reformers have called for some form of national health insurance. As a Progressive Party candidate in 1912, Theodore Roosevelt proposed a social insurance plan, which included health insurance.[30] His cousin, President Franklin Delano Roosevelt, tried multiple times to enact national health insurance, including attempting to tie it to the Social Security Act of 1935. Yet he was unsuccessful, in part due to the strong opposition from powerful interest groups, particularly physician groups and state medical societies who linked national health insurance to socialism.[30] President Harry Truman ran on a platform that included national health insurance, winning reelection in 1948. However, he failed to convince Congress, and opposition remained strong from employers and physician groups.[29]

It was not until the 1970s that universal coverage once again reached the national policy debate. Building on the enactment of the Medicare and Medicaid programs in 1965 (described in more detail later), Democratic Senator Edward (Ted) Kennedy introduced the Health Security Act in 1970, which would create a single federally operated health insurance program.[31] In response, Republican President Richard Nixon proposed his own comprehensive plan that mandated that employers provide private insurance coverage for employees and providing that a government-sponsored program cover everyone else. The Watergate scandal in 1974 derailed these efforts, and it was not until the 1990s that serious attempts were made to provide universal coverage.[30] It is also notable that the Nixon administration was the first to focus policy initiatives on addressing rising health care costs, such as supporting managed care models to promote "restraint, efficiency and the health of the patient."[29] In the late 1980s, Physicians for a National Health Program proposed a government-financed health insurance plan, a "single-payer" program, that would replace the multipayer private insurance system. While versions of the single-payer plan were introduced in Congress, none succeeded.

Upon taking office in 1992, President Bill Clinton made health care reform a centerpiece of his administration. His wife, Hillary Clinton, led a White House Task Force leading to a proposed plan called the Health Security Act.[30] In an attempt to achieve universal coverage while emphasizing cost containment, the proposal did not shift coverage from private to public like many prior proposals. Instead, it proposed to create regional "health alliances" that would include various plans competing for business among employers and individuals. To provide for cost containment, it established regional spending limits and caps on premium increases.[29] These proposals,

however, were formulated largely behind closed doors, out of sight of an increasingly skeptical Congress. Moreover, the health insurance industry perceived a strong threat to its market control and organized a successful public marketing campaign to convince mainstream Americans that their private health insurance plans were under attack. As with many of his predecessors' proposals for reform, President Clinton's plan met with failure in Congress. As health policy expert John McDonough noted, "This failure taught Democrats lessons galore, among them: the president should not micromanage the congressional process and the effort should not threaten coverage of Americans who want to keep what they have."[30] These lessons "weighed on the minds of political veterans who reengaged in 2008"[30] as they once again attempted reform through the ACA.

2. Major milestones in US health care reform

While many US health care reform efforts met with failure, others have profoundly shaped the system as it exists today. The most momentous change occurred with the passage of the Medicaid and Medicare programs in 1965, but smaller, more incremental reforms also set the stage for passage of the ACA in 2010. A few of these are highlighted next.

a. Medicare and Medicaid

The most significant health care legislative achievement of the 20th century in the United States came in 1965 when President Lyndon Johnson collaborated with strong Democratic majorities in the US House of Representatives and Senate to win approval for Medicaid and Medicare. Described in greater detail later, Medicaid and Medicare were structured as safety net programs designed to provide government-funded coverage to those unlikely to access the private insurance market—the elderly, disabled persons, and poor children.

Medicare was financed exclusively by the federal government. In contrast, Medicaid was financed through a combination of federal and state funds, building on a shared financing model for health care for the indigent established over prior years by the federal Kerr-Mills Act. Many believed at the time that Medicaid and Medicare were the precursors to publicly funded universal coverage.[30]

b. Health Insurance Portability and Accountability Act of 1996

Despite the failure of President Clinton's Health Security Act in 1994, he signed the Health Insurance Portability and Accountability Act (HIPAA) into law in 1996. Accomplished through the bipartisan leadership of Democratic Senator Ted Kennedy and Republican Senator Nancy Kassebaum, Title I of HIPAA addresses concerns about the continuity of coverage for workers and their families upon losing or leaving a job with private employer-based insurance coverage. The law creates a guarantee for eligible workers, so they can obtain health insurance in the group market. Title II of the law includes provisions for administrative simplification geared toward reducing bureaucratic burdens on health care providers and institutions. One important result of

HIPAA is the rapid expansion of health information technologies.[30] HIPAA is perhaps most well-known for its "privacy rule," regulating restricted use and disclosure of protected health information.

c. The state Children's Health Insurance Program

Another bipartisan achievement was the creation of the Children's Health Insurance Program (CHIP) through the Balanced Budget Act of 1997. Republican Senator Orrin Hatch and Democratic Senator Ted Kennedy worked together to establish a 10-year block grant to states to expand health insurance coverage for low-income children whose family income is too high to meet eligibility requirements for Medicaid.[30] President George W. Bush twice vetoed reauthorization legislation for CHIP in 2007 when the initial grant expired, instead signing a temporary expansion. President Barack Obama passed reauthorization legislation in 2009, extending funding until 2013. The ACA extended the program until 2019 with appropriation of funding through 2015. Subsequent legislation enacted in 2015 appropriated CHIP funding through 2017. Then after a period of uncertainty as to whether it would be funded beyond 2017, Congress passed legislation to fund CHIP through 2023.[32]

D. State health care reform

While the history and milestones in health care reform at the federal level are important for understanding the context for passage of the ACA in 2010, so are examples of state-level health care reforms. A few examples of state reforms that influenced the structure and approach of the ACA are described next.

1. Hawaii

An early state law aimed at expanding health insurance coverage was the Hawaii Prepaid Health Care Act, passed in 1974. The law expanded health insurance coverage by mandating that employers provide health insurance to employees working at least 20 hours per week. It also required that employers pay a minimum of 50% of the cost of the premium. The employees' share of the premium cannot exceed 1.5% of wages.[33] The employer mandate was a precursor to a similar mandate in the ACA.

2. Vermont

In 2011, Vermont enacted An Act Relating to a Single Payer and Unified Health System, intending to create the first state single-payer health system in the United States. The law created Green Mountain Care, "a state-funded-and-managed insurance pool that would provide near-universal coverage to residents with the expectation that it would reduce health care spending."[34] The legislation required the legislature to draft a plan for Green Mountain Care by 2013, but the plan was not completed until late 2014. In December 2014, the governor announced that the universal plan would be too costly for the state, requiring a significant tax increase, and the effort was abandoned.[35] The Vermont experience demonstrated the difficulty of achieving major health care system

transformation, such as the creation of a single-payer system, without a clear pathway to affordable financing for such a system.

3. Massachusetts

The state health care reform law that most influenced the approach taken in the ACA was the 2006 Massachusetts law signed into law by Republican Governor Mitt Romney, entitled An Act Providing Access to Affordable, Quality, Accountable Health Care. The law contains the following provisions: a mandate that nearly all state residents obtain a minimum level of insurance coverage; sliding-scale subsidized health coverage for individuals with incomes below 300% of the federal poverty level, with fully subsidized coverage for those below 150% of the federal poverty level; establishment of the Massachusetts Health Connector, an insurance exchange where consumers can select from private, subsidized, and free health insurance plans depending on their income and eligibility; and a requirement that employers with more than 10 full-time employees provide health insurance.[36] The Massachusetts law strongly influenced the approach taken to expansion of coverage in the ACA. A 2014 study of the law's impact found that it did not negatively affect access or quality of care for those already insured. It also had a modest impact on costs.[37]

V. The path to the Affordable Care Act

While many of the reforms and milestones at the federal and state levels focused on expansion of coverage, other aspects of the health care system—rising health care costs, research demonstrating poor quality of care, and evidence that US population health outcomes were far worse than peer nations—began to drive the discourse around health care reform. In other words, health services research increasingly pointed to the deficiencies in the health care system itself, not just problems with access to care.

Perhaps most significantly, evidence that the percentage of health care expenditures in the United States had almost doubled between 1980 and 2010 and now far surpassed that in peer nations led to calls for comprehensive reform. As health policy expert John McDonough noted: "Though the United States spent far more than any other advanced society on medical services, its health system's quality, effectiveness, efficiency, equity, and public health indicators were mediocre at best by international standards."[38]

Reformers began to frame the need for systemic change as multifaceted, recognizing that expanding access without reducing costs or that attempting to reduce costs without attention to quality measurement would be ineffective. The Institute for Healthcare Improvement's Triple Aim provided a framework for addressing the interconnected problems with the system. But despite the calls for reform from health policy advocates, no serious reform would be possible without political leadership, the support of key interest groups, bipartisan compromise, and some indication that health care reform was a priority for the American public.

A. Leadership

During the 2007 primary election, polls indicated that Democratic voters still viewed health care reform as a priority, ranking it second after the economy. Democratic candidates Barack Obama and Hillary Clinton both put forth comprehensive health care proposals, as did Republican candidate John McCain. With the financial crisis of 2008, many thought the newly elected President Obama might not pursue a major piece of legislation focused on health care reform.

However, against the advice of some of his advisers, Obama made health care reform a priority at the beginning of his administration. Aided by the leadership of Senate Majority Leader Harry Reid and House Speaker Nancy Pelosi, Obama held steadfast in pushing comprehensive legislation despite many setbacks, including the loss of former Senator Tom Daschle, his choice to lead the White House Office on Health Reform, to individual tax problems; the death of the longtime Democratic champion of health care reform in the Senate, Ted Kennedy, who was replaced by an antireform Republican, Scott Brown; and the challenges of managing multiple competing interests within the Democratic party.[29]

B. Interest groups

One of the lessons from President Bill Clinton's failure to pass comprehensive health care reform was that, without the support of key interest groups, legislation would likely fail. For the first time, interest groups that historically opposed health care reform added their voices to support it. Most notably, the American Medical Association, which had historically rejected reform efforts focused on expanding coverage and regulating costs, listed health care reform as one of its top priorities. In addition, other key interest groups came to the table: the Pharmaceutical Research and Manufacturers of America, the Federation of American Hospitals, and health insurance industry representatives.[30]

C. Opposition and the rise of the Tea Party

A new political movement known as the Tea Party, consisting of libertarian, conservative, and Republican activists, made defeating Obama's health care initiative the focus of their platform. The Tea Party and other opponents of the law successfully used the media to attack it as a "government takeover" of health care. For example, a provision in the law creating funding for consultation with Medicare recipients for advanced care planning once every 5 years or more frequently if they became seriously ill was characterized as the creation of "death panels," in which bureaucrats would determine whether or not to provide medical care to the elderly and disabled. Although the claim was discredited, it resonated with some Americans, who were already skeptical about a larger role for government in health care.[39]

D. Compromise

While Obama favored the public option strongly supported by liberal Democrats, ultimately political pragmatism won out over principle to achieve successful passage of reform legislation. The Obama administration also made concessions to the insurance and pharmaceutical industries to secure their support.[40] As Jonathan Oberlander explained, the final bill was the result of multiple compromises to ensure passage:

> Political pragmatism carried the day as reformers made compromises on a range of additional issues—abortion, cost control, the scope of benefits, the narrowing of universal into "near" universal coverage—in order to pass legislation. The all-or-nothing mind-set that more than once has sunk health care reform was history.[40]

E. Passage of the ACA

President Obama signed the ACA into law in March 2010, after a yearlong national debate. The law was passed by a Democratic-controlled House and Senate, without any Republican support. Despite the lack of support from Republicans, the final law is more reflective of prior proposals by Republicans for employer mandates for private insurance than by Democrats for single-payer or expanded publicly funded options. In

fact, as described earlier, the ACA is modeled on the Massachusetts law supported by Republican Governor Mitt Romney.[31] Polls continue to show that public opinion is deeply divided about the law, with the majority of Democratic voters in favor of the law and the majority of Republican voters against it. As of January 2019, 78% of Democrats supported the law while less than 12% of Republicans did.[41]

The partisan divide over the ACA has led to continuous legal challenges and multiple attempts at repeal. With the presidential election of Donald Trump in 2016, along with Republican control of Congress, attacks on the ACA accelerated. Republicans in both the House and the Senate proposed "repeal and replace" bills, only to fail to gain enough votes for passage. If passed, both the American Health Care Act (the House bill) and the Better Care Reconciliation Act (the Senate bill) would have significantly changed the approach to health care reform in the United States. Despite failure to pass repeal and replace legislation, Congress and the Trump administration have chipped away at core provisions of the ACA through legislative and regulatory actions. In describing the major components of the law in the next section, some of the key court cases challenging the law are highlighted, as well as legislative and administrative policy changes that have been made to the law since its passage.

VI. The major components of the ACA

Although the ACA has 10 titles, or major sections (Table 14.2), it is easier to break the key components of the law into four categories: (1) expanded access to health insurance; (2) consumer benefits and protections; (3) cost-saving mechanisms; and (4) quality improvement measures. Each of these is described briefly in this section.

TABLE 14.2

Ten Central Components of the Affordable Care Act

Title	Name	Purpose
I	Quality Affordable Coverage	To expand private health insurance coverage and to strengthen federal regulation of the health insurance industry
II	Role of Public Programs	To expand and improve Medicaid for lower-income adults and families
II	Improving Quality and Efficiency in Health Care	To improve the quality, efficiency, and effectiveness of medical care, especially in the Medicare program
IV	Preventing Chronic Disease and Improving Public Health	To advance health promotion and disease prevention, and to strengthen public health
V	Healthcare Workforce	To increase the numbers and improve the quality of the US health care workforce
VI	Transparency and Program Integrity	To combat fraud and abuse, to promote transparency in health care, and to advance comparative effectiveness research
VII	Innovative Medical Therapies	To permit the manufacture, marketing, and sale of biopharmaceutical similar drugs (biosimilars)
VIII	Community Living Assistance Services and Supports	To create an insurance program to provide cash assistance to disabled persons (repealed on 1/1/2013)
IX	Revenue Provisions	To establish new taxes and fees to pay for the programs and benefits created in the law
X	Strengthening Healthcare for All Americans	Composed of amendments and new additions to titles I–IX

From McDonough JE. The United States health system in transition. *Health Syst Reform.* 2015;1(1):39-51.

A. Expanded access to health insurance

The ACA strives for near-universal access to coverage for all Americans through several important mechanisms. All of these provisions went into effect by 2014.

1. The individual mandate

First, the law created an "individual mandate" requiring that all individuals maintain

"minimum essential health coverage" or pay a tax penalty. The individual mandate was necessary to create a large risk pool of premium-paying individuals to support the other insurance reforms required in the ACA, such as protections for those with preexisting conditions. Specifically, for insurers to provide coverage to previously uninsured individuals, particularly less healthy ones, the pool must include younger and healthier individuals whose premiums help to support these individuals. The individual mandate has been perhaps the most unpopular provision of the law, facing both legal and political challenges.

In 2012, the US Supreme Court upheld the individual mandate in *National Federation of Independent Business v. Sebelius,* saying that Congress had the Constitutional authority to impose a tax penalty on individuals who did not meet the ACA's mandate. However, in 2017, the Republican-controlled Congress passed a tax law repealing the tax penalty imposed by the individual mandate. While the individual mandate is still law under the ACA, as of 2019 the IRS no longer enforced the tax penalty.

In February 2018, a group of 18 state attorneys general sued in federal district court arguing that without enforcement of the individual mandate as a tax, the entire ACA should be overturned, and the Texas district court struck down the entire ACA as unconstitutional on this basis. At the time of the writing of this second edition, the case is on appeal.[42]

2. Health insurance exchanges

To create a stronger and more regulated insurance market in order to offer consumers more transparency and lower-cost insurance options, the ACA created health insurance exchanges. These exchanges serve as a competitive marketplace through which individuals can select and purchase insurance. To help facilitate enrollment, the ACA requires that exchanges fund navigator programs to provide education, outreach, and enrollment assistance to consumers. But funding for these programs was slashed by the Centers for Medicare & Medicaid Services from $62.9 million in 2016 to $10 million in 2018. Given the complexity of the insurance market, some worry that without assistance from trained navigators, some consumers will fail to enroll. Data suggest that enrollment declined from 2017 to 2018, particularly among low-income individuals.[43]

3. The employer mandate

In addition to the individual mandate, the law requires employers with 50 or more employees to offer affordable health insurance or pay a penalty. The purpose of the employer mandate was to ensure that employers continue to offer health insurance. Without such a mandate, there was a concern that employers would stop providing coverage, moving more workers onto the ACA exchanges.

4. Premium subsidies and cost-sharing subsidies

The law makes it possible for low-income individuals who do not qualify for Medicaid, Medicare, or CHIP or who may not have access to affordable employer-sponsored plans to purchase insurance through two mechanisms: premium tax credits and cost-sharing

subsidies, known as cost-sharing reductions (CSRs). Individuals with incomes between 100% and 400% of the federal poverty level are eligible for premium tax credits, while those with incomes between 100% and 250% of the federal poverty level are eligible for CSRs. Subsidies for CSRs are paid to insurance companies to help them keep copays, cost-sharing, and deductibles lower for low-income consumers.[44]

The legality of the ACA's premium and cost-sharing subsidies was challenged in *King v. Burwell* (2015). This suit challenged the authority of the HHS to issue regulations governing both state-run and the federal health insurance exchanges, arguing that the language in the ACA only allowed for subsidies for individuals who obtained their insurance through state exchanges, not federal exchanges. The challenge was particularly important because nearly 5 million people had obtained their insurance through federal exchanges at the time of the lawsuit, and because, if the challenge to the ACA was successful, people in the 34 states that had not set up state insurance exchanges for federally subsidized plans would lose their insurance subsidies. In a 6-3 decision, the Supreme Court rejected the argument that the language in the ACA only refers to exchanges set up by the states.[45]

However, the battle over subsidies did not end with *King v. Burwell.* The House of Representatives sued the Obama administration, claiming that HHS did not have the authority to make the subsidy payments without appropriation from Congress. The case was eventually settled. Then in 2017, Donald Trump, who had promised to "let Obamacare fail," announced that HHS would no longer pay for CSRs, creating enormous uncertainty for insurers who depend on the subsidies to keep premium rates low. States stepped in to prevent rising premiums for consumers by "silver loading," which "allows insurance companies to cover the cost of the mandated, but now unfunded, subsidies by increasing premiums of other plans."[46] The future of funding for ACA subsidies remains uncertain. The Trump administration has made it clear that it continues to seek ways to reduce federal funding associated with the ACA. In 2017, President Trump signed an executive order that directed federal government agencies to "exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the ACA that would impose a fiscal burden."[47]

5. Medicaid expansion

The ACA provides federal support to states to expand their Medicaid programs to cover all eligible US citizens and legal immigrants with incomes below 133% of the federal poverty level. However, in *National Federation of Independent Business v. Sebelius* (2012) the Supreme Court held that mandatory expansion of Medicaid under the ACA was overly coercive of the states. Because the ACA required that states participate in the expansion or lose federal Medicaid funding, the court said that the federal government was overstepping its Constitutional authority,[48] making it voluntary for states to participate in Medicaid expansion. As of 2019, 33 states have chosen to participate.

B. Consumer benefits and protections

One of the fundamental changes made by the law to the insurance industry was to restrict certain insurance company practices such as preexisting conditions exclusions and discriminatory enrollment practices based on health status. The law also maintains coverage for young adults, who may have difficulty finding coverage through employment or affording it on their own, by guaranteeing dependent coverage (through their parents' plan) until the age of 26.

Insurers must also provide under the plan a set of "essential health benefits" within defined cost-sharing limits. To promote preventive care, the law requires that new health insurance plans must cover certain preventive services without cost-sharing. These include services with an "A" or "B" rating from the US Preventive Services Task Force, immunizations recommended by the Centers for Disease Control and Prevention, and screening and preventive care for women based on guidelines from the Health Resources and Services Administration.

Under the Obama administration, HHS required coverage for certain types of contraception, except by certain exempted employers, including religious organizations. In 2014, the Supreme Court decided in *Burwell v. Hobby Lobby* that nonreligious organizations may also be exempted. Some types of corporations that have objections to certain types of contraception based on religious beliefs may also be exempted from the coverage requirement.[49] Challenges to the ACA's contraception mandate have continued. In 2017, the Trump administration issued new rules allowing a broad exemption to the contraception mandate for *any* employer claiming religious objections. Several lawsuits are pending that challenge the rules.[50]

C. Cost-saving mechanisms

The ACA is financed primarily through savings that are expected to be realized from changes to Medicaid and Medicare, as well as tax provisions and fees. Some of the Medicare cost savings are expected to be achieved by reducing payments for preventable hospital readmissions (as described previously) and hospital-acquired infections; reducing reimbursement rates and imposing cost-sharing limits for Medicare managed care plans; and increasing the Medicare Part A (hospitalization) tax rate and reducing Medicare Part D (prescription drug) subsidies for high-income beneficiaries.

Reduction in Medicaid spending comes from reduced payments to Disproportionate Share Hospitals, which have traditionally received federal funds to provide uncompensated care in low-income communities. The reduction in Disproportionate Share Hospital payments was based on the expectation that the expansion of Medicaid would lead to fewer uninsured patients using hospital services. Savings are also expected be realized through rebates to Medicaid programs from drug manufacturers.

The law also includes several taxes and fees. For example, the ACA imposes a tax on indoor tanning services and medical devices and imposes annual fees on the pharmaceutical manufacturing industry.[29]

It is too early to tell whether many of these cost-saving provisions will reduce overall health care spending in the long term. However, early trends in year-by-year health care spending at the national level indicated larger spending increases in 2014 and 2015

associated with expansions in coverage, followed by a slowdown in spending growth in 2016.[52] Recent projections are that national health spending will grow at a faster pace, 5.5% annually on average in 2017 through 2026, and will represent 19.7% of the economy in 2026.[53]

D. Quality improvement measures

The architects of the ACA sought to address not only access and cost savings but support for quality improvement measures as well. The law establishes the National Quality Strategy, led by the Agency for Healthcare Research and Quality, to set priorities for quality improvement and to develop quality measures. Also established was the Patient-Centered Outcomes Research Institute, to "identify critical research questions, fund patient-centered comparative clinical effectiveness research, and disseminate the results."[54]

E. Linking quality improvement and payment reform

In addition to establishing these initiatives, the law supports a range of demonstration and pilot programs designed to improve the quality and safety of care while also reducing unnecessary costs. These include models of care that shift to a managed care approach emphasizing quality of care with a focus on reducing costs by improving the coordination of care, such as ACOs and patient-centered medical homes.

F. Prevention and public health

As noted earlier, in addition to addressing increasing health care costs, reformers were also guided by the increasing body of research pointing to poor US population health outcomes. The ACA contains a range of provisions aimed at prevention and public health, including the establishment of the National Prevention, Health Promotion, and Public Health Council, whose primary task is to create and implement the National Prevention Strategy, and a Prevention and Public Health Fund to support initiatives aimed at improving public health and reducing medical costs. The Prevention and Public Health Fund, for example, provides grants from the Centers for Disease Control and Prevention to states, counties, cities, and nonprofit organizations to implement proven practices to improve nutrition and physical activity, reduce tobacco use, and control blood pressure and cholesterol. Initially funded at $15 billion, the fund has been subject to repeated cuts. The 2017 Tax Cuts and Jobs Act cut $750 million, diverting the money to the CHIP program. The 2018 bipartisan budget bill cut an additional $1.35 billion over 10 years.[55]

Additionally, the ACA fosters collaboration between health care, public health departments, and community organizations to address population health needs. The law requires that, in order for nonprofit hospitals to maintain their tax-exempt status, every 3 years they must conduct a community health needs assessment and develop an implementation plan to address identified needs. In creating its plan, the hospital must

include "input from people who represent the broad interests of the community served by the hospital facility, including those with special knowledge of, or expertise in, public health."[56]

G. Health equity

Parts of the ACA also explicitly focus on reducing health disparities and promoting health equity. These include requirements regarding the collection and reporting of data by race, ethnicity, and language; expansion of workforce diversity; support for cultural competence education and model curricula; promotion of health disparities research; prevention initiatives targeted at underserved communities; and expanding access to insurance coverage.[57] Some of these provisions are highlighted briefly here.

1. Equity in insurance coverage

Marked racial/ethnic disparities exist in insurance coverage in the United States. However, since passage of the ACA, uninsured rates have declined for both African Americans and Latinos. Between 2013 and 2017, uninsured rates for nonelderly African Americans declined from 19% to 11%. The uninsured rate for nonelderly Latinos declined from 30% to 19%. However, insurance coverage gains stalled between 2016 and 2017, with the uninsured rate rising for nonelderly African Americans by 0.5%.[58]

The insurance expansions of the ACA were expected to reduce the rate of uninsured across all groups, but because some states decided not to expand their Medicaid programs, declines have not been as robust as expected in all states. Because African Americans and Latinos are more likely than non-Hispanic whites to live in poverty and therefore rely on Medicaid, the failure to expand Medicaid in some states has left many without coverage.[58] Access to Medicaid will also be affected by the Trump administration's support of more restrictive state eligibility rules.

In 2017, the Trump administration encouraged states to apply for waivers under Section 1115 of the Medicaid law, which allows states to experiment with Medicaid delivery. The Trump administration explicitly supported waivers that include limits on eligibility such as work requirements. Unlike other government assistance programs, work requirements have never been used for Medicaid eligibility. As of July 2019, seven state work requirement waivers have been approved by HHS, with others pending. In 2018, Kentucky's waiver was successfully challenged in court by Medicaid recipients.[59] The court remanded the case to HHS and required it to fully respond to evidence presented in public comment that showed that thousands of Medicaid recipients would lose coverage, contravening the intent of the Medicaid statute's purpose of providing coverage to poor and vulnerable populations.[60]

2. Access to care

The ACA significantly expanded funding for community health centers, which provide primary care to predominantly low-income and diverse patient populations. In addition to expansion of access through community health centers, the ACA contains other

provisions aimed at improving access to care for underserved populations, such as support for nurse-managed health centers, community health workers, and school-based health centers.[57]

3. Expanded civil rights protections

Prior to the ACA, civil rights laws enforced by the HHS's Office for Civil Rights barred discrimination in health care based on race, color, national origin, disability, or age. Section 1557 of the ACA extends civil rights protections to ban sex discrimination in health programs and applies those protections to

> Health Insurance Marketplaces, any health program that HHS itself administers, and any health program or activity, any part of which receives funding from HHS, such as hospitals that accept Medicare patients or doctors who treat Medicaid patients.[61]

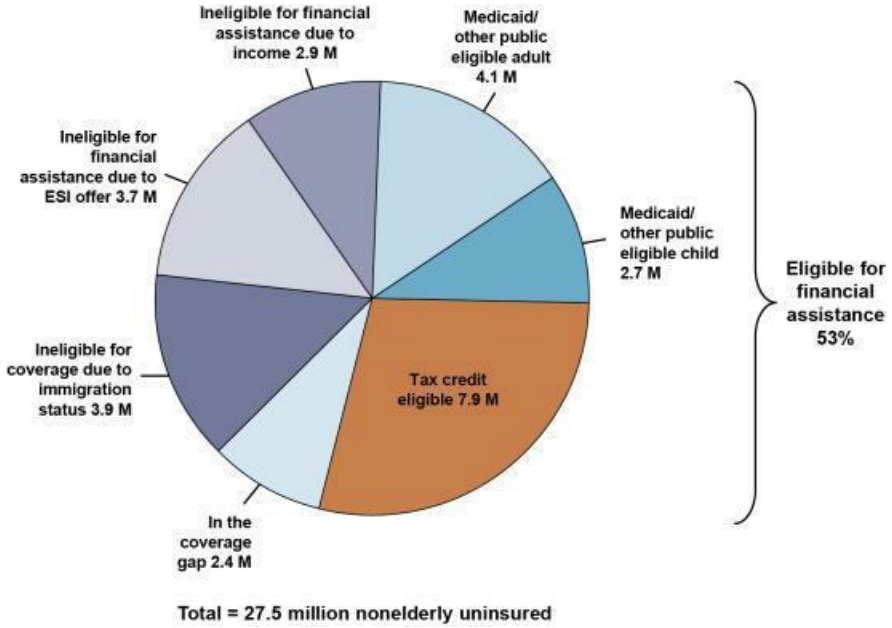
Some of the key civil rights provisions under the ACA and proposed HHS rules are as follows[61]:

- Prohibits women from being charged more than men for health insurance coverage or discrimination in health services
- Prohibits categorical exclusions on coverage of all care related to gender transition and ensures that individuals must be treated consistent with their gender identity, including in access to facilities
- Requires provision of language services, such as oral interpreters and written translations for patients with limited English proficiency, including in health insurance exchanges
- Requires provision of auxiliary aids and services and accessibility of programs offered through electronic and information technology for individuals with disabilities

VII. The effect of the ACA on patients, health care professionals, and institutions

A. Patients

The most significant impact of the ACA on patients has been expanded access to affordable health insurance and the creation of exchanges that have made obtaining insurance easier and more transparent. However, navigating the exchanges has proven to be challenging for some consumers, and significant cuts to the funding for outreach and navigation services under the Trump administration threaten enrollment. Additionally, equitable access to insurance remains a problem due to the coverage gap that resulted when some states chose not to expand Medicaid to low-income adults. In nonexpansion states, individuals with incomes below 100% of the federal poverty level are ineligible for subsidies to help them afford insurance through the exchanges. Even among those who are eligible for subsidies, some continue to find affordable coverage difficult to obtain due to broad differences in plan availability across markets. Fig. 14.5 illustrates eligibility for ACA coverage among the uninsured in 2016. Roughly half are eligible for financial assistance, but the other half cannot access coverage through the ACA due to their immigration status, their state's decision not expand Medicaid, or affordability issues.



• **FIG. 14.5** **Eligibility for ACA Coverage Among Nonelderly Uninsured, 2016.** Notes: Numbers may not sum to totals due to rounding. Tax Credit Eligible share includes adults in Minnesota and New York who are eligible for coverage through the Basic Health Plan. Medicaid/Other Public also includes CHIP and some state-funded programs for immigrants otherwise ineligible for Medicaid. *ESI,* Employer-sponsored health insurance. *Source:* (From

Kaiser Family Foundation analysis based on 2017 Medicaid eligibility levels and March 2017 Current Population Survey, Annual Social and Economic Supplement.)

Some of the Trump administration's backtracking on ACA coverage provisions will also likely have a negative effect on access to care. Indeed, coverage gains under the ACA declined between 2016 and 2018. Nearly 14% of Americans were uninsured at the end of 2018, up from 10.9% in 2016.[62] Additionally, efforts to undermine requirements for essential health benefits and preventive care (particularly contraception coverage) will reduce access to care for some patients, especially low-income women. On the other hand, roughly 20 million previously uninsured people have health insurance coverage because of the ACA. Furthermore, most research indicates that Medicaid expansion has led to improved access, utilization, and affordability of care as well as better health outcomes for recipients in states that participated in the ACA expansion.[63]

Beyond its health insurance coverage expansions, the ACA has encouraged a focus on patient-centered care and shared decision making. Regulations under the ACA emphasize the use of patient satisfaction surveys, and many of the quality measures described in the ACA are linked to patient experience of care. Additionally, provisions encouraging patient voices in research offer patients an opportunity to advocate for better health care.[64] Finally, the ACA's incentives for care integration, value-based payment, accountability for population health, and community-based health improvement initiatives have helped to put patient experience of care at the center of system reform and have challenged providers, payers, and policymakers to focus on evidence-based strategies to improve population health.

B. Health care professionals

Recognizing the need for expanded access to primary care as more people become insured, the ACA included a 10% bonus for primary care professionals working in underserved areas between 2011 and 2015. It also increased Medicaid reimbursement for certain services to create parity with Medicare in order to encourage more doctors to accept newly enrolled Medicaid patients in 2013 and 2014.[65] While these provisions were designed to expand capacity of primary care for a newly insured patient population, the increased incentives were temporary and have not addressed the systemic primary care shortage, which is a long-standing problem in the United States. Combined with the ACA's promotion of patient-centered medical homes, which place primary care at the center of care coordination, addressing this shortage promises to be an ongoing challenge for the system. One consequence has been stimulated growth in nonphysician primary care professionals, such as nurse practitioners and physician assistants.

Patient-centered medical homes and other integrated care models, driven by the shift toward value-based payment, are changing clinical practice from physician-patient focused to a team-patient model in which multiple players interact with patients to address multiple medical, behavioral health, and social needs. The ACA has stimulated significant delivery system changes aimed at improving care and reducing costs that have changed the nature of medical practice.

Another major change accelerated by recent health care reforms, before and during the ACA era, is the electronic health record. While critiques of electronic health records abound,[66] they are critical tools for documenting and coordinating patient care.

C. Health care institutions

The ACA contains many provisions aimed at improving quality and decreasing costs in hospital care. One particular focus is on reducing rates of hospital readmissions. The ACA holds hospitals accountable for their 30-day readmission rates for several conditions (e.g., heart attacks) and for hospital-acquired infections with financial penalties. Readmission rates continue to decline, indicating that the ACA has spurred hospitals to implement changes; however, hospitals that serve low-income patients have found it difficult to reduce readmission rates, suggesting that broader strategies and supports may be needed.[67]

An additional challenge for hospitals located in states that chose not to expand Medicaid is the ACA's reduction of Disproportionate Share Hospital payments. These payments to hospitals cover part of the costs of uncompensated care of patients without insurance. The architects of the ACA anticipated that hospitals' provision of uncompensated care would decline substantially as more low-income individuals enrolled in Medicaid. However, roughly 10% of nonelderly adults remain uninsured and will likely continue to need hospital care. Congress has repeatedly delayed the cuts to Disproportionate Share Hospital payments. Should such reductions finally take effect as was expected in 2019, hospitals in states that choose not to expand Medicaid could face serious budgetary crises as they remain responsible for providing uncompensated care.[55]

For hospitals, broadening coverage for nonelderly adults under the ACA has led to lower rates of hospitalizations overall for individuals who are uninsured,[68,69] as well as lower rates of hospitalization for common conditions such as cardiovascular disease (e.g., myocardial infarction, cerebrovascular accidents).[70] Decreases in hospitalizations for individuals who are uninsured translate into more favorable revenue for hospitals, even if the increases in coverage are largely attributable to higher proportions of patients with Medicaid.

VIII. Policy controversies and challenges

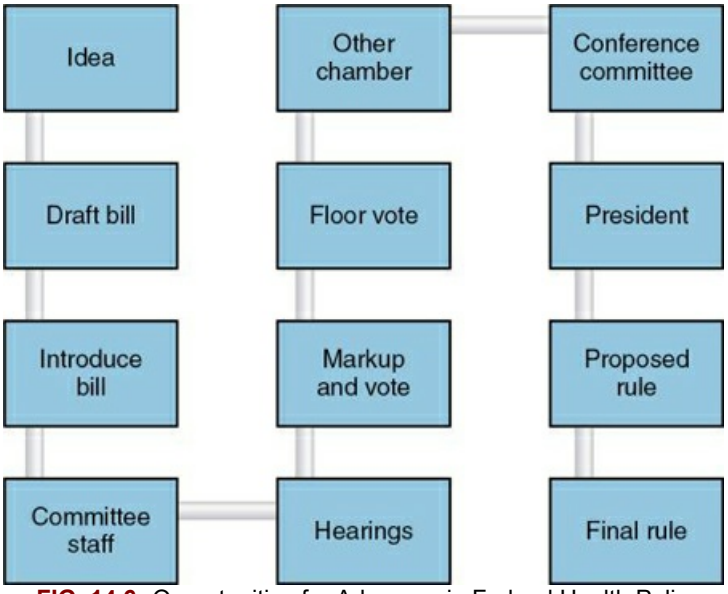
A. Legislation and rulemaking

Establishing and implementing health policy is a two-part process, requiring legislative and administrative law, respectively. Legislative law, or *statute* (how a bill becomes a law), is the underlying legal language, written in precise form. Administrative law, or *rule* (how a law becomes a rule), is the translation of statute into the more operational language of a rule to guide how public agencies establish or modify programs. Stated another way, administrative law is like the graphic user interface and operating manual for your smartphone application (app), while legislative law is like the computer programming code within the app.

A law is enacted when a bill is introduced by a member (sponsor) of Congress, passed by a majority of the relevant subcommittee and then full committee with jurisdiction over the issue, then passed by the House (at least 218 votes) and Senate (at least 51 votes) in identical form, and finally signed by the president. Most bills never see the light of day in subcommittee, let alone get considered or voted on by the House or Senate or make it to the president's desk. Fewer than 5% of bills introduced are signed into law at the federal level.

While that is challenging enough, it is only half the battle with regard to implementing a health policy change. In the federal rule-making process, the Executive Branch agency authorized in the law must prepare a Notification of Proposed Rulemaking—the draft language for the administrative law. For health care policy, this is usually one of the agencies in HHS, such as the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality. The proposed rule is open for public comment for 1 to 3 months. The agency then compiles and considers the comments and revises the Notification of Proposed Rulemaking into a final rule in the context of the authorizing statute.

In practice, law making and rule making are often iterative processes, with congressional and agency staff consulting with each another as they draft language. Key stakeholders and constituencies (interest groups and citizens) have multiple opportunities to advocate and to shape a particular policy through both the legislative and administrative law-making process (Fig. 14.6). Each provides several decision points and opportunities for leverage by advocates.



• **FIG. 14.6** Opportunities for Advocacy in Federal Health Policy.

B. Health care workforce policy

Health care in the United States is delivered by a multitude of health care professionals, including physicians, nurses, nurse practitioners, physician assistants, pharmacists, dentists, and many others. The Association of American Medical Colleges projects a total physician shortfall of between 42,600 and 121,300 physicians by 2030.[71] The size and distribution of this health care workforce (by profession, specialty, geography, gender, race/ethnicity, etc.) is shaped more by local practice models, marketplaces, reimbursement, and educational pipelines than by public policies to align the workforce with society's health care needs. Unlike many peer nations, the United States does not have a centralized body to shape the size or distribution of the health care workforce in response to needs for equitable access, geographic distribution, or workforce efficiency. Congress has been reluctant to weigh in on this issue, and they lack an unbiased source of information regarding workforce demand and supply. Policies to shape the health care workforce generally create winners and losers and, thus, happy and unhappy constituents.

To address this shortcoming in federal health care workforce policy, the ACA included a provision to authorize the establishment of a new National Health Care Workforce Commission, tasked with reviewing health care workforce and projected workforce needs. The commission would provide comprehensive, unbiased information to Congress and the administration about how to align health care workforce resources with national needs. However, as with most authorizing statutes, no activity is permitted until Congress also appropriates funds for that purpose. To date, Congress has not passed the appropriation of the $3 million required to establish the Workforce Commission and initiate its work.

C. Authorization versus appropriation legislation (and three kinds of money)

As noted earlier, action by authorizing and appropriation committees of Congress is required for many policies to be fully implemented. Authorizing committees establish or modify programs. In health policy, these committees in the House of Representatives are Ways and Means, Energy and Commerce, and Education and Labor. Their counterparts in the Senate are the Finance and the Health, Education, Labor, and Pensions committees.

Appropriations committees (12, each paired in the House and Senate) determine how much federal funding is allocated to discretionary programs for each fiscal year through the federal budgeting process, across all federal agencies. For example, of the roughly $4.1 trillion in total federal health-related spending in fiscal year 2018, about one-third went to these discretionary programs (e.g., funding for National Institutes of Health research, the Centers for Disease Control and Prevention, transportation, housing, education).[71a] The funding levels for these discretionary programs must be appropriated annually. This is a highly contentious, political process since increasing funds to one program often requires reducing funds to another in each year's budget negotiations.

In contrast to discretionary funding, about two-thirds of all federal spending is direct or mandatory (e.g., Medicare, Social Security), which guarantees funds for these services for as many Americans as are eligible; such services are referred to as *entitlement programs.* Mandatory funding does not require annual appropriations and can only be changed by modifying the underlying authorizing statute.

Besides mandatory and discretionary spending, there is a third kind of money in federal policy—tax spending. Operating with much less public attention than the first two kinds, tax spending is also a powerful and stealthy lever in shaping policy. Tax spending is "revenue foregone," money that would normally have come in as taxes but is, instead, kept by the taxpayer for other uses. This is usually implemented via a tax deduction or tax credit. Since the money never actually comes into the US Treasury, tax spending is an indirect form of spending. It may seem odd to refer to tax policy as a form of federal spending, but for budgeting purposes money that is not collected as taxes is equivalent to money that comes in and then goes out. Tax spending is rarely noted as part of the federal budget. Few realize that, in addition to the $4.1 trillion in mandatory and discretionary spending in 2018, the United States spent more than $1.5 trillion in such tax spending.[71b] Two of the largest sources of tax spending are the home mortgage interest deduction and the tax exclusion for employer-sponsored health insurance premiums.

D. Graduate medical education policy

Graduate medical education (GME) is the pathway through which resident physicians in all specialties develop the competence to practice independently. As another example of the decentralized processes shaping the US physician workforce, GME policy,

including how many residency training slots are available in each specialty each year, is mostly controlled by medical professional regulatory bodies—the Accreditation Council for Graduate Medical Education and the American Board of Medical Specialties—and influenced by powerful hospital and physician interest groups, such as the Association of American Medical Colleges, the American Hospital Association, and the American Medical Association, as well as specific physician professional societies. These groups generally advocate for expanded GME funding and for lifting the caps for the number of Medicare-funded residency positions, which have been frozen at 1996 levels, but also promote innovation in medical education.[72,73]

However, many professional organizations agree that the guaranteed federal funding policy of GME (more than $15 billion annually, mainly via Medicare and Medicaid) is not well aligned with the health care needs of the nation.[74,75] In a critical report in 2014, the Institute of Medicine (now known as the National Academy of Medicine) described a number of concerns about the US system of GME, including a mismatch between the health needs of the population and the specialty makeup of the physician workforce; persistent geographic maldistribution of physicians; insufficient diversity in the physician population; a gap between new physicians' knowledge and skills and the competencies required for current medical practice; and a lack of fiscal transparency.[76] The Institute of Medicine recommended significant reforms to GME financing and regulatory policy to address these concerns, including rationalizing and aligning GME policy with US physician workforce needs, promoting innovation, and increasing accountability and transparency of GME programs. These recommendations have been largely supported by various physician professional societies.[77] If political pressure grows toward fiscal austerity and responsible stewardship of taxpayer dollars, federal GME funding may become vulnerable. This could provide an opportunity to reform the GME financing system and to use such policy change to reshape the physician workforce to better meet the needs of society.

IX. Chapter summary

Health policy and health economics in the United States are inherently complex—just as clinical medicine is complex. Today's evolving health care system in the United States, with the highest per capita spending of any country in the world, is the result of a century of progressively increasing public demand for technologically advanced medical care delivered by a subspecialty-dominated workforce, paid for through a uniquely American combination of private insurance plans and government-sponsored programs as well as out-of-pocket spending by patients. Political debates about health care have been some of the most acrimonious political struggles of the last 50 years and more, yet have also led to programmatic linchpins of the current system (Medicare, Medicaid) that together currently provide coverage for almost 120 million Americans.

Moreover, there are disparities in health and health care for patients in the United States based on sociodemographic characteristics and geography—such as whether or not a person lives in a state that decided to expand Medicaid eligibility under the ACA. While health care professionals can address some of these disparities through the care they provide, health policy presents an indispensable avenue for standardizing approaches across the US health care system and ensuring that high-quality, affordable care is accessible to as many patients as possible.

The long-term sustainability of the US health care system, especially as paid for through government programs, is a major economic challenge that rests on successful containment of perpetually rising health care costs that are progressively consuming greater shares of the gross domestic product. State-level health care reforms that set the stage for the ACA, and the ACA itself, principally focused on expanding coverage rather than controlling costs. While cost control is not a broadly popular focus for policy reform because the public perceives that such reforms will limit their access to care, financial realities for government programs and private health insurance plans are likely to lead to increasing pressures on health care professionals and patients to adjust to a system with more constraints than they have experienced previously.

By understanding core principles and aspects of health policy and health economics in the United States today, physicians and other health care professionals can appreciate essential contextual details at the federal, state, and local levels that will help them provide high-quality care that is affordable for their patients. Individuals who are inclined toward advocacy may also decide to support future reforms in the US health care system. After all, despite multiple reform initiatives and clinical care that is popularly perceived as second to none in the world, the US population has worse population health outcomes than in peer nations, despite spending substantially more per person on health care.

Questions for further thought

1. Who pays for health care in the United States, and how?
2. Why does the US health care system include such a patchwork quilt of private health insurance plans and government-sponsored coverage?
3. What are key differences between Medicare and Medicaid, in terms of the roles of federal and state government and the population groups of patients who are served by these programs?
4. How did the ACA try to expand Medicaid coverage, and what legal challenges have such attempts faced?
5. What are the remaining challenges in the US health care system that the ACA did not address?

Exercise

For a health policy question that concerns you, consider which stakeholders influence how that policy has been formed and how it affects the US health care system today. Which stakeholders currently seem most influential, versus least influential? What would have to change to shift the balance of influence among stakeholders? If you were going to attempt to change this policy, what steps would you take? What are the intended consequences of the policy change? What are the potential unintended consequences? If you wanted to maintain this policy, what would you do to support its continued implementation?

Case Study 1

Jacinta and Evelyn are cousins in their mid-50s. They both have diabetes and take oral medications, but with progressively worse blood sugar control over the past few years. Jacinta lives in Michigan, which expanded income eligibility for low-income adults through its Medicaid program in 2014 with support from the ACA. Evelyn lives in Georgia, which chose not to expand its Medicaid eligibility. Both Jacinta and Evelyn hold a combination of part-time jobs that do not offer health insurance benefits. Both have incomes that place them just below the poverty line.

Although they were both uninsured as recently as 2013, their respective state programs now present quite different options for the cousins. In Michigan, Jacinta has signed up for the expanded Medicaid program and now has health insurance that covers hospitalizations, doctor visits, emergency care, prescription medications, mental health visits, and dental care. In Georgia, Evelyn is not eligible for the Medicaid program, which only provides coverage for individuals at lower incomes than hers. She cannot find a health plan that is affordable for her.

1. What policy decisions led to the differing circumstances for these women regarding availability of government-sponsored health insurance?
2. How does having health insurance alter Jacinta's behavior regarding seeking health care?

3. How does *not* having health insurance alter Evelyn's behavior regarding seeking health care?
4. What are some policy options that might make health care more affordable for both cousins, while also constraining growth in health care spending?

Case Study 2

Two physicians, early in their careers, want to achieve positive policy-focused change for clinicians in their specialties. Dr. Lin is a primary care physician who practices in a predominantly rural state; his state has decided not to expand Medicaid under the ACA. Dr. Fieldman is a neurosurgeon who practices in a state with several urban centers where high proportions of the adult population live in poverty; her state has expanded Medicaid under the ACA.

1. Based on health challenges facing populations in the United States today, what advocacy agenda would you suggest for Dr. Lin and Dr. Fieldman to have the greatest impact on their specialties and the patients they serve through changes in state and federal policy?
2. What stakeholders do you anticipate would share their views?
3. How could they seek to change guidelines, rules, or policies at different levels, and through what processes?

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Askin E, Moore N, Shankar V, Peck W. The Health Care Handbook A Clear and Concise Guide to the United States Health Care System 2nd ed 2014; Academic Publishing Services, Washington University School of Medicine St. Louis, MO.

This is an accessible "user's manual" that explains the US health care system and the policies that will change it. It is an excellent guide to the people, organizations, and industries that make up the US health care system and major issues the system faces today. It is rigorously researched and scrupulously unbiased yet written in a conversational and humorous tone.

Blumenthal D, Morone J. *The Heart of Power* Health and Politics in the Oval Office 2010; University of California Press Los Angeles, CA.

This engaging text offers a detailed examination of how several US presidents (from Franklin D. Roosevelt to George W. Bush) have wrestled with health policy challenges of the nation while also frequently facing health problems for themselves and their families.

McDonough JE. *Inside National Health Reform* 2011; Milbank Memorial Fund New York, NY.

This book offers a fascinating look at the inside politics of health reform, with a detailed account of the passage and provisions of the Affordable Care Act.

Teitelbaum JB, Wilensky SE. Essentials of Health Policy and Law 3rd ed 2016; Jones & Bartlett Burlington, MA.

This book covers the essentials of health policy and law, with topics ranging from health care economics to health care reform to the public health system. It is very accessible for readers not well versed in health policy and includes discussion questions and case studies. It is regularly updated to keep up with the changing policy landscape.

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15

Application of health systems science competencies in patient care

Sara Jo Grethlein, MD, Jose Azar, MD, Chemen Neal, MD

CHAPTER OUTLINE

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In this chapter

Learning content without applying it may lead to limited comprehension and practice. This chapter explores and provides examples of skills in the application of evidence-based medicine, communication, teamwork, and professionalism that were presented in previous chapters. How can adherence to the best evidence in care be operationalized? What are the pros and cons of using patient portals to communicate with patients? Practically, how can culturally competent care that accommodates less-common belief systems or gender identities be provided? How do physicians, other health care professionals, and leaders balance competing interests such as finance and ethics? This chapter walks through examples of where institutions and individuals got it right or wrong to learn key lessons from the past.

Learning Objectives

1. Describe how an evidence-based, data-driven approach can frame and address systems-level challenges.
2. Recognize the advantages and pitfalls in using technology to enhance communication skills.
3. Outline the critical role of interprofessional and hidden teams in health care system function.
4. Explain how unprofessional behavior impacts health care system function.

I. Introduction: Foundational skills for health care delivery

Learning individual skills in team sports is critical as an athlete, but additional, more complex competencies are required to succeed as a team playing a game. Previous chapters have explored foundational information in patient safety, quality improvement, teamwork, leadership, clinical informatics, and other domains critical to health systems science.

This chapter reviews the skills needed by health care professionals to be successful across the health systems science domains and explores examples of successful and ineffective approaches to demonstrate the importance of these skills. These cross-cutting skills generalize across system-related and provider-based competencies and may merge both domains through broader system awareness.

Physicians and other health care professionals are rarely presented with simple, straightforward, unidimensional issues. More commonly, they must identify interwoven threads and apply multifaceted approaches to provide patient-centered, high-value care for individual patients and populations of patients. Although this chapter focuses on one or two key domains in each example, the ability to communicate well, engage with colleagues, and inspire others through example underlies the successful execution of each of these illustrations.

II. Evidence-based medicine

Evidence-based medicine is the practice of identifying and applying the best available scientific evidence to guide practice and reduce unnecessary variation in health care delivery. This practice is required to ensure that care is effective, one of the six dimensions of quality from the Institute of Medicine (renamed the National Academy of Medicine in July 2015) reviewed in Chapter 7. Unnecessary variation is the variation in medical care when there is identified evidence for best practice. Up to 30% to 40% of patients in the United States do not receive care consistent with current evidence, and 20% to 25% of care provided is unnecessary or potentially harmful.[1-3]

As a clinical example, the use of beta blockers for patients with congestive heart failure has been shown to reduce mortality and improve overall outcomes; however, studies have shown significant variability in their use depending on the clinical setting and variability in the dosing. Registry studies in the mid-2000s reported rates of beta blocker use in heart failure patients of 34% to 57% in primary care, 66% to 74% in heart failure specialty clinics, and exceeding 80% in clinics with process improvement efforts.[4-6] A study conducted by the Department of Medicine at Baylor University showed that 50% of heart failure patients received suboptimal doses of beta blockers at discharge and up to 2 years later.[7] As discussed in previous chapters, unnecessary practice variation in care delivery is a common cause of unintended patient harm, reduced efficiency, suboptimal treatment effectiveness, and high costs of care.

Effective implementation of best evidence in daily practice remains a major challenge, with only 14% of published knowledge widely incorporated into daily practice.[8-10] Numerous barriers hamper successful implementation, including (1) poor generalizability of the evidence to the real world since most studies are conducted in academic medical settings, (2) lack of systems designed to support best practice, (3) complexity of the intervention or new practice, (4) lack of readiness for adoption of change, and (5) underuse of effective strategies, approaches, and tools to facilitate change, such as behavioral economics, change management, Lean, Six Sigma, and implementation science tools. In order to improve the adoption and implementation of best evidence into daily practice, health care delivery systems can deploy several strategies, including practice guidelines, evidence-based pathways, and drug formularies.

A. Clinical practice guidelines and clinical pathways

Since the 1990s, clinical practice guidelines have been developed and published to enhance the adoption of best evidence in clinical practice. Clinical practice guidelines, when consistently adopted, may enhance the practice of medicine by helping to reduce inappropriate practice variation and to improve the quality and safety of health care.[11] Guidelines are typically published by large national networks, professional societies, and government agencies; therefore their recommendations are based on consensus, include multiple possible evidence-based options, and are not localized to a specific

practice or health care delivery system.

Clinical pathways are standardized, evidence-based clinical decision tools developed to guide practice at the local level. They are integrated management plans that provide the sequence and timing of specific clinical actions aimed to achieve specific clinical goals. Clinical pathways aim to standardize clinical processes in order to improve clinical effectiveness and efficiency. Therefore they are tools used by physicians and other health care professionals to treat patients with specific diagnoses or conditions according to evidence-based medicine. They are also used by health care teams and practice leaders to identify, define, and implement the best process for their organization. Clinical pathways may help health care systems reduce variation in clinical performance, identify patients who are eligible for clinical trials, improve the efficiency of care delivery, improve the quality and outcomes of patient care, improve the safety of care delivery, and reduce the costs of care.

In order to optimize the successful implementation of and compliance with clinical pathways, a health care system should incorporate the pathways into the routine workflow of its clinicians and, preferably, simplify the use of the pathways by integrating them into the electronic health record (EHR). Pathways cannot be followed in 100% of cases because a clinician needs to personalize the therapy by taking into account the patient's preferences, comorbidities, and the acuity of the patient's presentation. Therefore pathways become a tool to balance the need to reduce variation in practice among clinicians while allowing for personalization of therapy. It is generally accepted that pathways apply to 80% of cases, and personalization of the pathway is needed 20% of the time. It is essential that the personalization be based on the individual patient rather than the personal preferences and biases of clinicians. Cost and resource savings derived from the reduction of unnecessary variation can become assets that can be applied to the provision of care for the outlying 20% of patients. Pathways will not capture the uniqueness of all patients, but, for example, reducing hospitalizations for average-risk patients with community-acquired pneumonia will make beds available for those patients the physician still determines need admission due to factors not accounted for by the pathways.

Since clinical guidelines and pathways are developed by a consensus on best evidence, they are inherently at risk of biases, and they have the potential to be manipulated by the sponsors of the studies generating the evidence. In addition, some argue that evidence-based medicine has failed as a model to address the problems it was designed to solve, such as bias in practice and the influence of vested interests. Others argue that evidence-based medicine needs to go back to its roots, and there are several campaigns attempting to redirect it to its founding principles. One of these principles is to use evidence as support for shared decision making between patients and their clinicians and to develop personalized unbiased expert judgment rather than to use evidence to generate mechanical and algorithmic rules that clinicians must follow. In an attempt to improve the quality of evidence-based medicine and clinical guidelines, the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) Working Group developed the Evidence-to-Decision (EtD) Framework.[12] This approach can help clinical guideline panels in making decisions that are

transparent and highlight the strength of their recommendations. The justifications for the decision are based on the criteria used in their assessment. Therefore the clinicians using these clinical guidelines can then personalize their decision to the specific situation of a patient because of the transparency of the justification and the criteria taken into consideration (Table 15.1).[13]

TABLE 15.1

Criteria for Clinical Recommendations From a Population and an Individual Patient Perspective

Population Perspective	Individual Patient Perspective
Is the problem a priority (from a population perspective)?	Is the problem a priority (from the perspective of individual patients)?
How substantial are the desirable anticipated effects?	
How substantial are the undesirable anticipated effects?	
What is the overall certainty of the evidence of effects?	
Is there important uncertainty about or variability in how much people value the main outcomes?	
Does the balance between desirable and undesirable effects favor the intervention or the comparison?	
How large are the resource requirements (costs)?	
What is the certainty of the evidence of resource requirements (costs)?	Does the cost-effectiveness of the intervention (the out-of-pocket cost relative to the net desirable effect) favor the intervention or the comparison?
Does the cost-effectiveness of the intervention favor the intervention or the comparison?	
What would be the impact on health equity?	
Is the intervention acceptable to key stakeholders?	Is the intervention acceptable to patients, their caregivers, and health care providers?
Is the intervention feasible to implement?	Is the intervention feasible for patients, their caregivers, and health care providers?

Reprinted with permission from Alonso-Coello P, Oxman AD, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. *BMJ.* 2016;353:i2089.

Adult oncology specialty practice in the United States provides a successful example of development and utilization of practice guidelines as well as standardized clinical pathways in three ways: (1) guiding clinical decision making and facilitating insurance prior authorizations and pay-for-performance programs, (2) defining quality care and facilitating external quality monitoring, and (3) improving the quality of cancer care (efficiency and effectiveness) through implementation of clinical pathways through an EHR.

Despite their effectiveness and use for value-based care, oncology guidelines and pathways could potentially limit patient-centered care by limiting patient choice, hindering access to innovative treatments, and interfering with shared decision making. To that effect, the Turning the Tide Against Cancer Initiative recommends placing the patient at the center of value-based care and pathways in oncology by convening an

independent third party to accredit the pathways and by engaging the oncology patient community up front in the development and adoption of the pathways.[14]

1. Guiding clinical decision making and facilitating insurance prior authorizations and pay-for-performance programs

The National Comprehensive Cancer Network (NCCN) is an alliance of 26 of the world's leading cancer centers dedicated to improving the quality and effectiveness of care provided to patients with cancer.[15] The NCCN has developed guidelines for treatment of 35 major cancers as well as for supportive care and cancer screening in order to help guide decision making in oncology. Because these guidelines are a consensus at a national level, the majority of the recommendations issued in the NCCN guidelines are developed from lower levels of evidence but with uniform expert opinion. Nevertheless, NCCN guidelines are the most comprehensive and widely used oncology standard in clinical practice in the world. These guidelines are accepted by the Centers for Medicare & Medicaid Services and most private insurance companies and are used to facilitate prior authorizations for diagnostic tests and cancer therapy. These guidelines are also under consideration to be used as the reference for **pay-for-performance** and value-based care programs by third-party payers.

2. Defining quality care and facilitating external quality monitoring

The American Society of Clinical Oncology developed the Quality Oncology Practice Initiative (QOPI) in 2006 as a voluntary quality reporting program. The QOPI assesses the quality of cancer care by measuring adherence to evidence- and consensus-based **process measures**.[16] QOPI measures are aimed at supporting an environment for practice improvement and chemotherapy safety. The QOPI has demonstrated mixed results regarding compliance with guidelines. For measures regarding chemotherapy where evidence is widely accepted, the QOPI has identified minimal gaps in care. For other measures that reflect adoption of more recently published high-level evidence (e.g., testing for mutations in intracellular molecular targets, such as the proto-oncogene *KRAS,* that can impact treatment decisions for patients with metastatic colon cancer), the QOPI identified initial gaps in care that have been reduced over the course of a few years. In other QOPI measures, a wide gap and lack of improvement have been observed. Such challenging measures include psychosocial distress assessment, smoking cessation counseling, fertility preservation, and chemotherapy treatment summary.

3. Improving the quality of cancer care (efficiency and effectiveness) through implementation of clinical pathways through an electronic health record

In 2012, Mount Sinai Medical Center in New York implemented the chemotherapy module of their EHR.[17] In addition to the usual goals of implementing an EHR, such as increased legibility, record accessibility, and a more efficient order entry system, they aimed to increase the use of evidence-based chemotherapy regimens and supportive

care medications. Their primary goals were to reduce errors, improve practice efficiency, reduce the cost of care, and improve adherence with evidence-based practice. To accomplish these goals, they created an interprofessional chemotherapy council that reviewed and validated 600 evidence-based protocols that were integrated into standardized pathways. They also developed an electronic tool to track practice variation regarding the protocols, which allowed them to monitor compliance, improve their practice, and improve the protocols. The implementation of these standardized protocols allowed them to achieve 86% compliance with evidence-based practice, improve appropriate antiemetic use by 20%, and increase their infusion volume without compromising patient wait times or patient safety.

B. Formularies

A formulary is a continually updated list of medications and related information representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication use policies, important ancillary drug information, decision support tools, and organizational guidelines.

A **formulary system** is the ongoing process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population. Formulary systems are used in many different settings, including hospitals, acute care facilities, home care settings, and long-term care facilities, as well as by payers such as Medicare, Medicaid, insurance companies, and managed care organizations.

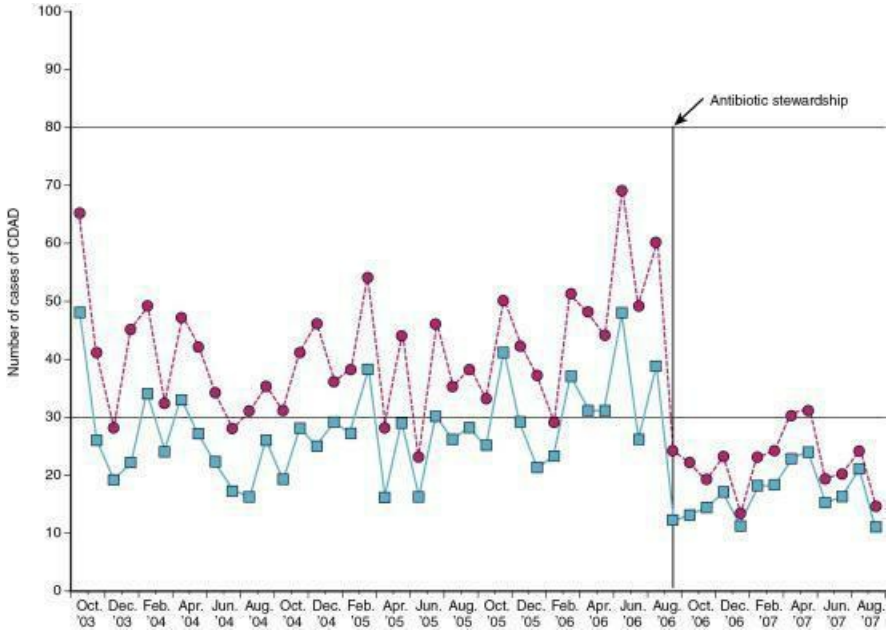
Formulary systems are considered an essential tool for health care organizations. Formularies have grown from simple drug lists to comprehensive systems of medication use policies intended to ensure safe, appropriate, and cost-effective use of pharmaceuticals in patient care.

The pharmacy and therapeutics (P&T) committee at each health care institution is responsible for managing the formulary system. It is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication use process. The P&T committee should be responsible for overseeing policies and procedures related to all aspects of medication use within an institution. Other responsibilities of the P&T committee include evaluation of medication use, adverse drug event monitoring and reporting, medication error prevention, and development of clinical care plans and guidelines. P&T decisions should be evidence based through unbiased reviews of the literature and address conflict of interest in the decision-making process. In addition, the P&T committee should systematically address patient safety in its decision-making process by taking into consideration the potential for medication errors related to ordering, sound-alike or look-alike drug names, and dosing, storage, preparation, and administration of medications. The P&T committee should consistently monitor medication errors and near misses and make

recommendations to prevent future events by ensuring that policies address the potential risks or by conducting improvement projects to reduce these risks.

Antimicrobial stewardship is one of the activities conducted and monitored by the formulary system[18] and used to improve care delivery (decreasing unnecessary variation and improving safety). Antimicrobial stewardship is a method by which health care institutions manage the appropriate selection, dosing, route, and duration of antimicrobial therapy. It is primarily aimed at improving quality of care and patient safety by optimizing clinical outcomes while minimizing the unintended consequences of antimicrobial use, including the emergence of resistance and selection of pathogenic organisms, such as *Clostridioides* (formerly *Clostridium*) *difficile. C. difficile* infection rates, disease severity, and associated mortality rates are rising amid growing concern for rising treatment failure rates and emergence of more virulent strains. According to the Centers for Disease Control and Prevention, *C. difficile* was estimated to cause almost 500,000 infections in 2011, and 29,000 patients with *C. difficile* infection died within 30 days of the initial diagnosis. The associated economic burden is also significant. Nosocomial *C. difficile* infections increase the cost of otherwise matched hospitalizations by fourfold, translating to a cost reported as up to $4.8 billion per year in the United States.

Antibiotic use is a major risk factor for the development of *C. difficile* infection. Antimicrobial stewardship programs have been successfully used as a method to regulate antibiotic use and reduce the rate of these infections. For example, the Michael E. DeBakey Veterans Affairs Medical Center and the Department of Medicine at the Baylor College of Medicine have reduced the rate of *C. difficile*–associated disease (CDAD) by nearly 50% through the implementation of an antibiotic stewardship program (Fig. 15.1).[19] In their 550-bed hospital, the rate of CDAD remained constantly elevated despite multiple interventions such as hand hygiene and isolation procedures. Therefore after 3 years of unsuccessful interventions, they decided to implement an antibiotic stewardship program. Under this program, prescriptions for most parenteral antibiotics required approval by an infectious-disease physician or clinical pharmacist. The program included a list of acceptable antibiotics that did not require prior approval; daytime orders for all other antibiotics outside the list were honored only if approved. Overnight orders for formulary antibiotics were honored until the following day, when the pharmacist and infectious-disease specialist reviewed them, either approving the order or making other recommendations. Implementation of the antibiotics stewardship program was associated with a reduction in the rate of all cases of CDAD from a baseline of 3.3 cases per 1000 bed-days to 1.7 cases per 1000 bed-days during the ensuing 12 months, a 47.2% decrease with a P value of 0.001 by t test.



• FIG. 15.1 Incidence of *Clostridium* (now *Clostridioides*) *difficile*–Associated Disease (CDAD), Before and After Implementation of the Antibiotic Stewardship Program. *Upper dashed line,* total number of cases of CDAD, as defined in the Centers for Disease Control and Prevention criteria during the years under study; *lower solid line,* number of first-time cases, as determined from the EHR. *Source:* (From Nuila F, Cadle RM, Logan N, Musher DM; Members of the Infectious Disease Section of the Michael E DeBakey VA Medical Center. Antibiotic stewardship and *Clostridium difficile*–associated disease. *Infect Control Hosp.* 2008;29[11]:1096-1097.)

III. Communication skills via new technology

The physician-patient relationship has evolved over decades from a paternalistic relationship where the physician is the primary decision maker to a partnership where the patient is an autonomous and competent partner in the decision-making process. In order to be an active partner in this relationship, the patient must be empowered and well informed. Communication during a clinic visit is the foundation of the relationship between the patient and the physician, but there is often information (such as a laboratory test result) that is not available and therefore cannot be exchanged during the clinic visit. In addition, patient-centered care and efforts to provide high-value care and advance the **Triple Aim** require a mechanism for patients to interact with care teams with concerns or questions that do not require face-to-face visits. A patient-centered communication system also ensures patients access to their medical records. Traditionally, health care systems have relied on phone communication or providing paper copies of records by mail, by fax, or in person. In order to more actively and efficiently engage patients in their own care and improve patient satisfaction, health care delivery systems may leverage information technology by designing and implementing **electronic patient portals** and engaging in the use of social media. The federal government has worked to ensure implementation of these communication mechanisms by auditing them as part of their assessment of adherence to the meaningful use standards of the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was passed as part of the American Recovery and Reinvestment Act of 2009. In April 2018, the Centers for Medicare & Medicaid Services renamed the EHR Incentive Programs as the Promoting Interoperability Programs. The intent of this change was to move the programs beyond existing meaningful use requirements to an increased focus on interoperability and improving patient access to health information.[20]

If one imagines a simple goal such as increasing a practice's footprint within a geographic area, it quickly becomes apparent that there are a myriad of elements to consider. Setting aside the business assessments that would be important to any expansion, a robust understanding of the community's characteristics, medical practices, and beliefs would be an asset to help design an ideal communication system. If striving to improve services to elderly nursing-home residents, a communication strategy built on social media platforms would likely be ineffective, and similarly, a preventive health program for teens that relies on traditional mail would be suboptimal.

A. Electronic patient portals

Electronic patient portals are electronic communication platforms that provide patients with different degrees of access to their health information stored in an EHR and managed by the health care system. Patients are granted access to the EHR via the portal to select clinical information such as laboratory test results or treatment plan summaries. In addition, electronic patient portals may provide patients the ability to

electronically request medication refills, schedule appointments, and communicate through a secure messaging system with their care teams. Health care professionals must evaluate thoughtfully how these messages are received and responded to in a timely manner. Initiating communication with patients through this means creates an expectation that the provider will receive it and incorporate transmitted information into the patient's care. Critical information that is not attended to due to a staff member's absence from the office or being tied up in other patient care or administrative activities can result in patient harm. Well-defined and efficient processes need to be established to receive, review, and respond to patient portal requests in a timely manner. The processes must include clearly defined roles, criteria for nurse and physician review, protocol for internal communication among team members, and timely communication back to patients.

In management of chronic diseases such as diabetes and congestive heart failure, electronic patient portals have been reported to enhance physician-patient communication and improve patient satisfaction, compliance with prescribed treatments, disease management, and patient outcomes.[21,22] In addition, electronic patient portals have the potential to improve efficiency of care, reduce the frequency of patient clinic visits, and reduce the cost of care. Additional possible benefits include improved coordination of care by allowing patients to monitor various processes, such as the accuracy of their listed medications.

Despite the positive impact of electronic patient portals, several challenges and barriers limit their effectiveness and widespread use. Not all patients are currently using electronic patient portals when available, possibly because of low computer literacy or low motivation among less-ill patients. There are also concerns about patients viewing new clinical information outside of the context of the complete clinical picture. Patients may experience confusion or distress when they view abnormal test results before a physician or other health care professional is able to explain the results. One solution to this challenge is to delay the release of the clinical information to patients until after it has been reviewed by the clinician or after the patient meets with the provider; however, this approach may prevent the patient from having timely access to the information. Another challenge is that the documents and information are presented in a medical clinician–centric rather than a patient-friendly language. Therefore the information presented in the electronic portals may not be understood by patients, which may limit the effectiveness of the communication. Additional limitations of electronic patient portals include the cost of technology, the security of the information, the liability of the providers, and the potential that the increased access to physicians will translate to increased nonreimbursed physician effort.

B. Social media

More than 80% of Americans seek health information online.[23] The adoption of social media, especially social networking, by health care systems and professionals may lead to a more patient-centered health care system and may enhance patient engagement, health information exchange, and the communication between patients, health care

providers (physicians, nurses, pharmacists), and health care administrators. Social media is used in different ways and for multiple purposes by the health care system; the following are three examples:

1. Health care systems are utilizing social media to engage their patients and the community at large in customer service, promotion and advertisement, and provision of news and information and fund-raising.
2. Physicians and health care professionals may use social media for professional purposes: to network with other colleagues, seek expert advice, listen to experts, and research new medical developments. In addition to professional development, physicians use social media to interact with patients and support groups around patient education, health monitoring, health behavior, and medication adherence.
3. Patients and support groups are the most frequent users of social media. They use social media for a wide variety of reasons that include education, networking, seeking support, finding information, access to care, and searching for research participation. In addition, patients are utilizing social media and online applications to monitor their health, track their progress, and set health-related goals. Social media may be beneficial for patients with chronic diseases, cancer, complex care needs, and rare diseases as well as aid patients with general wellness, prevention, and lifestyle modification. There is more evidence that the use of Internet-based interventions may have a positive impact on weight loss, tobacco cessation, and physical activity.

Although the use of social media has many promising benefits, numerous challenges remain. Health care systems, health care professionals, and patients are faced with challenges regarding confidentiality, privacy, personal identity, professionalism, and information inaccuracy.

Physicians and health care professionals need to ensure a strict and clear separation between their personal and professional presence on social media. Interactions between patients and their physicians online present challenges given the lack of regulation that takes into account professional and ethical considerations. Privacy of patients and physicians may be compromised during these online interactions.

Patients also face the threat of finding false information that may lead to confusion, poorly informed decisions, or harm. In addition, sharing of sensitive private information online may have negative repercussions on patients in regard to their employment or their insurance cost and coverage.

Social media is a promising platform for more effectively engaging patients, the community, health care professionals, and health care systems in improving health and the quality of care. However, these entities need to develop methods to regulate the use of social media taking into consideration privacy, professional, and ethical concerns.

C. Telemedicine

There is a vast mismatch between the geographic distribution of physicians and health

care professionals and those in need of care in the United States. As an oversimplification, physicians tend to cluster in large cities, leaving rural Americans with less access to care. Even when primary care physicians are available, specialists may be in short supply. Telemedicine is emerging as one strategy to bridge this gap. Utilizing technology that has supported field-deployed troops and individuals at remote work outposts, leaders in health care are establishing systems to provide medical care through video conferencing. Connected devices can transmit results of point-of-care laboratory testing, electrocardiograms, or some limited physical examination findings (e.g., otoscopy, blood pressure, oximetry). Patients can transmit reports from continuous monitoring devices such as glucose monitors and heart rhythm event monitors.

Challenges to the successful use of telemedicine are abundant, including concerns about the limitations in assessing patients, privacy and security of communication, accreditation, licensure, and billing and insurance reimbursement, to name a few. Potential benefits in addition to access to physicians and other health care professionals are significant, including improved access for homebound patients, decreased costs of travel, and convenience. Some specialties, such as psychiatry, may be better suited to this modality due to decreased reliance on physical examinations.

IV. Teamwork

Delivering care to a patient requires a complex network of professionals: physicians, other health care professionals, and supporting staff who are semiautonomous and interdependent. At a basic level, a simple clinic visit requires the coordinated work of a receptionist, a medical assistant, a nurse, and a physician, and possibly a pharmacist, a physician assistant, and a social worker. However, the visit would not be possible without the work of environmental services, maintenance personnel, supply delivery personnel, and a clinic manager. The level of complexity increases when a patient has to navigate multiple settings and interact with multiple teams. For example, if a medication is prescribed in clinic, the patient will have to interact with the dispensing pharmacy, which has its own complex network of individuals to deliver the medication. An even more complex situation occurs if a patient is referred to a consultant clinic, and then asked to undergo an imaging study and obtain blood studies. The highest complexity occurs when patients are admitted to the hospital from clinic or the emergency department and undergo diagnostic tests and therapeutic interventions and then are discharged to another setting such as home or a subacute facility for convalescence. The physician and the nurse play a central role in the health care delivery process; however, they are only a part of the system.

Unless the members of the delivery network are able to function and interrelate to each other as a functional team, the patient will suffer and health care delivery will be suboptimal. Health care professionals working in highly functional teams tend to have higher job satisfaction and less burnout. Health care errors, unintentional patient harm, and health care inefficiencies are often attributed to aspects of team dysfunction such as poor coordination of care, poor communication among team members, and lack of mutual respect. On the other hand, health care delivery systems can design teams and workflows to facilitate the optimal interactions among the entities within the network and improve the care for patients.

A. Impact on quality of care and health care professional satisfaction

A study by Baggs and colleagues examined provider self-reports of collaboration at three intensive care unit (ICU) sites and found that both medical nurse reports of collaboration and unit-level reports of collaboration were positively associated with patient outcomes.[24] Shanafelt and associates showed that the likelihood of reporting a medical error increased with higher reported physician burnout measures.[25] Measures of burnout that correlated with increased reporting were depersonalization and emotional exhaustion. Shortell and coworkers collected data from 17,440 patients, all nurses on all shifts, physicians, residents, and ward clerks/secretaries across 42 ICUs and found that caregiver interaction (culture, leadership, coordination, communication, and conflict management) was significantly correlated with lower risk-adjusted length of stay, higher evaluated technical quality of care, and greater evaluated ability to meet

family member needs.[26] Benzer and colleagues correlated patient data from 223 primary care clinics with provider organizational climate survey data and reported relational climate as a strong predictor of high-quality diabetes care.[27] Leykum and coworkers found significant associations between reciprocal learning (intrateam learning and problem solving that occurs through conversation and reflection among team members) and chronic disease care in 40 small primary care practices.[28] Gittell and colleagues found associations between **relational coordination** (defined as coordination among team members that occurs through frequent, high-quality communication supported by relationships based on shared goals, shared knowledge, and mutual respect) and improved quality of care, reduced postoperative pain, and decreased length of hospital stay in a nine-hospital study of orthopedic patients.[29]

Risser and colleagues report the findings of a retrospective study of claims files, using a convenience sample drawn from eight participating hospitals. Fifty-four cases were reviewed by physician-nurse teamwork-trained pairs to identify whether the absence of teamwork contributed to the medical error in each case.[30] The pairs judged over one-half of the deaths in the malpractice cases to be avoidable under conditions of better teamwork. Donchin and coworkers studied the rate of errors in a medical-surgical ICU of a university hospital over a 4-month period and concluded that a significant number of the errors could be attributed to physician-nurse communication.[31]

Aiken and colleagues compared risk-adjusted mortality rates for Medicare beneficiaries cared for at 39 hospitals characterized by nurses as having a positive work environment (defined as level of status, autonomy, and relationships with physicians).[32] They found a 5% lower risk-adjusted mortality rate for these hospitals when compared with the 195 hospitals selected as matched controls. Uhlig and coworkers studied the introduction of a new "interdisciplinary care team" model that included a collaborative communication protocol and daily team rounds at each patient's bedside and reported a 56% reduction in risk-adjusted mortality for cardiac surgery patients.[33] Neily and colleagues analyzed Veterans Health Administration (VHA) quality improvement data and structured interviews to determine whether correlations existed between a VHA team training program and surgical mortality; they found a 50% greater decline in the risk-adjusted surgical mortality rate in the training group when compared to the nontraining group.[34] Kim and coworkers conducted a population-based retrospective cohort study of statewide hospital organizational survey and hospital discharge data in 112 acute care hospitals.[35] They found (after adjusting for patient and hospital characteristics) that daily rounds by an interprofessional team were associated with significant reductions in the odds of death.

In addition to the compelling link between high-functioning teams and quality of care, numerous studies link collaborative workplace culture with increased job satisfaction, lower levels of burnout, and decreased turnover. Baggs and colleagues found that higher levels of physician-nurse collaboration in decision making around patient care correlated with increased nurse satisfaction.[36] Vahey and colleagues conducted cross-sectional surveys of 820 nurses and 6212 patients from 40 units in 20 urban hospitals across the United States and found that nurses reporting a positive

working environment (including good relationships between physicians and nurses) also reported significantly lower burnout.[37] Shortell and coworkers collected data from 42 ICUs and found significant associations between caregiver interaction and lower nurse turnover.[26]

B. Creating and sustaining high-functioning teams

As demonstrated in the studies discussed earlier, teamwork significantly influences patient outcomes, including quality, safety, and mortality, as well as efficiency of care delivery and health care professional job satisfaction. As health care organizations seek to improve care, reduce cost, and reduce provider burnout and turnover (also associated with decreased efficiency), development of effective care teams is critical. Yet while the evidence linking teamwork to key outcomes is robust, the development of collaborative, high-functioning interprofessional teams in health care remains a complex and challenging task for many reasons, including differing perceptions of collaboration; the need for shared and clear goals, communication, and tasks; and barriers to team collaboration.

1. Differing perceptions of collaboration

Makary and colleagues surveyed operating room personnel in 60 hospitals using the Safety Attitudes Questionnaire and found that ratings of teamwork differed substantially by operating room caregiver type, with physicians rating the teamwork of others as "high" or "very high" and nurses rating the teamwork as "mediocre."[38] Thomas and coworkers surveyed physicians and nurses working in ICUs in two teaching and four nonteaching hospitals and found that 33% of nurses rated the quality of collaboration and communication with the physicians as high or very high, in contrast to the 73% of physicians who rated collaboration and communication with nurses as high or very high.[39] O'Leary and colleagues surveyed nurses, primary care hospital physicians, and medical subspecialty consultants on four general medical units on the quality of communication and collaboration with their own and other disciplines.[40] Survey results indicated that the majority of physicians rated collaboration with nurses as high or very high, but a minority of nurses rated collaboration with physicians as high or very high.

2. Factors that influence the quality of team collaboration

Effective **interdisciplinary teams** are composed of members with particular skills and capacities who intentionally and successfully collaborate to accomplish well-defined, shared goals, and are supported by facilitating organizational structures and administrative policies. The Pew-Fetzer Task Force report *Health Professions Education and Relationship-Centered Care* outlines four core capacities that are essential for the development of effective interdisciplinary teams: (1) self-awareness, (2) knowledge of other health professions, (3) team-building abilities, and (4) understanding of team dynamics.[41] Lanham and colleagues analyzed data sets from four National Institutes of

Health studies of primary care practices and identified seven key relationship characteristics that together are associated with high-performing teams: (1) trust, (2) openness, (3) performing individual tasks with an understanding as to how they relate to the larger group tasks, (4) respectful interaction, (5) appreciation of diversity of perspectives, (6) social and task relatedness, and (7) rich and lean communication.[42]

San Martín-Rodríguez and colleagues explored links between factors influencing collaboration within health care teams and distinguished three major categories of determinants that influence successful collaboration: (1) macrostructural determinants or determinants outside the organization, (2) determinants within the organization, and (3) interpersonal determinants.[43] Determinants outside the organization include social determinants, such as power differences among professionals; cultural systems that may foster individualism; professional systems that may foster autonomy; and educational systems that may or may not educate professionals with knowledge of the values and perspectives of other professions. Determinants within the organization include organizational structures and hierarchies; organizational values such as openness, fairness, and interdependence; administrative support that encourages and rewards collaborative practice; and team resources such and time and space to meet.

Interpersonal determinants are those that individual health care professionals and trainees must learn to effectively contribute to high-functioning teams. These attitudes and skills include a willingness to collaborate, ability to build trust, skills in communication, and knowledge that enables mutual respect among team members.

Gittell has identified a specific construct of team interactions that they term *relational coordination.*[44] The theory of relational coordination asserts that work involving multiple roles and tasks is most effectively carried out through high-quality communication and high-quality relationships that support each other and together enable high-quality coordination of work. The communication domain in this construct includes four dimensions: accuracy, timeliness, frequency, and problem solving. The relational domain includes the three dimensions of shared goals, shared knowledge, and mutual respect. Gittell's research has found associations between relational coordination and improved quality of care, reduced postoperative pain,[29] reduced length of stay, lower total cost of hospitalization, better-quality outcomes for medical patients,[45] increased quality of life for long-term care residents, and improved job satisfaction for physicians and other health care professionals.[46] Gittell also found important correlations related to role definition, including associations between boundary spanning (the ability to perceive flexible job boundaries and crossover between roles to achieve shared goals), shared knowledge (an understanding of the roles of others and how those roles relate to one's own), and relational coordination.[47]

Research on the efficacy of interdisciplinary teams has identified several barriers to health care teamwork. In the primary care setting, Shaw and coworkers interviewed members of the interdisciplinary teams in 21 practices and found that lack of shared or identifiable goals, hierarchical structures, and poor team communication were impediments to effective teamwork.[48] Wittenberg-Lyles and Oliver conducted ethnographic observation of interdisciplinary team meetings for five teams in a

Midwest hospice and found that the introduction of psychosocial information by the case managers created tension in the team and clearly deviated from the standard biomedical format.[49] Thomas and colleagues surveyed physicians and nurses working in ICUs in six hospitals and found that relative to physicians, nurses reported that it is difficult to speak up, disagreements are not appropriately resolved, more input into decision making is needed, and nurse input is not well received.[39] Weber and coworkers analyzed taped recordings of physician and nurse interactions on ward rounds in two general internal medicine wards and found that they were physician-led and physician-centric, while nurses did not contribute substantially to what was said.[50]

3. Knowledge of other health professions

All of the models of effective teamwork outlined earlier identify knowledge, appreciation, or both, of the roles, tasks, or perspectives of other team members as factors influencing effective teamwork. Yet many health care professionals have little knowledge of the education, roles, or practices of other health care professionals. Health professions education is commonly siloed into separate schools or training programs with little shared clinical or content education and differing professional languages. Processes that enable team members to better understand the unique contributions of each team member to the shared work increase shared knowledge and mutual respect and improve work processes as each provider develops an enhanced understanding of how his or her own work activities fit with those of his or her colleagues.

4. Systems that support teams

Team-supporting systems help teams to clearly understand their shared mission and goals, which furthers the abilities of team members to carry out their individual work within the larger perspective of the team. These systems promote a culture of collaboration and coordination rather than hierarchy and an orientation toward group problem solving. A culture explicitly oriented to promote and reward team success enhances the motivation for members to share responsibility, maintain an openness to others' ideas, trust, empathize, and act generously. Systems that recognize that the strength of the group is greater than any one individual actively encourage multiple perspectives and foster appreciation of diversity. Systems that value interprofessional communication will foster opportunities to bring diverse team members together for collaboration and communication. Effective health care teams require both individual members who possess key teamwork capacities and a systems infrastructure that facilitates effective team development and interactions.

Health care systems have designed and developed health care teams and supporting systems to improve the quality, safety, and efficiency of the care they provide. The development of **accountable care teams**, **rapid response systems**, and EHRs are examples of applications of these concepts.

Accountable care teams are a model of collaborative inpatient unit-based practice.[51] Each team is composed of an interprofessional group of physicians and other health care professionals who assume accountability for the clinical, service, and financial

outcomes of the patients on their respective inpatient unit. This model has been developed and implemented since 2012 at Indiana University Health Academic Health Center in Indianapolis. The model is founded on three principles: enhancing interprofessional collaboration, enabling data-driven decisions, and providing accountable leadership. The implementation of the model was based on eight interventions rooted in the principles of the accountable care teams.

In order to enhance interprofessional collaboration, this health center implemented geographic cohorting of patients, physicians, and other health care professionals. Before the model was implemented, the **hospitalists** covered patients on multiple different units and worked independently of the nurses. In the accountable care team model, each hospitalist is localized to one specific unit and provides care only to patients on that unit. An interdisciplinary team including a **case manager**, clinical nurse specialist, pharmacist, nutritionist, and social worker are also assigned to one specific unit. Learners (residents as well as pharmacy and medical students) are embedded in the team. The unit-based hospitalist collaborates with the **nurse manager**, and they are jointly accountable for the outcomes of patients on their unit.

Interprofessional collaboration also includes bedside collaborative rounding. Unit-based physicians round on their patients with the bedside nurse guided by a customizable script. It also involves a daily huddle. The hospitalist, learners, and the interdisciplinary team for the unit meet each weekday to discuss each patient's quality of care, discharge planning, and needs for a safe transition out of the hospital. Additionally, each unit has a whiteboard at the nursing station that captures the components of the daily huddle discussion pertaining to quality of care, discharge planning, and safe transition. Guidelines delineating responsibilities for physicians of each specialty were developed in order to facilitate the comanagement of patients between the unit-based hospitalist and the surgical or medical specialists.

Data-driven decisions were enabled through a monthly review of unit-level data. A unit-specific data dashboard was developed to track key metrics, including quality and safety metrics, length of stay, patient satisfaction scores, readmission rates, and costs. The data are reviewed monthly in interdisciplinary meetings, and improvement plans are developed in order to meet the goals. The unit's nurse manager and physician leader also conduct patient rounds weekly focusing on patients' experiences and opportunities for improvement.

Accountable leadership is provided by designating unit-based physician leaders who are committed to serve each unit for at least 1 year as a resource for both medical and operational problem solving. The leader collaborates closely with the unit's nurse manager, and they are both responsible for their unit's quality, efficiency, and patient experience outcome trends.

Within 12 months of the implementation of the accountable care team model at the Indiana University Health Academic Health Center, the units adopting all components of the intervention were able to improve the quality and safety of care provided and the patient and provider satisfaction as well as the efficiency of the care delivery. These units were able to achieve a statistically significant reduction in their patients' length of stay and their variable direct cost adjusted for severity of illness. The rate of

readmission remained stable overall. The units adopting the model had fewer safety events and less unintended patient harm. Patient satisfaction improved with geographic cohorting of patients and physicians. Team members reported that they were more engaged and satisfied with their job after implementation of the model.

Rapid response systems are interprofessional teams that are developed to intervene when patients show early signs of clinical deterioration on general hospital wards in order to reduce the rate of "failure to rescue," the incidence of cardiopulmonary arrest, and hospital mortality.[52,53] "Failure to rescue" is a failure to react promptly or adequately escalate care when a patient's condition is unexpectedly deteriorating. Patients commonly show signs and symptoms of deterioration for hours before cardiopulmonary arrest. When these arrests occur outside of the ICU setting, the outcomes are poor, with only 15% of patients surviving the event. Cardiopulmonary arrests have a common set of antecedent signs and symptoms; however, they are often unrecognized by health care professionals due to infrequent assessments of vital signs, lack of clearly defined triggers, individual and subjective interpretation of clinical condition by the clinical staff, delays in physician notification, a long chain of command for escalation (nurse to charge nurse, to intern, resident, fellow, and then to attending physician), unavailability of the nurse or physician because he or she is busy with other tasks, failure to attend to and assess the patient's deteriorating condition, suboptimal response to the urgency of the symptoms, and failure to seek help or advice. Overcoming these barriers to an effective and timely recognition and response to a clinical deterioration may reduce the chance of a cardiopulmonary arrest and death.

Rapid response teams generally have the following four components:

1. The **afferent limb** is designed for identifying a patient deterioration and activating the rapid response team using predefined trigger criteria. These criteria usually include vital signs and general concern expressed by a clinician or family member. The afferent limb empowers bedside clinicians to trigger the response team, bypassing the traditional hierarchy and expeditiously delivering the necessary expertise and equipment to the bedside.
2. The **efferent limb** is the rapid response team. The response team is most frequently composed of ICU-trained personnel and equipment. Team composition varies based on the local needs. Most rapid response teams do not include a physician and are usually led by advanced practice providers, nurses, or respiratory therapists.
3. The quality improvement component provides a feedback loop by collecting and analyzing data from events to guide improvement of prevention and response.
4. The administrative or governance component is in charge of coordinating resources, purchasing equipment, and coordinating the education of hospital staff regarding the rapid response process.

Rapid response systems were initially introduced in the 1990s in Australia. The Institute for Healthcare Improvement introduced the concept in the United States. Since then, these systems have been associated with improved outcomes such as reduced

anxiety among nursing staff, increased interdisciplinary teamwork, decreased cardiac arrests outside of ICUs, and a reduction in hospital mortality.

EHRs provide the ability to coordinate patient care among team members and across different teams, facilities, or health care settings. The electronic transfer of patient health information is especially important when information is needed quickly, for example when a patient presents at the emergency department or when the patient transitions from an inpatient to an outpatient setting. In addition, the electronic exchange of data is faster, more efficient, more complete, and more accurate than traditional written, faxed, or phone communications. Computerized provider order entry (CPOE) is the process by which a physician enters medical orders directly into an EHR and manages the results of these orders.[54,55] The Institute of Medicine (renamed the National Academy of Medicine in 2015) has identified the implementation of CPOE as an opportunity to improve medication safety, reduce ordering errors, and enhance compliance with guidelines, therefore improving patient safety. Sometimes the CPOE system is supported by a decision support system, making the system capable of alerting physicians about drug interactions, inappropriate dosages, and other drug-related problems. In addition, CPOE may reduce order duplication, reduce the time required to complete clinical tasks, and reduce the time that nurses spend on reviewing, verifying, and correcting clinical instructions.

Although CPOE may have significant positive impact on coordination of care and patient safety, if its implementation is not planned well, it may have negative impacts on clinical workflow and collaboration between physicians and nurses. The clinical workflow can be disrupted by the use of CPOE systems because of asynchronous communication among team members, problems with human-computer interactions, change in the sequence and dynamics of clinical activities, and reduced clinical situation awareness.

V. Professionalism

Medical professionalism has been defined by many individuals and organizations. One of the more widely used definitions was formulated by the Accreditation Council for Graduate Medical Education.[56] Professionalism is:

> a commitment to carrying out professional responsibilities and an adherence to ethical principles. Residents are expected to demonstrate: compassion, integrity, and respect for others; responsiveness to patient needs that supersedes self-interest; respect for patient privacy and autonomy; accountability to patients, society and the profession; and sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

Professionalism is a desired behavior of not only individual practitioners but also organizations that have been entrusted with the care of vulnerable individuals. There are many opportunities for tension between institutional goals and the ideals espoused earlier. Balancing the needs of the individual versus the needs of the system can be one of the most challenging tasks that health care professionals, including leaders, face. Maintaining appropriate oversight of professionals to ensure that their actions are in the best interests of patients is now an expectation of institutions and their leaders.

Extensive utilization of limited resources for the care of a single patient may make them unavailable for others. For example, when an extremely ill patient requires a high volume of platelet transfusions, how does one determine which of several other patients in need must be denied platelets for transfusion due to an inadequate supply? This also occurs at an institutional level. For example, a patient who remains hospitalized for social reasons, such as a homeless person who has no ability to receive necessary reliable care and is in need of parenteral antibiotics after discharge, blocks the bed's availability for other patients in need of acute hospitalization. Developing an infrastructure to support decision making that is based on medical need rather than bias is one of the ways that a system can enhance professionalism.

A. Balancing finance and ethics

While most health care clinics or hospitals are not-for-profit, they still must function as businesses. Leaders in these institutions are entrusted with "keeping the lights on" and are increasingly selected for their financial acumen. Reimbursement for delivered care is complex and ever-changing; operating margins (defined as the ratio of dollars remaining after costs and operating expenses have been paid) are shrinking, and expectations by patients and communities are high. In this complicated environment, where multiple stakeholders are impacted by each decision, it is particularly important to center decisions in a manner that reflects professionalism.

The operating margin determines the ability to pursue activities. This is often summarized as "no margin, no mission." For example, choosing to deliver a costly therapy that may benefit a small handful of patients has to be weighed against a less expensive treatment that may prevent disease for large numbers of patients. If the hospital is unable to contain operating expenses, there may not be money for either. Politically, selecting not to provide services on the basis of cost can be unpopular. These kinds of decisions might best be decided by society at large, but often this is not the case. Rather, insurance companies and health care organizations must craft decisions aided by published guidance from professional organizations and the judgment of their leaders. Because they answer to more than one constituency, executives rarely face simple choices. In a particular health care delivery situation, the ethical constructs of altruism, beneficence, nonmaleficence, truth-telling, and justice may come into conflict with the perceived best interests of the institution.

Creutzfeldt-Jakob disease (CJD) is a devastating prion disease affecting the brain. At present it is not treatable and is usually rapidly fatal. The infectious prions of CJD are not really destroyed by the techniques normally used to sterilize surgical equipment between patients. In order to minimize the risk for transmission from one individual to another, when the presence of CJD is suspected, protocols for diagnostic brain biopsies will use either disposable equipment or more expensive and prolonged sterilization. These cases are typically scheduled at the end of the surgical day to allow sufficient time for operating rooms to be intensively cleaned prior to their use for the next patient. Rarely, the diagnosis is an unexpected finding on pathologic specimens, and investigation determines that patients were treated with surgical instruments that were not adequately sterilized. This is described as an *iatrogenic exposure.* When this unexpected situation is uncovered, it may be days to weeks after the incident.

Hospital leaders are faced with a decision about disclosing CJD exposure to affected patients, potentially triggering emotional harm or expensive lawsuits. Some argue that since there is no intervention that can alter the patients' outcome, informing patients may trigger severe emotional trauma and may expose the hospital to financial harm from legal action. One published study interviewed 11 individuals who had been notified about being exposed to CJD. Using quantitative techniques, attitudes and responses to the disclosure were evaluated. There was no evidence of lasting psychological harm in this limited study. Most subjects reported that their anger and fear were short lived, and they coped by pushing the concern to the back of their minds. Adherence to prevent forward transmission was variable. "The two exceptions had been notified of surgical exposures after media reports: they questioned hospital practices and still felt angry."[57]

Although CJD exposure is a relatively rare and extremely serious exposure, there have been many other larger-scale examples of inadvertent exposure to harm, including inadequately cleaned endoscopic equipment and examples of errors (such as incorrect hormone receptor tests performed on breast cancer pathologic specimens) that have impacted large numbers of patients and likely caused some of them tangible harm.

In the event of such complex decision making, there is a risk that leaders will make choices based on their own self-interests. If a hospital suffers the financial and public

relations fallout from disclosing a large-scale medical error, it is common for leadership to be penalized, lose their jobs, or both. The VHA has formulated a process that may aid leaders. VHA directive 2008-002, "Matrix to Aid in Adverse Event Disclosure Decisions for Large Scale Events," outlines an inclusive process to identify and involve all stakeholders in decision making, using surrogate decision makers where necessary to stand in for the patients' best interests. Ethicists are part of the multidisciplinary advisory panel that uses a structured set of questions to examine the situation in as transparent, comprehensive, and fair way as possible.[58] A 2010 *New England Journal of Medicine* article evaluated this and other approaches to making such decisions.[59]

Unfortunately, this situation is not as rare as one would hope, with at least two widely publicized disclosures of CJD exposure in 2013 and 2014.[60,61] The leaders of Forsyth Hospital in North Carolina were praised for the forthright and compassionate way in which they handled this disclosure.[62] Although no organization wants to deal with the publicity, potential litigation, and harm to reputation that can follow acknowledgment of errors, there is the possibility that timely, accurate, and compassionate disclosure can enhance trust.

A culture of professionalism is essential to the delivery of high-value care. Aligning physician and organizational understanding and behavior is a critical step. Mission statements and codes of conduct have been used to formalize expectations, but cannot succeed unless they are universally applied and adherence to them is enforced equitably. Education and opportunities for professional development around this content are essential to creating a community that supports these goals.

Some organizations have developed programs that provide support for physicians who are challenged by adherence to these expectations. When remediation or disciplinary actions are applied inconsistently, they can undermine the establishment of a professional environment; when high-revenue generators are observed to be held to the same behavioral standards as other physicians, these guidelines reinforce professionalism. Ensuring equity in these matters falls to institutional leaders.

B. The disruptive physician

This chapter has discussed the importance of ensuring that organizations function in alignment with ethical and professional principles, as leaders' decisions can have a dramatic impact on the function of the system. Beyond their own clinical microsystem, an individual physician's behavior can significantly interfere with the system's delivery of safe, effective, compassionate, and cost-conscious care. There are many examples of the impact that criminal behavior can have on an institution, and physicians are not immune from the temptations that can lead to felonious acts. Physicians have access to information, drugs, and individuals in ways that can be abused for personal gain. In addition, physicians are humans and are subject to the same frailties as anyone else. Depression, anxiety disorders, and substance abuse by a physician can negatively impact the delivery of care. This section focuses on the "disruptive physician." There is some overlap with mental health and substance abuse, but the issue is much broader than mental health and substance abuse alone. Providers in other professions may

exhibit these behaviors, but given traditional hierarchical structures this is often most damaging when displayed by physicians. Unfortunately, many institutions have historically tolerated these actions in physicians, especially those seen as "rainmakers" (those who generate significant income).

There are many definitions of disruptive behavior by physicians, but they generally include elements of intimidation, outbursts (angry or threatening), passive behaviors of nonparticipation in activities that impact patient safety, and refusal to perform routine tasks. This may include things such as failure to complete charting, nonresponse to pages, or treating peers, patients, or staff with condescension. A survey by the American Association for Physician Leadership found that 38% of physicians surveyed believed that "physicians in my organization who generate high amounts of revenue are treated more leniently when it comes to behavior problems."[63] In the last several decades, it has been recognized that disruptive behavior impacts health care delivery and patient safety. The Joint Commission has begun to address this issue by requiring demonstrated compliance with standards to achieve accreditation. In 2008, they issued a Sentinel Alert Bulletin that explained the rationale for new leadership standards in two of its elements of performance (EPs)[64]:

> EP 4: The hospital/organization has a code of conduct that defines acceptable and disruptive and inappropriate behaviors.
> EP 5: Leaders create and implement a process for managing disruptive and inappropriate behaviors.

An important part of the impact of disruptive physicians was described by a survey on workplace intimidation conducted by the Institute for Safe Medication Practices. In this survey of 2095 hospital-based health care providers (1565 nurses, 354 pharmacists, 176 others), a direct connection between intimidating behavior and overriding patient safety practices was seen. Seventeen percent of respondents had felt pressured to accept a medication order despite concerns about its safety on at least three occasions in the previous year, 13% had refrained from contacting a specific prescriber to clarify the safety of an order on at least 10 occasions, and 7% said that in the previous year they had been involved in a medication error where intimidation played a part. Sixty-four percent of pharmacists and 34% of nurses reported that, during the past year, they had assumed that a medication order was correct and safe rather than interact with a particular prescriber.[65] Health care systems have an obligation to identify and solve the issue of disruptive physician behavior (Box 15.1).

• BOX 15.1

The Joint Commission's Recommended System Approach to Disruptive Behavior

1. Educate all team members—both physicians and nonphysician staff—on appropriate professional behavior defined by the organization's code of conduct. The code and education should emphasize respect. Include training in basic

business etiquette (particularly phone skills) and people skills.

2. Hold all team members accountable for modeling desirable behaviors, and enforce the code consistently and equitably among all staff regardless of seniority or clinical discipline in a positive fashion through reinforcement as well as punishment.
3. Develop and implement policies and procedures/processes appropriate for the organization that address:
    - "Zero tolerance" for intimidating and/or disruptive behaviors, especially the most egregious instances of disruptive behavior such as assault and other criminal acts. Incorporate the zero tolerance policy into medical staff bylaws and employment agreements as well as administrative policies.
    - Medical staff policies regarding intimidating and/or disruptive behaviors of physicians within a health care organization should be complementary and supportive of the policies that are present in the organization for nonphysician staff.
    - Reducing fear of intimidation or retribution and protecting those who report or cooperate in the investigation of intimidating, disruptive, and other unprofessional behavior. Nonretaliation clauses should be included in all policy statements that address disruptive behaviors.
    - Responding to patients and/or their families who are involved in or witness intimidating and/or disruptive behaviors. The response should include hearing and empathizing with their concerns, thanking them for sharing those concerns, and apologizing.
    - How and when to begin disciplinary actions (such as suspension, termination, loss of clinical privileges, reports to professional licensure bodies).
4. Develop an organizational process for addressing intimidating and disruptive behaviors that solicits and integrates substantial input from an interprofessional team including representation of medical and nursing staff, administrators, and other employees.
5. Provide skills-based training and coaching for all leaders and managers in relationship-building and collaborative practice, including skills for giving feedback on unprofessional behavior, and conflict resolution. Cultural assessment tools can also be used to measure whether or not attitudes change over time.
6. Develop and implement a system for assessing staff perceptions of the seriousness and extent of instances of unprofessional behaviors and the risk for harm to patients.
7. Develop and implement a reporting/surveillance system (possibly anonymous) for detecting unprofessional behavior. Include ombuds services and patient advocates, both of which provide important feedback from patients and families who may experience intimidating or disruptive behavior from health professionals. Monitor system effectiveness through regular surveys, focus groups, peer and team member evaluations, or other methods. Have multiple

and specific strategies to learn whether intimidating or disruptive behaviors exist or recur, such as through direct inquiries at routine intervals with staff, supervisors, and peers.

8. Support surveillance with tiered, nonconfrontational interventional strategies, starting with informal "cup of coffee" conversations directly addressing the problem and moving toward detailed action plans and progressive discipline, if patterns persist. These interventions should initially be nonadversarial in nature, with the focus on building trust, placing accountability on and rehabilitating the offending individual, and protecting patient safety. Make use of mediators and conflict coaches when professional dispute resolution skills are needed.
9. Conduct all interventions within the context of an organizational commitment to the health and well-being of all staff, with adequate resources to support individuals whose behavior is caused or influenced by physical or mental health pathologies.
10. Encourage interprofessional dialogues across a variety of forums as a proactive way of addressing ongoing conflicts, overcoming them, and moving forward through improved collaboration and communication.
11. Document all attempts to address intimidating and disruptive behaviors.

From The Joint Commission. Sentinel Event Alert. Behaviors that undermine a culture of safety. http://www.jointcommission.org/assets/1/18/sea_40.pdf. Published July 9, 2008. Accessed September 10, 2019.

In addition to issues of patient safety, an individual physician's disruptive behavior can negatively impact other aspects of health care systems. An institution that does not effectively address disruptive behavior experiences higher staff turnover, lower patient satisfaction, and increased medical errors. One attempt to quantify the cost of disruptive behavior was published in 2013. The authors estimated costs based on the prevalence of particular behaviors and the financial impact attributed to them. In a 400-bed academic hospital, the cost due to medication and procedural errors, along with staff turnover, exceeded $1 million.[66]

In some cases, individuals identified as disruptive report that they were acting as "whistle-blowers," trying to address a concern and escalating their actions until a response was elicited.[67] Health systems must provide opportunities for those impacted by policies to have a say in their construction and implementation. In addition, maintaining robust and nonpunitive pathways for providers and staff to raise concerns may also reduce this issue. In turn, physicians and other health care professionals must be self-aware about the impact their behaviors can have on their colleagues and the broader health care community. Providing stress management, anger management, and other supportive care services can be an important component of reducing disruptive behaviors.[68]

VI. Chapter summary

This chapter has reviewed some of the skills needed by health care professionals to be successful across the health systems science domains. These cross-cutting skills generalize across system-related and provider-based competencies and are important skills for physicians to apply.

Evidence-based medicine helps define the best options based on current science. This chapter reviewed several methods employed to support translating that information into practice. Clinical practice guidelines and pathways provide specific and concrete algorithms for decision making. Monitoring adherence to these algorithms allows health care leaders to give feedback to practitioners frequently operating outside of these guidelines. Formularies are another mechanism to support moving evidence into operations. When implemented well, formularies limit the ability to provide care outside of that supported by the best evidence unless a rational justification is given.

Expanding modalities of communication present both challenges and opportunities. Striving to "meet people where they live" includes communicating with them in the way they prefer. This chapter has discussed some of the advantages and perils of opening new channels such as electronic patient portals. Physicians and other health care professionals need to ensure that they do not create risks for themselves or patients by making assumptions about communication being completed when it has merely been initiated. This chapter also has explored how social media can be used as an effective tool to disseminate information or gather opinions and discussed some cautionary information about hazards of health care professionals having a social media presence.

Health care is delivered via teams. Providing care today requires an understanding of how effective teams function. This chapter includes two examples of formal teams that have been designed to enhance health care quality. Accountable care teams foster interprofessional collaboration and collegiality. Rapid response systems have demonstrated significant improvements in patient survival and other metrics through enhanced teamwork.

In new and unique ways, health care professionals face challenges to their professionalism. These challenges may take the form of crises, such as the determination that patients may have inadvertently been exposed to infectious disease risks such as CJD through medical procedures, or that errors that impact patients' health may have occurred. Balancing the potential liabilities of disclosure against the ethical imperatives to protect a patient's autonomy can be difficult. Other formidable conflicts can require weighing financial realities with community clinical health imperatives. Institutions can also face the challenge of dealing with disruptive professionals, staff, and clients and can prepare through formulating appropriate responses.

This chapter reviewed examples of the systems-level impact of a variety of domains. Leaders are presented with opportunities to excel in providing service to diverse communities through innovation and sensitivity. Operationalizing the best evidence in

medicine can enhance patient safety, and failing to do so can be detrimental to both patients and organizations. Fostering excellence in teamwork and communication can raise the quality of care delivered, as well as enhance the satisfaction of patients and staff. While mastering all of these areas can seem a daunting task, awareness of their importance is a first step.

Questions for further thought

1. In order to keep up with modern times, a practice is trying to increase its accessibility by setting up a Twitter account. Can you identify the challenges this might raise?
2. A complaint is brought to the attention of the chief medical officer of a hospital alleging that a physician is continuously texting during surgery (she has her cell phone wrapped in a sterile bag to maintain "scrub"). Can you identify any concerns this raises?
3. A patient is in need of a surgical intervention due to a life-threatening condition. The patient's culture does not accept direct discussions of death, fearing that speaking about it brings it to pass. How can informed consent be obtained in this context?
4. As a member of an interprofessional working group responsible for improving care for patients with mental health challenges in the ambulatory care setting in your institution, you observe that the group and all of its subcommittees are headed by physicians. Is this likely to help or impair the success of the work?

Exercise

Identify the health systems science domain that you are most interested in. As you go about your day, how does this domain impact you as a health care professional? As a student? As a patient? Consider how this domain could impact your work as a health care professional. What are the ways this domain can improve the patient care you deliver? What are the ways this domain may negatively impact the care you deliver? How can this domain be applied to your life, your work, or both? What about this domain do you find most interesting?

Case Study 1

One of the tenets of the Jehovah's Witnesses' faith is a prohibition against receiving blood products. During earlier eras, patients of this faith were often barred from receiving potentially lifesaving procedures due to concerns that this restriction would put patients at risk without physicians having the ability to rescue them with traditional interventions. Elective or semi-elective surgeries, some chemotherapies, and other therapies were deemed "too risky." Some hospitals and physicians, however, chose to work closely with this faith group to explore the options and identify new approaches. The New Yorker *magazine in 2015 ran a three-part series chronicling advances in "bloodless medicine" and described how Englewood Hospital and Medical Center of New Jersey is providing advanced care while respecting patients' beliefs.*[69] *Extremely complex operations, including lung transplantations, have been successfully performed without the otherwise routine use of transfusion in highly selected patients. The Institute for Patient Blood Management and Bloodless Medicine and Surgery at Englewood Hospital and Medical Center has become an international leader in this field and trains health care professionals and administrators in the care of patients without transfusion. Their advances*

have enhanced care for patients in circumstances in which blood is not available, not only when it is religiously prohibited. In addition, less reliance on transfusion in general reduces transfusion-related infections and other complications for all patients.

1. What health systems science principles come into play in this situation? How have they been applied?
2. What can you learn from this situation that may be applied to other challenges in health systems science?
3. What interventions might be counterproductive to efforts to better serve Jehovah's Witnesses? What steps would you take to improve care for this population?

Case Study 2

Serving the health care needs of the Amish population depends on enhanced understanding and respect for their belief systems and willingness to meet them within the boundaries of their community. Leaders at Lancaster General Hospital in Pennsylvania made a commitment to addressing the Amish population within their region. They engaged a research firm and conducted focus groups to identify the needs, utilization, and barriers to care. In respect for their faith, women and men met in separate groups. Examples of important concepts identified included reliance on natural products, willingness to engage the English health care system only for illness, and lack of acceptance of preventive care. Barriers to care included transportation, confusion about costs and billing, and a lack of factual information about health care. Scheduling multiple appointments at a time was viewed as a way to mitigate the transportation barriers.

Other institutions have improved care delivery to the Amish community through respectful, culturally sensitive initiatives. There is an increased prevalence of hemophilia among the Amish. This disorder is lifelong, debilitating, expensive to treat, and best managed through prevention and rapid intervention for bleeding. Especially in children, inadequate dental care can be a preventable source of bleeding and complications. Distrust of prescription medicine, lack of cultural acceptance of preventive care, cost, and complexity are barriers to successful treatment. Akron Children's Hospital manages the largest hemophilia B population in the world. Irene Boehlefeld, BSN, RN, CPON, a nurse educator, worked with leaders of the Amish community on a task force that ultimately led to the development of a home infusion training program for affected families, establishment of a community-based dental clinic, training of nurses to apply fluoride as part of a visiting dental van program, and creation of a culturally appropriate educational curriculum for the schools. As a result of this program, there were significant improvements in rates of factor infusion within 1 hour of the start of bleeding, number of home infusion patients, and completion of training logs. Additional benefits have included enhanced trust and relationships between the community, physicians, and other health care professionals.[70]

1. What health systems science principles did health system administrators, physicians, and other health care professionals utilize when delivering care to this population?
2. What additional steps can a health system, physician, or other health care

professional take to improve care to this population? What are the potential pitfalls to programs such as these?

3. How might you apply the lessons learned in this situation to another situation in your medical school or clinic?

Case Study 3

Chemotherapy regimens are a complex set of orders that include orders for the chemotherapeutic agents, supportive care medications, laboratory tests, nursing orders, and parameters for modifying the dose or withholding the chemotherapy infusion. For example, a standard chemotherapy infusion order set includes the chemotherapy agents, the dosing of each chemotherapy agent, the route and rate of administration, and the parameters for dose reduction. In addition to the chemotherapy agents, the order plans include orders for laboratory tests, intravenous fluids, supportive care medications for prevention of nausea and vomiting, prophylactic antibiotics for prevention of infections, and colony-stimulating factors. The order sets also include nursing orders that provide instructions regarding the sequence and relative timing of the infusions, frequency of clinical monitoring, call orders regarding specific parameters such as vital signs and laboratory results, and discharge information. The order sets can include references for the chemotherapy regimen publication and supporting evidence.

Computerized provider order entry (CPOE), if appropriately implemented with careful consideration for workflow and coordination of care, can be an effective tool to manage the complexity of the order sets. The electronic orders allow for asynchronous workflow, where multiple team members can be working on different aspects of the regimen in parallel rather than in sequence (synchronous process in the case of paper order sets that can be used by one team member at a time), therefore allowing for a more efficient process. For example, after the physician enters the orders electronically, the precertification clerk can work on the insurance approval process while the clinic secretary schedules the infusion time, the clinical pharmacist can double-check the accuracy of the orders and review any medication adverse interactions while the infusion nurse is providing the patient chemotherapy education, and the staff pharmacist can start mixing the chemotherapy agents.

In addition, CPOE can provide the possibility of efficient and frequent communication among team members through electronic messages that allow for clarification of specific modifications to the chemotherapy regimen as well as exchange of information relevant to the planning and administration of therapy. For example, traditional paper order entry (synchronous workflow) can be bypassed, and it is possible for the pharmacist to prepare the chemotherapy agents before the insurance approves to cover the regimen. Or the nurse may start giving the prophylactic medications before the pharmacist has started preparing the chemotherapy agents.

1. While CPOE has a great deal of potential in this situation, disruptions to the traditional sequential workflow introduce a risk for serious errors and unintentional patient harm (financial or medical). How would you overcome this challenge?
2. What other health systems science principles would you implement to further improve the care of patients with cancer?

Case Study 4

Becoming a physician is a transformative event. Society has expectations of physician behavior that may make it difficult for physicians to have full expectations of privacy, especially in the age of social media. As students transition to their professional role, they may not fully comprehend this challenge. Patients and potential employers may make judgments about their character or qualifications based on their media presence. Health care professionals do not always live up to the professionalism they use in person in their virtual lives.[71] *A published survey of medical schools found that students were identified as using profanity, appearing intoxicated, and sharing sexually suggestive material commonly in their social media presence. More concerning was the finding that 13% of schools reported students sharing patient information online. Three schools reported student dismissals due to their online behavior, and 67% had issued warnings to students.*[72] *A survey of program directors for surgical residencies found that 33% of respondents who reviewed applicants' social media presence had lowered a student's standing on the rank list due to his or her postings. The percentage of programs screening applicants in this manner was low (17%), but survey respondents anticipated that it will increase.*[73] *A variety of sources have created tips for maintaining an acceptable online presence.* Forbes *magazine recommended performing a personal audit, deleting questionable postings, updating privacy settings, and reviewing them intermittently.*[74] *A physician-specific guideline gives a brief set of "Dos and Don'ts"*[75]*:*

DO respect patient confidentiality.
DON'T blur professional boundaries.
DO be open about conflicts of interest.
DON'T make abusive or gratuitous comments about individuals online.
DO identify yourself by name when posting as a physician on publicly accessible social media.
DO use appropriate channels to raise concerns rather than social media.

1. How would you apply these guidelines to yourself?
2. How should health systems use these guidelines when considering hiring, disciplining, or dismissing a physician or other health care professional? What other guidelines should be considered?
3. What are the potential hazards for medical students, physicians, and other health care professionals who do not follow these guidelines?

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16

The use of assessment to support students' learning and improvement in health systems science

Kimberly D. Lomis, MD, Karen E. Hauer, MD, PhD

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In this chapter

This chapter focuses on the use of assessment in driving and measuring learning and improvement in health systems science (HSS). It begins by describing the increasing attention to the assessment of HSS principles throughout the medical education continuum. Competency-based assessment frameworks of competencies, milestones, and entrustable professional activities (EPAs) are described, and specific relevance to HSS is highlighted. The chapter provides a list of common assessment methods currently in use to monitor learner development of the knowledge, skills, and attitudes intrinsic to HSS. Because HSS is an emerging area of expertise, there is need for students to take initiative in defining their learning, assessment, and improvement needs. The concept of self-regulated learning is introduced as the means by which learners can achieve their goals. Key elements of self-regulated learning include goal setting, self-efficacy, attributions of learning outcomes, self-assessment, feedback seeking, and reflection. Finally, the student's critical role as assessor, particularly in contributing to the function of teams and systems, is highlighted.

Learning Objectives

1. List key behaviors that will promote success in acquiring the knowledge, skills, and attitudes intrinsic to health systems science (HSS).
2. Describe the representation of HSS principles in the major assessment frameworks of competencies and entrustable professional activities.
3. Describe the various methods used in the assessment of HSS domains and how they may be used to identify learning and improvement needs.
4. Describe the elements of self-regulated learning and how they may be used to support lifelong learning.
5. Describe how informed self-assessment, feedback seeking, and reflection can identify learning and improvement needs and lead to enhanced performance.

I. Introduction

The preceding chapters of this text encourage the reader to view the delivery of health care from the perspective of a system. Most learning occurs in the context of a system as well, either in a structured educational environment or in a clinical workplace environment. In order for students to optimize performance, they need to understand the system in which they learn and are assessed. The intent of this chapter is to empower students by providing guidance on tracking and improving their own performance. It also provides an overview of current assessment strategies for faculty and staff implementing new curriculum.

Each individual within a system must strive to develop the personal knowledge, skills, and attitudes requisite for patient care. However, to accomplish learning or care delivery, a high-performing system also relies upon meaningful interactions among members. This demands that each individual possess greater awareness of the collective performance goals and develop a broader set of competencies.[1]

This chapter offers two major perspectives to assist students. Health systems science (HSS) is increasingly addressed by major assessment frameworks in the United States. However, since this is a relatively new content area, motivated students will also need to take more ownership for their own learning and assessment. The first section of the chapter provides an overview of current assessments of HSS. Because more medical schools are beginning to directly address HSS, this chapter describes a variety of frameworks used in formal educational programs to assess a student's performance. A stronger understanding of the rationale for common assessment methods will enhance student success in both HSS and other competencies. Because the learning environment of the clinical workplace is less structured, the second section of this chapter offers tips for successful self-regulated learning habits that will be necessary throughout one's medical career. Provided are "keys to success" (Box 16.1), which integrate content from this chapter into actionable steps that students can practice.

• BOX 16.1

Keys to Success in Health Systems Science

Since health systems science (HSS) is an emerging content area, you may need to take initiative to understand whether you are developing the necessary knowledge, skills, and attitudes in this domain.

1. Be aware of competencies and entrustable professional activities related to HSS and seek opportunities to practice and receive feedback.
2. In addition to personal performance, consider how well you contribute to the system, help your teams attain their desired results, and support positive patient outcomes.
3. Be aware of your personal perspectives on learning and how you define success.
4. Strive for a growth mindset.
5. Take ownership of your learning and performance.

6. Identify areas in need of improvement and areas of strength upon which to build.
7. Set goals and identify resources for learning.
8. Protect time to reflect upon performance and to follow through on goals.
9. Seek opportunities to contribute to the teaching and assessment of HSS in your institution.

II. Current attention to health systems science in major assessment frameworks in US medical education

A. Overview of assessment frameworks: Competencies, milestones, and entrustable professional activities

Competency-based medical education (CBME) explicitly aligns programs of teaching and assessment with desired learning outcomes, which are in turn driven by the needs of patients, populations, and society. This approach is gaining significant momentum at all levels of the medical education continuum, both in the United States and internationally, because it fosters a shared language around the performance expectations for members of the health professions. CBME employs multiple methods of assessment but is grounded in direct observation of authentic tasks in the workplace. As physicians and other health care professionals advance through their education and migrate among various health care systems, CBME offers a common platform for professional development throughout one's career. Just as this textbook discusses systems of health care delivery, CBME enables a systems approach to medical education. This section clarifies key aspects of CBME, then highlights the specific application of HSS in these frameworks.

Because CBME focuses on outcomes over process, it supports individualization in education. Learners may take varying paths toward the same goal and will require varying amounts of time to advance in competency. Individuals also differ in their relative strengths and weaknesses among domains of performance. Thus the outcomes language of CBME informs individualized learning plans. It is critical that learners study the expectations outlined in the framework used in their training program in order to take ownership of their education and optimize their contribution to the health system (see the section on Student-Directed Assessment Strategies for the Clinical Workplace later in this chapter).

An aspect of CBME that many students find challenging is that it emphasizes growth throughout one's career over judging performance at any particular stage of training. Rather than describing a student's performance as "above expectations for a third-year student" (normative framing), CBME is couched in terms of readiness for responsibility (criterion based). The scale of performance does not change with level of training. For medical students accustomed to performing highly on any assessment metric, accepting that one is at the low end of a developmental scale can be difficult. Additionally, a learner may attain high levels of performance in a given setting but fall in performance ratings when placed in a more challenging clinical environment. Students who embrace the principles of continuous improvement will be more comfortable using these frameworks to understand their own growth as professionals. The key to student success is to focus on the language of competency descriptions rather than scores.

In the United States, there are two major competency-based assessment frameworks that students and residents will encounter to varying degrees in their local institutions: competencies and entrustable professional activities (EPAs). Competencies are broad attributes of performance that an individual can continually develop throughout his or her career, such as communication skills or medical knowledge. EPAs are more task oriented; these are units of daily work, such as performing a history and physical, entering orders, or conducting an informed consent process. These two frameworks—competencies and EPAs—offer complementary views of performance. Clinical teams manage their daily work in terms of tasks (EPAs); the supervising resident or attending faculty assigns each team member specific duties throughout the day. These assignments reflect the supervisor's judgment of team members' readiness to complete each task safely. Competencies are useful to describe the complex nature of any given EPA; to perform any given task well, the trainee must draw upon multiple competencies simultaneously. For example, conducting an informed consent for a procedure is a discrete task that can be assigned to one team member (an EPA). To do this well, the trainee must have adequate knowledge of the procedure and the associated risks, must communicate effectively to ensure mutual understanding, and must display professionalism that engenders the patient's trust in the team (associated competencies).

1. ACGME milestones

The Accreditation Council for Graduate Medical Education (ACGME) has described domains of competency that US resident physicians across all clinical disciplines need to develop in order to transition into independent practice successfully. The domains include medical knowledge, patient care, interpersonal and communication skills, professionalism, systems-based practice, and practice-based learning and improvement. Subsequently, each clinical discipline (emergency medicine, pediatrics, surgery, etc.) has defined subcompetencies within each of these domains that reflect the unique practices and priorities of that field. For each subcompetency, educators have articulated developmental milestones typically displayed as learners advance from novice levels of performance toward mastery. Commonly referred to as "the milestones," these developmental steps are the basis for assessment of each resident's performance. Aggregate milestone performance of cohorts of residents reflects the effectiveness of each training program in preparing trainees for practice.

Many US medical schools have aligned their assessment programs with the ACGME competency domains, and some have defined milestones for students. The ACGME subcompetencies and milestones differ by clinical discipline, so these are less readily applicable to "general" medical students. The Physician Competency Reference Set offers an overview of unifying themes reflected in competency sets established by many individual medical schools and those recurring in ACGME milestones across multiple disciplines.[2] Awareness of these expectations can guide learners in their studies. Premedical and pre-clerkship students would benefit from understanding the major domains of competence; medical students in clinical phases of training should be aware of both the competency domains and common subcompetencies; and senior students

nearing the transition to residency should study the subcompetency milestones of their intended residency discipline.[3]

2. AAMC Core EPAs for entering residency

Health care delivery systems place limits on the roles of medical students in the clinical environment. Issues of patient safety and the rapid pace of care delivery can create constraints on the ability of students to meaningfully engage in clinical duties. This in turn can result in graduates who are not fully prepared to assume the responsibilities expected of them early in residency. Recognizing a growing gap between the results of undergraduate medical education and the entering expectations of residency, the Association of American Medical Colleges (AAMC) launched an initiative to describe specific tasks that incoming interns should be prepared to complete with minimal supervision. The EPA framework is used to provide a more concrete representation of the level of competency development necessary to transition from student to resident. The Core EPAs for Entering Residency were described in 2014 and are being piloted throughout the United States.[4] Medical students, interns, and supervising faculty should familiarize themselves with the 13 tasks outlined by this model; the AAMC guidebooks provide rich clinical vignettes to describe an "entrustable" level of performance for each task.[4]

The concept of entrustment is critical to the EPA model. Entrustment intentionally brings the welfare of patients into the assessment process.[5] In addition to the specific knowledge, skills, and attitudes required of any given task, learners must display overarching elements of trustworthiness in order to be entrusted. Honesty, conscientiousness, and discernment (knowing one's limits) are essential daily habits of work that demonstrate to all members of a team that the learner is ready for more responsibility.[6] These attributes may appear to be innate; however, the demands of clinical care environments place unique pressures on all team members such that the elements of trustworthiness require active consideration and development just as the EPA-specific skills do.

B. Representation of health systems science in CBME frameworks

The principles of HSS permeate the major assessment frameworks described previously. Assessment reflects what is valued by an educational program, so this increasing representation serves as a testament to the growing recognition of HSS as the third pillar of medical education, alongside basic science and clinical skills.[7]

As is apparent throughout this text, HSS encompasses many diverse topics and competencies. HSS is most directly described in the ACGME competency domain of systems-based practice. The ACGME Pediatric Milestones document provides a useful framing of the systems-based practice domain:

> The competencies within this domain call upon the physician to broaden her view of care and advocacy beyond the individual patient to the community level and ultimately to a population level. She must accept and embrace responsibility for personal and systems error recognition and prevention, promoting patient safety through systems change.[7a]

Common systems-based practice subcompetencies across clinical disciplines invoke principles of teamwork, interprofessional care delivery, patient safety, safe transitions of care, value-based care, social determinants of health, and contributing to the improvement process of the system in which the resident works.

Another ACGME domain directly related to principles of HSS is practice-based learning and improvement. This domain fosters trainees' ability to compare data about current performance at the individual, team, or systems level, or a combination of these, with expected outcomes and identify and implement the learning strategies needed to improve performance. Practice-based learning and improvement is essentially an application of the principles of quality improvement to one's own learning and practice. These skills encourage a growth mindset and are essential to a medical student's success and continued progression toward mastery throughout one's career.

Among the AAMC Core EPAs, some speak directly to elements of HSS, such as EPA 8, "Give or receive a patient handover," and EPA 13, "Identify system failures and contribute to a culture of safety and improvement." The overarching framework of trustworthiness (honesty, conscientiousness, and discernment) also reflects essential behavioral expectations among members of health care delivery teams.

Other ACGME domains and other Core EPAs contain scattered references to key principles of HSS, such as teamwork, social determinants of health, systems thinking, patient safety, quality improvement, and value-based care. Additional highlights of the integration of HSS into these national frameworks are outlined in Table 16.1.

TABLE 16.1

Representation of Health Systems Science Principles in Major US Assessment Frameworks

ACGME Competency Domains	Health Systems Science (HSS) Topics Represented	Sample Language That Reflects Systems Thinking
Medical Knowledge	Foundational knowledge and application of knowledge of health care structures, processes, policy, population health, principles of improvement, etc.	"Collaborates with the participants necessary to address important health problems for individuals and communities" (Family Medicine Milestones MK2)
Patient Care	Patient-centered care	"Involves appropriate resources (e.g., primary

	Value-based care	care physician consultants, social work, physical therapy/occupational therapy, financial aid, care coordinators) in a timely manner" in arranging disposition (Emergency Medicine Milestones PC7)
Interpersonal and Communication Skills	Teamwork Interprofessional care	"Anticipates logistical issues regarding the procedure and engages members of the operating team to solve problems" (General Surgery Milestones ICS3)
Professionalism	Ownership for system advocacy	"Extends the professional role beyond the care of patients and sees self as a professional who is contributing to something larger (e.g., a community, a specialty, or the medical profession)" (Pediatric Milestones PROF2)
Systems-based Practice	This is the domain most directly aligned to HSS systems thinking	"Coordinates care within and across health delivery systems to optimize patient safety, increase efficiency, and ensure high-quality patient outcomes" (Internal Medicine Milestones SBP4)
Practice-based Learning and Improvement	Principles of quality improvement (QI) applied to one's learning and practice Master Adaptive Learner Clinical Informatics	"Demonstrates understanding of the basic concepts of QI"; "Identifies quality of care issues within one's own practice with a systems-based approach" (Obstetrics and Gynecology Milestones PBLI)
AAMC Core EPAs for Entering Residency	**Health Systems Science Topics Represented**	**Sample Language That Reflects Systems Thinking (AAMC EPA Guide)**
EPA 1: Gather a history and perform a physical examination	Patient-centered care Social determinants of health	"Demonstrate patient-centered interview skills (attentive to patient verbal and nonverbal cues, patient/family culture, social determinants of health, need for interpretive or adaptive services; seeks conceptual context of illness; approaches the patient holistically and demonstrates active listening skills)."
EPA 2: Prioritize a differential diagnosis following a clinical encounter	Evidence-based medicine Teamwork Health information technology Electronic health records	"Synthesize essential information from the previous records, history, physical exam, and initial diagnostic evaluations." "Engage with supervisors and team members for endorsement and verification of the working diagnosis in developing a management plan."
EPA 3: Recommend and interpret common diagnostic and screening tests	Value-based care	"Recommend first-line, cost-effective diagnostic evaluation for a patient with an acute or chronic common disorder or as part of routine health maintenance."

EPA 4: Enter and discuss orders and prescriptions	Health information technology Electronic health records	"Demonstrate working knowledge of the protocol by which orders will be processed in the environment in which they are placing the orders."
EPA 5: Document a clinical encounter in the patient record	Health information technology Electronic health records	"Comply with requirements and regulations regarding documentation in the medical record." "Verify the authenticity and origin of the information recorded in the documentation (e.g., avoids blind copying and pasting)."
EPA 6: Provide an oral presentation of a clinical encounter	Teamwork Patient safety	"Assure closed-loop communication between the presenter and receiver of the information to ensure that both parties have a shared understanding of the patient's condition and needs."
EPA 7: Form clinical questions and retrieve evidence to advance patient care	Evidence-based medicine Health information technology	"Identify and demonstrate the use of information technology to access accurate and reliable online medical information." "Demonstrate basic awareness and early skills in assessing applicability/generalizability of evidence and published studies to specific patients."
EPA 8: Give or receive a patient handover to transition care responsibly	Transitions of care Patient safety	"Conduct handover communication that minimizes known threats to transitions of care (e.g., by ensuring you engage the listener, avoiding distractions)." "Ensure that the health care team (including patient/family) knows that the transition of responsibility has occurred."
EPA 9: Collaborate as a member of an interprofessional team	Teamwork Interprofessional care	"Communicate with respect for and appreciation of team members and include them in all relevant information exchange." "Understand one's own roles and personal limits as an individual provider and seek help from the other members of the team to optimize health care delivery."
EPA 10: Recognize a patient requiring urgent or emergent care and initiate evaluation and management	Teamwork Interprofessional care Transitions of care	"Engage team members required for immediate response, continued decision making, and necessary follow-up to optimize patient outcomes." "Understand how to initiate a code response and participate as a team member."
EPA 11: Obtain informed consent for tests and/or procedures	Patient-centered care Electronic health records	"Communicates with the patient/family and ensures their understanding of the indications, risks, benefits, alternatives, and potential complications." "Documents the discussion and the informed consent appropriately in the health record."

EPA 12: Perform general procedures of a physician	Patient-centered care Teamwork	"Communicate with the patient/family to ensure pre- and post-procedure explanation and instructions."
EPA 13: Identify system failures and contribute to a culture of safety and improvement	Systems thinking Patient safety Quality improvement	"'Speak up' in the face of real or potential errors." "Recognize the use of 'workarounds' as an opportunity to improve the system."

AAMC, Association of American Medical Colleges; *ACGME,* Accreditation Council for Graduate Medical Education; *EPAs,* entrustable professional activities.

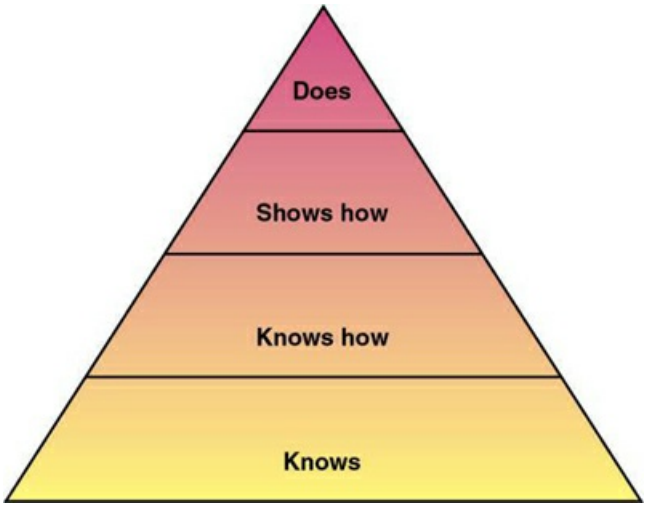
Students and residents should recognize that they are increasingly assessed in elements of HSS. Careful review of the ACGME milestones for the intended clinical discipline and the detailed descriptions of the AAMC Core EPAs for Entering Residency will help students understand performance expectations at the transition to residency.

III. Assessment of knowledge, skills, and practice performance in health systems science

The frameworks described in the previous section articulate the major outcomes expected of the medical education process. Educational systems employ a variety of assessment methods to ensure that students gain the knowledge, skills, behaviors, and attitudes that are consistent with those overarching educational goals and objectives. Students who have a basic understanding of the rationale behind the specific assessment methods employed will be better positioned to use assessment results to improve personal performance. This section outlines basic principles and common tools used in measuring student performance.

A. Overview of escalating progression of assessment methods (Miller's pyramid)

One of the ways in which educators think about the development of knowledge, skills, and attitudes and their subsequent integration into clinical practice is through the lens of Miller's pyramid (Fig. 16.1). This model articulates to learners the progressive and developmental acquisition of clinical competence and helps faculty to apply different assessment tools across the levels of the pyramid.[8] For many complex skills or competencies, a certain level of knowledge (*knows*) must be present first. For example, learning how to function effectively on a health care team will require some knowledge about the concept of mutual performance monitoring and its importance to successful team function. Next along the developmental trajectory is *knowing how* to apply that knowledge in practice, for example, how to provide feedback to a team member to facilitate self-correction. Possession of the requisite knowledge base and understanding how to apply that knowledge in practice are essential for the next step, demonstrating or *showing how* the skills are executed in practice. Lastly, the ability to perform a skill or demonstrate mastery of a competency does not necessarily mean that a physician or other health care professional will properly do so in the daily practice of medicine, so assessment of what one actually *does* in practice is the top level of Miller's pyramid.



• **FIG. 16.1** Miller's Pyramid.

It is important to understand how different assessment methods target different levels in Miller's pyramid and how this match influences the validity of assessment results.

B. Specific modalities used to assess health systems science knowledge, skills, and attitudes

1. Assessment of knowledge in health systems science domains

Multiple-choice question examinations are a valid and reliable means of broadly assessing knowledge in a given content area. Course and clerkship directors have begun developing and administering examinations in HSS content areas over the last several years concomitant with the increasing recognition of their importance in preparing for residency and clinical practice. Recent articles describe the use of locally developed assessments or the adoption of nationally available assessments to address knowledge and knowledge application in quality improvement, patient safety, evidence-based practice, and teamwork.[9-14]

The National Board of Medical Examiners (NBME) subject examinations and the United States Medical Licensing Examination (USMLE) increasingly include HSS content (Box 16.2). Licensing authorities have a duty to protect the public good, thus the NBME focuses on knowledge essential for the competent physician to possess in order to provide safe and effective care for patients. The evidence base in some of the HSS domains has matured enough to agree upon key principles that impact direct patient care. However, for some HSS content domains such as health care policy, leadership, or scholarship, a direct relationship to safe or effective patient care practices may not exist to warrant inclusion in licensing examinations at this time. The American Medical Association has collaborated with the NBME to develop a new subject examination on HSS, which has been piloted at multiple US medical schools for administration by any interested schools in 2020 and beyond.

• **BOX 16.2**

Content Recently Added to the USMLE Related to Health Systems Science

Systems-based practice

- Complexity/systems thinking
- Characteristics of a complex system and factors leading to complexity
- Health care/organizational behavior and culture

Quality improvement

- Improvement science principles
- Specific models of quality improvement
- Quality measurement
- Strategies to improve quality
- Attributes of high-quality health care

Patient safety

- Patient safety principles
- Specific types of error
- Strategies to reduce error

Health care policy and economics

- Health care policy
- Health care economics/Health care financing

USMLE, United States Medical Licensing Examination.

Student motivation for learning is substantially influenced by what is covered in NBME subject examinations (which often contribute to final course and clerkship grades) and in the USMLE (which plays a role in the residency selection process in addition to licensing). Likewise, medical education leaders appreciate the importance of USMLE scores and often prioritize their teaching and assessment based on USMLE content outlines and reports of student cohort performance in previous examinations. Students sometime perceive curricular activities related to HSS as secondary to "real science"; the increasing presence of HSS content in these examinations prompts students to recognize HSS as a high priority, even when time and resources for study are limited.

The review questions at the end of each chapter in this text are useful in assessing a student's grasp of the knowledge and principles addressed in each chapter, and the

authors advise that students take advantage of these exercises and discuss these items with faculty, peers, or both.

2. Assessment of skills acquisition in health systems science and practice performance

a. Assessment via simulation

Simulation-based assessment methods vary in their level of complexity, the extent to which they include technology-based methods, and their fidelity to actual patient care. There are several advantages of simulation-based methods in medical education: (1) they are available when needed to meet learner needs, (2) difficulty can be adjusted based on learner level or standardized across learners to ensure fairness in assessment, and (3) their use can guarantee that learners have some exposure to important clinical material when opportunities to perform tasks in actual clinical care may be limited (such as for EPA 10, "Recognize a patient requiring urgent or emergent care and initiate evaluation and management"). Another important advantage of simulation-based methods is that there is no risk to patient safety when they are used to teach or assess procedural skills or difficult communication skills such as delivering bad news to a patient. Challenges to using simulation-based methods include their cost, the need to make sure that the skills and behaviors assessed are consistent with good clinical care, and the difficulty that some learners may have in suspending reality during simulated clinical scenarios.

A common low-tech "simulation" method used in medical education is role playing. Role playing is often used in teaching and assessing acquisition of data gathering and communication skills and will be increasingly useful to assess similar tasks at the nexus of direct patient care and systems-based practice. Examples include role-playing scenarios involving counseling a patient about the cost-effectiveness of different therapies, disclosing a medical error, or holding a team briefing. While many role-playing activities are directed by faculty, there is no reason that such experiences cannot be conducted within a peer-based learning or assessment session, or both.

The use of simulated patients (also referred to as standardized patients or SPs) for learning and assessment is widespread in medical education, and a robust evidence base supports their use for assessing a broad range of data gathering, communication, and interpersonal skills. Simulated patients are also a well-suited method for assessing integration of direct patient care skills and system-related skills. Simulated patient exercises may be supplemented with a range of clinical materials (medical records, diagnostic results, web-based content provided by "patients," etc.) and assessment formats (virtual electronic health records with patient notes and computerized order entry, computerized mannequins, and other technology-based simulation) that require integration of various competencies to effectively manage.

Simulated patients (and other clinical content and assessment formats) may be incorporated in objective structured clinical examinations to assess broadly across HSS domains or may be used to focus in depth on a particular domain (such as patient safety). Varkey and colleagues described the use of a multiple-station Objective

Structured Clinical Examination to assess the performance of fellows in the practice-based learning and improvement and systems-based practice competencies, which overlap with many of the HSS domains. Cases included assessment of the following: planning a quality improvement activity, performing a root cause analysis, evidence-based medicine skills, knowledge about insurance, prescription writing, team collaboration, and negotiation skills.[15]

Actors can also play the roles of other members of the health care team to support learning and assessment of teamwork skills. As long as the simulations are realistic in representing authentic clinical situations, students feel that they provide effective ways of teaching and assessing their teamwork skills.[16] The use of standardized assessment instruments in team-based simulation facilitates delivery of effective feedback on important team skills and behaviors such as leadership, structured and closed-loop communication, situational awareness, assertiveness, conflict resolution, and mutual support.[10,17]

b. Assessment via direct observation in the workplace

Direct observation of performance in the workplace, as part of workplace-based assessment, is currently an area of intense research and development. Efforts are underway to optimize the reliability and validity of different assessment methods targeting a wide variety of skills and behaviors that can be demonstrated during authentic clinical situations. Many of the skills and behaviors within HSS domains are natural targets for assessment in the workplace. A number of HSS domains could be assessed in real clinical settings by faculty, residents, or peers, including the following examples: handover of a patient to a colleague who is on call or receiving the patient in a different hospital unit, informed decision making with a patient regarding the risks and benefits of a surgical procedure, counseling a patient who requests a diagnostic test that is expensive and not clinically indicated, and working with a health care team to discharge a patient from the hospital.

The competency-based frameworks described at the beginning of this chapter call for criterion-based assessments. Workplace-based assessment in medical education has traditionally been normative based, meaning that each assessor rates students relative to each other ("honors" or "high pass" student) or based on the assessor's expectations for a given level of training ("as expected," "below" or "above" expectations). New models are criterion based, in which a continuum of competency development is described by faculty. Student performance is compared to those standards, and assessments provide formative and summative feedback about each learner's developing competency for patient care responsibilities.

As newer assessment frameworks emerge, students and residents are likely to encounter assessment scales that use supervisory and co-activity language. Supervisory scales align with the type of ad hoc assessments clinical supervisors make daily in the clinical workplace as they assign tasks to various team members; high-performing, trustworthy students are given more independence. The supervisor may recommend that the learner practice a given task with his or her supervisor actively participating, in the room watching, or not present in the room but available to assist. Co-activity scales

are similar but more retrospective, asking supervisors to report how much they intervened in a given task being performed by the student, ranging from the supervisor taking over the task to providing guidance during the task or simply debriefing afterward (Table 16.2 and Box 16.3).

TABLE 16.2

Supervisory Scale Language for Assessment

Corresponding Excerpt From Original Chen Entrustment Scale	Modified Chen: "If you were to supervise this student again in a similar situation, which of the following statements aligns with how you would assign the task?"
1b: Not allowed to practice EPA; allowed to observe	**1b:** "Watch me do this."
2a: Allowed to practice EPA only under proactive, full supervision as co-activity with supervisor	**2a:** "Let's do this together."
2b: Allowed to practice EPA only under proactive, full supervision with supervisor in room ready to step in as needed	**2b:** "I'll watch you."
3a: Allowed to practice EPA only under reactive/on-demand supervision; with supervisor immediately available, all findings double-checked	**3a:** "You go ahead, and I'll double-check all of your findings."
3b: Allowed to practice EPA only under reactive/on-demand supervision; with supervisor immediately available, key findings double-checked	**3b:** "You go ahead, and I'll double-check key findings"

From Association of American Medical Colleges. Core Entrustable Professional Activities for Entering Residency. https://www.aamc.org/system/files/c/2/482210-epa12toolkit.pdf. Published 2017. Accessed September 23, 2019.

• BOX 16.3

Co-activity Language for Assessment

Modified Ottawa

In supervising this student, how much did you participate in the task?

1: "I did it." (Student required complete guidance or was unprepared; I had to do most of the work myself.)

2: "I talked them through it." (Student was able to perform some tasks but required repeated directions.)

3: "I directed them from time to time." (Student demonstrated some independence; only required intermittent prompting.)

4: "I was available just in case." (Student functioned fairly independently, only needed assistance with nuances or complex situations.)

No level 5 within modified Ottawa.

From Association of American Medical Colleges. Core Entrustable Professional Activities for Entering Residency. https://www.aamc.org/system/files/c/2/482210-epa12toolkit.pdf. Published 2017. Accessed September 23, 2019.

In addition to capturing the level of independence granted, such forms also gather contextual details about the specific encounter, which can significantly impact performance ratings. To guide students toward greater independence in the future, qualitative feedback should relate to the specific competency domains. For example, if a learner is deemed not ready to lead an informed consent discussion independently, the supervisor must clarify whether the concern is related to knowledge deficits, poor communication skills, or lack of a professional demeanor.

Another novel tool, the Teamwork Mini-Clinical Evaluation Exercise (T-MEX), was developed to directly observe and assess medical student collaboration in health care teams.[18,19] The T-MEX focuses on student competence in developing supportive team relationships, self-awareness and responsibility, and safe communication in different team-based care contexts, such as team meetings, discharge planning, and handovers. Assessment using the T-MEX instrument is intended to provide focused feedback to facilitate reflection and informed self-assessment.[18,19] Another example is an instrument developed to assess intern sign out of a patient to the oncoming night float team.[20] Aggregate data from the intern assessment was used for program evaluation and led to both curricular modifications and system-level changes to improve the safety of the sign-out process.[20]

c. Monitoring trends in workplace performance ratings

The clinical workplace is a complex environment with many factors beyond the performance of the individual student that can impact ratings during single episodes of assessment. Students have long been skeptical of the variability in their clinical evaluations. The specific clinical context, the willingness of a supervisor to grant independence, and even the time of day have been shown to influence ratings.[21] Acknowledging the limitations of these emerging assessment forms is essential, just as one would acknowledge the limitations of a clinical diagnostic test. Research in the outcomes associated with these various assessment forms and subsequent iterative improvements are necessary to boost the confidence of both learners and the educational system in the results.

To account for the reality of clinical context variability and support a developmental approach to assessment, it is critical to monitor trends in a learner's performance across settings, across courses, and over time. Regardless of the specific forms used to capture assessments in the workplace, most CBME programs compile assessment evidence into a digital portfolio or dashboard. The shared language for performance across settings allows the learner, ideally with the support of a faculty adviser, to evaluate the merit of any specific rating, place it in context, and determine his or her overall trajectory of development. This allows for correction of the inherent limitations of any individual

data point, enabling learners to embrace the complexity of the workplace and benefit from many different perspectives on their performance. The global view informs the identification of specific goals for improvement and the development of a targeted plan for continued growth. Judgment regarding the student's overall performance is elevated to a committee process and is based on these trends in performance. Such structures foster learner development in the practice-based learning and improvement domain and mimic the continuous improvement process demanded of physicians to monitor practice outcomes throughout their careers.

d. Assessment of work products

Examples of work products that may be assessed or serve as a stimulus for assessment include notes or orders entered in an electronic health record, a report from a literature search, a written description of a quality improvement or safety activity such as a Plan-Do-Study-Act cycle or event analysis, or analysis of a database regarding a particular patient population question or problem. These notes, reports, or analyses may themselves be assessed, or they may serve as the substrate or stimulus for assessment, for example as part of a case-based discussion between a supervisor and trainee. In addition, assessment of some nontraditional competencies might involve the use of more unconventional methods such as field notes, reflective essays, or written project reports based on community or health system experiences.[22] Although such methods are often qualitative or subjective in nature and less structured, they can contribute to the overall evidence base regarding a student's performance.

Evidence-based practice consists of multiple stages: asking a clinical question, searching the literature, appraising the literature, applying the evidence to the clinical question, and reviewing the process and outcome. Each of these steps requires related but different skill sets, for which different assessment methods might be best suited.[23] There are only a few validated approaches to assess the complete range of skills comprising the individual steps of evidence-based practice.[23,24] A case-based discussion after a patient encounter or based on an electronic health record note is one approach to assessing the quality of clinical query that leads to the literature search. A printout or keystroke capture of the actual search itself might be directly assessed, while literature appraisal may be summed in a report for assessment purposes. Application of the retrieved evidence to the patient problem could be the target of a reflective essay or a case-based discussion.

e. Assessment via multisource feedback

Multisource feedback (MSF)—also referred to as 360-degree feedback, an approach widely used in business and industry—is increasingly being used in medical education and clinical practice. In medical education and practice, MSF involves gathering information from peers and other health care professionals based on observations of the learner in different contexts. Such observations are generally considered indirect, since the person being observed may be less aware that the observation is taking place. An important assumption is that learner behaviors in this situation may be more representative of authentic clinical behaviors than when one is more conscious of being

observed, as during a simulation exercise.

One area in which MSF may be especially useful is in the assessment of teams and individuals within teams. Feedback from members of the health care team (residents, peers, nurses, administrative staff, patients) has been found to be acceptable to both the assessors and the students receiving feedback.[25] Narrative descriptions that stem from specific interactions or events, based on observed behaviors, may be especially helpful in identifying opportunities for growth or improvement. Residents, peers, nurses, and administrative staff are able to provide specific comments on a student's contribution to team performance based on the different contexts in which performance is observed and based on their unique perspectives.[26]

f. Peer-based learning and assessment

The use of peer assessment is common across the continuum of medical education and practice, from assessment of various tasks and behaviors in basic science courses to assessment of the clinical performance of physicians in practice. In medical education contexts, one of the more common uses of peers is in the assessment of professional behaviors.[27,28] However, peers may also provide reliable and valid assessment of specific clinical tasks (performing a literature search), other competencies (interpersonal skills), or complex clinical interactions (diagnostic evaluation of a patient).[27,29-32] Peer assessment is often, but not universally, well received.[33] Those who receive peer feedback may experience both cognitive and emotional reactions that may have a more significant impact on attitudes and behaviors.[34]

Research shows that assessing one's peers has beneficial impact on the professional behavior and learning outcomes of the assessors themselves.[29-31,33,35] In addition to a positive impact on immediate learning outcomes, engagement in providing peer assessments may help instill the attitudes and skills that will serve students well as future lifelong learners engaged in professional self-regulation.[33] Making judgments about peers' performance may lead to more critical thinking about clinical competence in general and provide useful insights about the learner's own performance.[28] In many education programs, faculty resources may be limited and student peer assessment may offer supplementary insights since students observe their peers in many different contexts.[29,33] In particular, peers may be able to offer relevant observations regarding domains that are difficult to assess, such as leadership, initiative, work ethic, respect for all, collaboration, and teamwork.[31]

There are some potential risks involved in peer assessment in medical education. Some individuals do not appreciate assessment by their peers and will resist and devalue the feedback received.[34] With training, most individuals can learn to provide specific, constructive feedback, but occasionally inappropriate or harmful comments are conveyed.[27] An institutional culture that endorses the importance of peer feedback and offers a safe environment may mitigate some of the potential adverse consequences.[35] It may be useful for faculty to help monitor, if not filter, feedback and be available should students need assistance in interpreting and responding to feedback.[27] Based on

research in peer assessment, there are a few guidelines that should be followed in developing a peer assessment process that will optimize the quality of the assessment and feedback process.[27,32-34]

Experts who have written about peer assessment generally suggest that, in order to optimize the validity of assessment results, the assessment should occur in a low-stakes setting. Ratings should be provided anonymously.[27,30,32] However, some students feel that feedback is more meaningful when it is signed by the person providing the assessment.[34] Such transparency is more aligned with the principles of systems and safety—all members of a team should be empowered to speak up, and all members should be open to feedback that supports continual improvement. Some programs implementing competency-based approaches cite the common language to describe performance as an important tool enabling peers to provide each other meaningful feedback in a nonconfrontational manner.

IV. Student-directed assessment strategies for the clinical workplace

Despite the increasing presence of the principles of HSS in structured frameworks of assessment, this is an emerging field. The attention to HSS in any given institution will vary, making this an area in which students should take more personal ownership in ensuring their readiness to contribute effectively to the system.

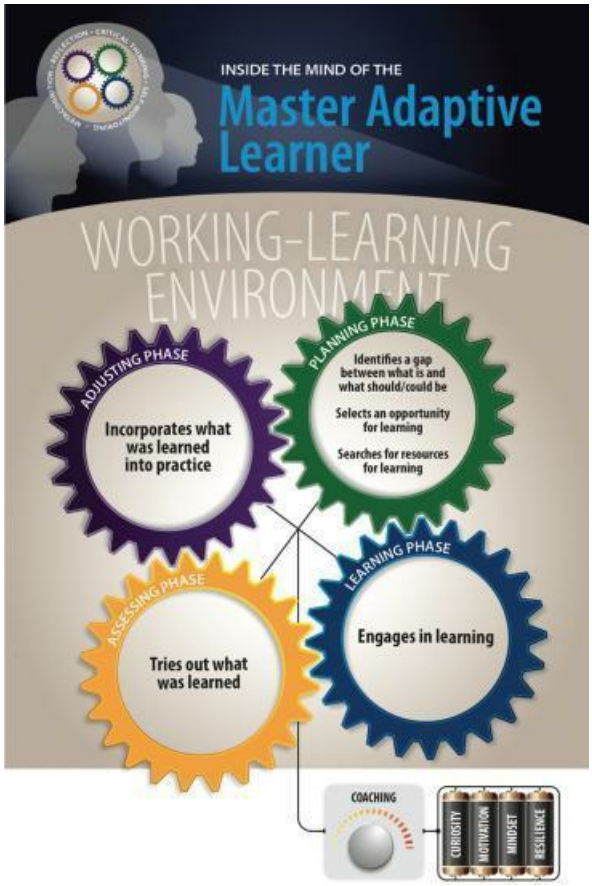
Students participating in the health care delivery system quickly recognize that the educational process is less structured in the workplace than in traditional classroom environments. Learning strategies that served students well in other contexts are insufficient to promote success in the workplace. The scaffolding that was provided earlier in their education (such as uniform lecture notes and published learning objectives) is withdrawn, and learners must assume more self-direction in setting and achieving individual learning goals. Additionally, since HSS is a relatively novel area of expertise for physicians and other health care providers, students may encounter inconsistent role modeling in the workplace. By taking initiative in this domain, students can become change agents in the health system.

The modern health care environment is dynamic and rapidly evolving, demanding that physicians continuously update their knowledge and skills to keep pace with scientific advances and changes in systems of care. Physicians in practice are expected to monitor their knowledge and skills, take action to address personal gaps, and stay current with new developments in the field.[36,37] Each physician must engage in repeated cycles of learning: seeking meaningful evidence about one's performance, identifying gaps, creating goals, pursuing resources, and reassessing. The concepts of lifelong learning and self-direction of one's learning are increasingly emphasized for physicians and trainees.[38,39] Despite the attention to this process, it remains challenging for students, residents, and practicing physicians to implement this in practice. There is a natural tendency for students who are eager to be accepted into the system to focus their energies on *appearing* to perform well. True growth requires a willingness to openly acknowledge one's limitations and actively pursue learning opportunities. This strategy can be daunting, but is critical to the delivery of safe, effective patient care and contributes to professional confidence and satisfaction.

A. Becoming a Master Adaptive Learner: Self-regulated learning as the basis for lifelong learning

The Master Adaptive Learner conceptual model[40] serves as a guide for how physicians continuously learn and improve (Fig. 16.2). This process is based on self-regulated learning theory, which describes the processes by which individuals adjust their behaviors to achieve goals.[41] Self-regulation comprises one's thoughts, feelings, and actions directed toward achievement of goals.[42] Self-regulated learning describes a cycle of control of one's academic and clinical performance through goal-directed behavior,

the use of specific strategies to attain goals, and adapting and modifying behaviors or strategies to optimize learning and performance.[43]



• **FIG. 16.2** The Master Adaptive Learner Model. *Source:* (Reprinted with permission from Cutrer WB, Atkinson HG, Friedman E, et al. Exploring the characteristics and context that allow Master Adaptive Learners to thrive. *Med Teach*. 2018;40[8]:791-796. Adapted with permission from Cutrer WB, Miller B, Pusic MV. Fostering the development of Master Adaptive Learners: a conceptual model to guide skill acquisition in medical education. *Acad Med.* 2017;92[1]:70-75.)

Self-regulated learners take charge of their own learning through strategies that involve their thoughts and actions. They actively monitor their own learning rather than more passively waiting to be told what and how to learn. Though many people believe they are learning and growing, making these behaviors as intentional and habitual as possible can maximize learning. Self-regulated learning behaviors can be fostered from the beginning of medical school.

A master adaptive learner enacts self-regulated learning through a series of phases:

Planning: Before a learning activity, the student prepares by reading the assignment or gathering information about the activity and sets goals and plans to achieve those goals.

Learning: During the activity, the student uses strategies to focus and optimize

learning. These can entail when and where to study, with whom to study or practice, how to participate in a small group, and what strategies to use (e.g., quizzing, rehearsing).

Assessing: After an activity, the student reviews what happened and reflects on what worked well and what could have worked better.

Adjusting: This reflection informs the next attempt with the same or a similar learning activity.

Teachers can create an environment that invites these learning behaviors by helping the student understand the desired performance, guiding the student toward that performance, and motivating the student. Specific skills and attitudes are described next, with examples from medical education to illustrate how students can take charge of their own learning.

1. Goal setting

The first phase of self-regulated learning includes setting a goal for what is to be accomplished. Based on this goal, the student can begin goal-directed behavior. Students' goal orientations vary based on the goals to which they aspire. Students with mastery-oriented goals want to improve, learn materials, and develop skills. Students with performance-oriented goals want to earn high scores or good grades, win awards, or avoid public failure. Mastery goals are better for learning because they are associated with internal motivations, greater effort, and willingness to attempt challenges and new learning experiences.

Useful goal setting involves goals that are achievable and measurable within a defined time frame, so that the student or the teacher can determine whether the goal was accomplished. There are different kinds of goals:

- **Process goals:** the steps to take to achieve an outcome. For medical students, process goals could include how much or when to study for an examination, how to practice cardiac auscultation and seek feedback during a clerkship, or learning a mnemonic for a patient handoff.
- **Outcome goals:** the end product the student seeks. Outcome goals for students can include achieving a certain milestone level, mastering a new procedure, earning a course grade, acceptance to a residency, or successfully leading a team briefing.

In general, process goals are more helpful for early learners because they clearly define the steps needed for improvement. However, over the long run, a balance of process and outcome goals is effective.

2. Self-efficacy

Self-efficacy entails one's belief in one's own ability to accomplish something. Strong self-efficacy increases one's performance of a given action—that is, if you believe you can do something, you are more likely to succeed. In medical education, carefully

designed early clinical experiences can promote the self-efficacy critical to self-regulated learning. These experiences should expose students to the people and practices of the clinical context and provide opportunities to meaningfully contribute. This situation could occur in an early preceptorship, in which first-year medical students see patients and help the interprofessional staff or physicians with clinical tasks. Providing students with clear roles and opportunities to build necessary knowledge and skills will create a sense of self-efficacy that positions them to succeed in later clinical rotations.

3. Attributions

In the third phase of self-regulated learning, students reflect on how they did and interpret why their performance played out as it did. In this phase, students engage in attribution by identifying the primary reasons for the results they achieved. Attributions can be understood in these dimensions, as outlined in Table 16.3.[44]

TABLE 16.3

Examples of the Dimensions of Attribution in Self-Regulated Learning

Dimension of Attribution	Why Student Achieved a Certain Learning Result	
Locus of control	**External:** My score is due to the difficulty of the assignment or the help I got from my friends or my teachers.	**Internal:** My score is due to the amount of effort I applied, the strategy I used to learn the material, and understanding of the material in the text.
Stability	**Stable (ability):** My grade is due to my intelligence; I'm always going to be good at certain things but not others.	**Unstable (modifiable with effort):** My grade is due to the time I spent studying. When I worked harder or wrote brief quizzes for myself on the material, my performance improved.
Controllability	**Uncontrollable:** Outcomes due to luck. I did not learn because my attending was too hard on me.	**Controllable with effort:** I worked very hard in my peer group and learned all of the material.

Adapted from Graham S. A review of attribution theory in achievement contexts. *Educ Psychol Rev*. 1991;3:5-39.

The attributions that best promote learning and self-regulated learning behaviors are internal, unstable, and controllable. Students who will achieve the best performance will believe that performance in clinical settings or on examinations is due to the effort or approach used to study and gain the knowledge and skills. For example, a student may note that his or her efforts during the pediatrics clerkship, which entailed setting and following a reading schedule and practicing patient sign-out skills with his or her resident, led to improvements in the team's evaluation of his or her performance.

Carol Dweck's work on a growth mindset builds on this information about attributions.[45] In order to fulfill their potential, students should have a growth mindset, believing that their potential to improve is within their control. When faced with a challenge, students should focus on their efforts and study strategies rather than worrying, "Am I smart enough?" Teachers and clinical supervisors should promote students' effort, persistence, the strategies they use, and choices they make rather than

their innate ability or intelligence. Pressures to earn certain grades or licensing examination scores in order to secure residency positions in competitive specialties and programs interfere with cultivation of a growth mindset among medical students, but high-performing systems rely upon individuals continually (and transparently) seeking growth.

B. Self-assessment and feedback seeking

To engage in self-regulated learning, a student must set goals that are appropriate to the learning needs. To identify those goals, the student must be able to assess how he or she is doing and what improvements are needed. This process of individually evaluating one's performance is called *self-assessment.* For example, a student preparing for the Medical College Admission Test reviews his or her prior performance on practice tests to decide how much to study for each section of the test. Self-assessment without data is often flawed. Studies have shown that low-performing students or physicians tend to overrate their performance (due to poor insight) and high-performing students or physicians may underrate their performance (due to their tendency to perpetually aim for higher and better performance).[46-48]

This illustrates the need for evidence-based self-assessment, also known as *informed self-assessment.*[49] From the student's perspective, it is possible to engage in informed self-assessment by seeking and reviewing any performance information available. It is important for students to begin by asking supervisors of their expectations up front, and then, after some time working together, soliciting honest and specific constructive feedback on ways to improve. A student can ask for feedback, scores, and written comments from assessments—for example, after being observed presenting or seeing patients in a clerkship, after taking a written examination, or after interacting with a small group of peers. Observing a near-peer slightly ahead in development can also serve as a source of information about ways to do things better.

Fortunately, there are strategies to improve the accuracy of self-assessment:

- **Clarity and understanding of the expected level of performance.** The first is defining the performance expectation. For a student self-assessing how well he or she used evidence-based methods in addressing a difficult patient problem, he or she would want to know which skills and behaviors were expected, such as developing a good clinical question, searching and appraising the literature, and applying best available evidence to his or her patient's problem and how those will be assessed.
- **Feedback.** Students who receive feedback from a preceptor or watch a video of their performance interacting with standardized patients are more likely to rate themselves similarly to the ratings provided by a faculty or standardized patient. Students should seek feedback from their supervising attendings and residents, as well as their advisers and mentors, to improve their understanding of their own performance and thereby strengthen their self-assessment, which in turn should guide learning planning.

- **Experience.** More experience with a skill may improve self-assessment due to greater understanding of what is expected, more prior practice, or more opportunities for feedback.
- **Assessment.** Test-enhanced learning describes the learning benefit of taking tests. Testing can improve self-assessment when it is coupled with feedback on performance. Students learn more when they are regularly tested compared to when they continue to study without being tested. Taking a test requires the student to recall information, and this strengthens memory. This effect is particularly strong if the test requires the student to retrieve information (as with a short answer or fill-in-the-blank examination) rather than just recognizing it (as with a multiple-choice question).[50]
- **Mentoring.** Many medical schools pair students with a faculty member who will serve as a guide in the learning process. This person may be called a *mentor, coach, adviser,* or *master.* Regardless of the title, a faculty mentor can be very helpful in guiding a student through the process of self-regulated learning. The mentor may provide clarification of expected performance, assist in interpreting feedback, directly offer feedback, facilitate the student's reflections, and help set learning goals. Self-regulation does not mean solo; students should seek mentorship from trusted faculty to guide them in this process.

C. Reflection

Reflection on one's performance should occur during each phase of self-regulating learning. Before an activity, the student reflects upon what he or she has learned in the past and considers how to prepare for the activity. During the activity, reflection occurs in real time as the students monitor their performance and make needed adjustments. Reflection occurs most prominently after the activity, as the student self-assesses, reviews any feedback received in relation to expected benchmarks for performance, and identifies the gap between actual and ideal performance.

Readers may recognize that the process of self-regulated learning has many similarities to strategies for quality improvement of clinical systems described elsewhere in this text. The competency domain of practice-based learning and improvement can be equally applied to one's learning practice as to one's clinical practice.

Case Study

Joe is a second-year medical student preparing to meet with his adviser to review his performance. Joe's digital portfolio maps all of his performance ratings and comments from assessors onto a dashboard for each competency domain. He is dismayed because his ratings in communication skills are consistently below the expected benchmark. Peer feedback includes a few comments about his quiet nature and concerns that Joe seems hesitant to speak up in small-group activities, while acknowledging that he seems to be knowledgeable and well-prepared with notes and diagrams. One peer wrote, "Joe sometimes doesn't say anything in small group."

1. How does this assessment evidence relate to Joe's development of competency in HSS?
2. How can Joe demonstrate self-regulated learning?

Joe's adviser asks him to reflect on reasons why he may appear to be nonparticipatory, and helps him understand that the team is counting on his contribution for its success, similar to how ward teams rely on everyone's contribution to care for patients. She asks how Joe thinks he can improve (internal, unstable, controllable attributions). Joe sets the process goals to make at least two comments in each small-group session and to seek feedback about communication skills from his preceptors in clinical sessions. When he transitions to his first clerkship, Joe realizes that he again feels hesitant to speak up in the context of the fast-paced surgical service. He recognizes this challenge within the first 2 weeks and focuses on the process goals of asking one question and offering one suggestion during each day's interdisciplinary rounds. When Joe meets with his adviser again, they are both pleased to note that Joe's communication ratings are all on target, with several positive comments about his teamwork skills.

V. Assessment of team performance

The heightened acknowledgment of health care delivery as a team process drives health care systems to increasingly evaluate performance at the level of care delivery units in addition to monitoring the performance of individuals: the sum is greater than its parts.

Students have experience in leading teams and managing group projects in classroom or extracurricular settings, but often assume that assessing the function of their clinical teams is beyond their scope. Due to the nomadic nature of clinical assignments, students may feel more like guests rather than true members of the team. This section highlights why and how students should engage in assessing team performance.

As novices to the health care delivery system, students learn by closely observing the activities of others. Students may thus identify important issues that other busy team members fail to notice. Not limited by preconceived ideas about how things are done, they are in a unique position to question existing processes and to notice inefficiencies that may have evolved unintentionally. Many students would hesitate to raise such questions, assuming that the more established team members know better. However, if one accepts that complex care delivery systems are prone to error, the student should consider such observations as potential contributions to the team's success. Indeed, it is a student's duty to improve the system in which he or she learns and works. With careful phrasing, a student's inquiry can be framed in a manner that is not confrontational and communicates the intent to enhance team outcomes.

A first step to judging the success of a team is to clarify common goals. This may not be straightforward, since the goals of the individuals within each team often differ significantly. Clinical care teams are composed of members at varying stages of development across a mix of professions, each with differing individual outcomes expected from a given clinical placement. Gaining clarity about what success looks like for the team is important, and remaining focused on meeting the needs of patients is fundamental. Residents are often tasked with directing the daily work of clinical teams. A resident who is just developing management skills, challenged by frequent changes in team membership, may not have established a habit of orienting each member as he or she rotates onto the team. Students should take the initiative to clarify their supervisors' expectations at the beginning of each clinical placement and routinely seek guidance from all members of the team,[51] which will enable them to actively pursue opportunities to contribute meaningfully to the team's function.

True teamwork is difficult to attain; there is a difference between working next to one another and truly working together. The clinical workplace is demanding, placing many pressures on individuals and on the team. Maintaining productive, positive interactions among team members requires active management. This may be intimidating for students to tackle; however, any interpersonal conflicts or unprofessional behaviors should be addressed openly. Gaining the maturity and confidence to address interpersonal challenges is essential to a student's full development as a professional.[52] It is helpful to approach such conversations with the goal of optimizing team performance rather than viewing this as a personal issue.

Phrasing that conveys an observation rather than judgment is less threatening. All team members can serve as role models in the workplace as either positive or negative influences. Helping one another maintain professional standards enhances the working-learning environment and thereby improves the quality of care that is delivered.

Increasingly, formal team briefings, huddles, and debriefings are being instituted to address the issues outlined previously. A huddle at the start of a clinic session or before beginning a procedure can clarify expectations and roles for each member. Similarly, a brief review at the end of a session confirms whether goals were met and can help address any problems that arose. Students who routinely reflect on how they can best contribute will feel empowered to participate in these structured discussions. Observing and practicing these strategies as students will prepare them to transition successfully into leadership roles as residents.

VI. Chapter summary

This chapter provided perspectives on assessing student performance in HSS. Major frameworks of assessment and their relevance to HSS were reviewed. Specific modalities commonly used to assess HSS skills were described. Since HSS is a relatively new area of focus in medicine, the role for student-directed processes of self-assessment and self-regulated learning was emphasized. Students who understand how they are being assessed and who integrate assessment results into their personal learning and improvement plans are more likely to succeed.

Exercise

Consider an aspect of health systems science, such as patient safety. Using the Master Adaptive Learner model, consider your own competency development in this area.

Competency frameworks: Do you know the performance expectations for interns regarding patient safety? (*Tip:* Review the description of AAMC Core EPA 13, Toolkit: "Identify system failures and contribute to a culture of safety and improvement," at https://www.aamc.org/system/files/c/2/482212-epa13toolkit.pdf.)

Planning: Do you have any assessment evidence about your own performance in this area? Can you identify a gap between what is and what could be? Set a goal.

Learning: How can you use upcoming courses or rotations to improve your knowledge and skills in this area? Is there a resident or more senior student from whom you could seek advice? Are there online resources you can use? (*Tip:* https://edhub.ama-assn.org/health-systems-science.)

Assessing: How will you know if you are getting better? What types of feedback could you seek from supervisors?

Adjusting: How will you leverage your strengthened skills in your daily work? How will you contribute differently to your team or institution?

Questions for further thought

1. What key behaviors will enhance student attainment of the competencies intrinsic to health systems science?
2. How does explicitly linking assessment to the needs of patients, populations, and society empower students to focus more on their development as professionals than on grades and rankings?
3. What are attributions in self-regulated learning, and how can the way in which students attribute various learning outcomes impact their learning process and development of competence?
4. How can students deal with the complexity of the clinical learning environment in interpreting performance evaluations?
5. What assessment methods could be used for assessing acquisition of skills in quality improvement? What methods could be used for assessing performance of quality improvement in clinical practice?
6. How does peer teaching and assessment benefit students who are teaching or providing the assessment?

Annotated bibliography

Chen JY. *Why peer evaluation by students should be part of the medical school learning environment* Med Teach 2012;34: 603-606.

Finn GM, Garner J. *Twelve tips for implementing a successful peer assessment* Med Teach 2011;33: 443-446.

Furmedge DS, Iwata K, Gill D. *Peer-assisted learning—beyond teaching* how can medical students contribute to the undergraduate curriculum Med Teach 2014;36: 812-817.

These three articles provide a rationale for involving peers in teaching, assessment, and other activities involved in undergraduate medical education. They help define the roles that learners may play and provide useful advice in establishing peer-assisted learning and peer-assessment programs.

Hickson GB, Pichert JW, Webb LE, Gabbe SG. *A complementary approach to promoting professionalism* identifying, measuring, and addressing unprofessional behaviors Acad Med 11, 2007;82: 1040-1048.

Using a program that tracks unsolicited patient complaints to identify team members who would benefit from coaching regarding professionalism, Hickson's group has noted that many physicians demonstrating unprofessional behaviors self-correct after an "awareness" intervention. Additionally, systematic intervention improves patient safety and the work environment for all. The group is now advocating that team members address (or report) unprofessional behaviors promptly. Table 2 of this article outlines potential actions a resident might take upon observing an incident, and the potential drawbacks of each. The description of a "cup of coffee conversation" offers a validated approach to share concerns with a colleague.

Miller GE. *Invited reviews* the assessment of clinical skills/competence/performance Acad Med 1990;65: S63- S67.

This often-cited article was actually an invited review regarding the state of the art of standardized patients for assessing clinical competence. While many new assessments have since been developed and studied and the concepts of health systems science and "systems competencies" were not yet anticipated, this article helped many to understand the developmental nature of clinical competence and performance and the principles underlying the reliability and validity of assessment approaches.

Sandars J, Cleary TJ. *Self-regulation theory* applications to medical

education. AMEE Guide No. 58 Med Teach 2011;33: 875-886.
This comprehensive and readable review defines the three phases of self-regulated learning: (1) goal setting and planning for learning activities, (2) application of learning and practice strategies, and (3) reflection on their learning. Multiple examples from medical education in the classroom and in clinical settings show how self-regulated learning behaviors can improve students' performance.
Sklar D. *Integrating competencies* Acad Med 2013;88: 1049-1051.
In this editorial, Dr. Sklar, editor of Academic Medicine, uses a patient vignette to illustrate the need for physicians to possess a breadth of competencies and an awareness of the larger health care delivery system in order to successfully care for patients.
Telio S, Ajjawi R, Regher G. *The "educational alliance" as a framework for reconceptualizing feedback in medical education* Acad Med 2015;90: 609-614.
Telio and colleagues advocate for a shift in our thinking about feedback as a unidirectional (teacher-to-student) process. They advocate instead for a "dialogue occurring within an authentic and committed educational relationship that involves seeking shared understanding of performance and standards, negotiating agreement on action plans, working together toward reaching the goals, and co-creating opportunities to use feedback in practice.".

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17

Looking ahead: The dynamic nature of health systems science, future trends, and the role of learners as change agents

Jeffrey M. Borkan, MD, PhD, Victoria Stagg Elliott, MA, Therese Wolpaw, MD, MHPE, Iman Hassan, MD, Kimberly D. Lomis, MD

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In this chapter

This chapter explores the inherently dynamic nature of health systems science as a developing domain and field of inquiry. It explores future trends in health care and how they are influenced by societal, system, physician, and other health care professional trends. It delves into the potential impact of these trends on the health care system and the resulting implications for health professions education, including health systems science. Finally, it briefly examines the role of learners as change agents. The authors view learning as a key activity of all members of the health care delivery system and believe this will impact future changes in health professions education and training. In the spirit of futurism, this chapter also takes a nontraditional approach to exploring these possibilities.

Learning Objectives

1. Provide the rationale for viewing health systems science (HSS) as a dynamic and evolving domain and field of inquiry in terms of focus, knowledge, attitudes, and skills.
2. Articulate several future trends and their possible implications for the health system and for health professions education, including HSS.
3. Examine the role of learners as change agents—for patients, the health care system, and the future of HSS.

I. Health systems science—a dynamic, rapidly developing domain and field of inquiry

6:00 a.m., MAY 15, 2041; CITY 11, BLOCK 25, HOME OF ALEX, A MEDICAL STUDENT:

Alex was excited, even though he knew he shouldn't be. It had been 3 days since the most recent outbreak of Abrac Pox Virus had been detected. He was only nearing the completion of his first year of medical school, but everybody with even a minimum of medical training was taking part in some way in the actions needed to stop this epidemic from spreading farther.

The epidemic had been detected by a citywide alert system that not only linked the electronic records in physician practices and other health settings but also pulled key data from devices worn by people to track their health status and from purchase records of over-the-counter (OTC) medications. The first suggestion of an impending epidemic was a significant decrease in the average number of steps people at highest risk for this infection were taking and the amount of sleep they were getting. These data combined with increases in sales of seventh-generation OTC nonaddictive pain relievers and anti-itch creams triggered the alert. For some, Abrac Pox Virus was nothing more than a minor nuisance, like a summer cold with an inconvenient rash. For others, the infection could be deadly. Health care professionals were ready for the first severe case when the patient contacted his primary care physician through a secure messaging portal that simultaneously displayed holograms of the patient and measured several key vital signs and biometric indicators. While the physician was assessing the patient virtually, augmented intelligence (advanced artificial intelligence) suggested that Abrac Pox Virus was a possibility. The man was quarantined in his own home, and the appropriate treatment was delivered securely to his door.

Today Alex, as part of his training, would be accompanying his preceptor Dr. Bella and others studying other health professions to deliver vaccines and treatment, as appropriate, to Block 43, a neighborhood on the other side of City 11. This area was diverse and challenging, with both very wealthy people and those on the other end of the socioeconomic spectrum. Social determinants of health had been addressed for the past 20 years, but differences remained that affected health, disease, and well-being. Alex's team, along with others, have to get prevention and treatment out promptly or people will start dying.

The goal of this textbook is to enhance the education and training of health professions students, faculty, and other individuals interested in advancing their knowledge and skills in health systems science (HSS), with the ultimate aim of improving the health of patients and populations. Each chapter of this book is intended to provide an overview of useful, applicable information and concepts in HSS—the third medical science—as part of an integrated triad with the basic and clinical sciences. Competence in HSS is necessary for practitioners to proficiently serve patients in both current and future health care environments. The story of Alex and the Abrac Pox Virus that begins before this section continues throughout the chapter and demonstrates how HSS makes stopping this future epidemic possible before anyone dies or is severely affected by this

fictional virus. The domains of HSS range from patient safety to teamwork to social determinants of health, though all are rooted in systems theory. Physicians and other health care professionals with awareness of HSS principles are better positioned to ensure that patients, communities, and populations achieve optimal health outcomes.

HSS should not be viewed as a static set of domains and processes. Rather HSS is a dynamic, developmental, contextually based paradigm that will demand transitions in focus, curricular objectives, knowledge, attitudes, and skills as the domains of science it represents change, evolve, morph, and are created de novo. For example, who would have predicted 50 years ago that electronic media would be as central to most people's professional lives as it is today? Who can predict how electronic health records and other clinical informatics will develop in the next 50 years? Critical discoveries of the last decades in the basic sciences that have gone "bench to bedside," such as genomics, are often outpacing HSS elements—from ethics and policy to financing. HSS needs to constantly evolve. Physicians and other health care professionals engaged in lifelong learning need to incorporate these developments into their practice of medicine as quickly and seamlessly as possible.

The future is impossible to predict, but it is wonderful to speculate. It is also critical that current health professions students and practitioners prepare themselves for whatever develops if they are to be effective in providing powerful preventive and curative services. Having a framework that includes HSS should assist in this preparation. The gap between changes in the health care system and developments in health professions education must be as narrow as possible, and the catalyst for transformation may come from either direction. The area of value-added educational interventions illustrates this; students are capable of providing population-based interventions that can change the function and outcomes of the health care system.

Viewing medical education as an element of the health care delivery system provides a new perspective on the goals of, and processes for, training. This textbook has elucidated multiple challenges in the current system, potential drivers of suboptimal performance, and strategies for improvement. If the system is not performing at its best, gaps in education and how to fill them should be considered. Anticipating the future of the health system enables agility in educational approaches to better integrate learning with care delivery.

In a learning system, all learners work and all workers learn—and this dynamic should begin early and continue throughout one's professional lifetime as part of lifelong learning for the master adaptive learner. Some medical schools are now implementing early experiences in HSS, reminiscent of the movement in the latter half of the 20th century to implement early clinical experiences into what was a predominantly basic science curriculum during the first 2 years of medical school.

For example, Penn State College of Medicine has successfully incorporated a core course in HSS that simultaneously pairs conceptual learning in the classroom with experiential learning in the health system.[1] First-year medical students within a few of months of entering medical school engage in value-added roles by serving as patient navigators across the health care system. Similarly, at the University of California, Davis, School of Medicine, a select group of students admitted to an accelerated

primary care track begin a longitudinal preceptorship experience almost upon entry to medical school.[2] They immerse themselves in a practice setting and very quickly identify with their roles as advocates and change agents. At the University of California, San Francisco (UCSF), School of Medicine, first-year students learn how to improve the health of populations and effectiveness of health care systems. They are taught early clinical skills and health systems improvement skills and embedded into clinical microsystems where they identify quality improvement and patient experience needs which they can help to address. At the Warren Alpert Medical School of Brown University, students in the dual-degree MD-ScM Primary Care-Population Medicine program participate in the integrated HSS curriculum (with population health, patient navigation, quality improvement, research, and leadership components) throughout their 4 years of study with clinical experiences tailored for their developmental and curricular stage.[3]

Health professions learners across the full educational continuum are co-creators of the evolving health care system and its alignment with the future of HSS. The drive to prepare systems-ready caregivers will also involve facilitating the development of systems-ready patients who will increasingly engage in bidirectional communication and shared decision making for individual decisions and for those involving the scope and direction of the health care system.

Future societal, systems, physician, and other health care professional trends will dramatically affect HSS. This chapter attempts to identify some of these major trends and how they might influence the future of the field.

II. Future trends and their implications for health systems science

A. Societal trends

1. Demographics—population change

7:00 a.m., MAY 15, 2041; IN TRANSIT TO BLOCK 43:
While in transit to Block 43, Alex, his preceptor Dr. Bella, and the others on the team review the demographic data on the area, an educational module on Abrac Pox Virus, and strategies for containing an outbreak. They are not traveling together but are able to have a virtual meeting to discuss potential strategies. Their augmented intelligence tools constantly provide graphic input as to the spread of the outbreak, the spectrum of cases, and the resources immediately available for prevention and treatment, as well as analysis of data and therapeutic options.

Everyone living in Block 43 has at least some access to a base level of health care, although the top 15% of earners have the most access. Vaccination rates are lowest at the bottom because structural issues such as lack of transportation or technology interfere with accessing care. There are also competing priorities, including accessing food and care for ongoing chronic conditions, that can take precedence over preventive care.

Vaccination rates are equally low among top earners because although Abrac Pox vaccines have an excellent safety record, untrue stories about side effects have been circulating and increasing resistance to vaccination. In addition, about 10% of the population are recent immigrants. They do not speak the language of the team or others who live in the neighborhood, and although interpretation tools are easily available, there are pockets of mistrust about the use and potential abuse of this technology. Other challenges in the neighborhood include an elderly population (average age 109), some of whom are socially isolated but who are at high risk of death if they contract this virus.

Abrac Pox Virus is highly contagious. It only takes two unvaccinated individuals to trigger an outbreak.

Simply stated, US health care providers provide care for the US patient population—and that population is rapidly changing. The US Census Bureau estimates that by 2030, one in every five Americans will be older than age 65 and that immigration will overtake natural increase (the excess of births over deaths) as the primary driver of population growth.[4] These demographic changes will require physicians and other health care professionals to care for an aging and a more diverse population. Chronic conditions such as heart disease and stroke, cancer, diabetes, respiratory ailments, and arthritis will take up an expanding proportion of the United States' health care effort and health care dollars. Six of 10 Americans have at least one chronic condition,[5] and the care of chronic disease is one of the leading drivers of the nation's $3.3 trillion in annual health care costs.[6] Caring for a growing number of patients with expanding lists

of chronic conditions will require significant understanding of and changes to HSS—from health care organization and financing to workforce considerations. In addition, the greater population and ethnic diversity will demand improved language skills, translator services, or both and greater cultural and epidemiologic appreciation of patients and communities who are different from their physicians and other health care professionals.

2. Environmental—climate change

7:30 a.m., MAY 15, 2041; IN TRANSIT TO BLOCK 43:
One of the main sticking points in the virtual meeting was how to address, if they address it at all, the issue of climate change in their response. They were going to be down a team member because wildfires in Block 24 meant that one of the nursing students could not leave his home. The rise of 4° in the average temperature in the region over the past 50 years was the reason they were even dealing with Abrac Pox Virus in their area. As their region got hotter and dryer, Abrac Pox Virus and others formerly unknown to the region had been spreading. The response plan had been written in consultation with a physician with more expertise in the disease who lived 7000 miles away but was connected to their information system through the globally compatible electronic health and wellness record. They decided that the current situation was in part created by climate change, but they otherwise did not have to alter their response, although they did have to move fast. A tornado, which previously had been a rare occurrence in the area, was expected that night. They needed to get in, do their best, and get out safely before transit would become impossible for a few hours.

Environmental changes brought on by global warming will have ever-increasing effects on the health of the population and future health systems. Despite political controversy, most of the leading scientific organizations worldwide have issued statements endorsing the findings that climate warming is extremely likely to be due to human activities and that this warming is expected to impact population health. Two former US surgeons general, one nominated by a Republican president and the other by a Democratic president, declared that they "see climate change as a growing threat to the health of all Americans."[7] There are clear signs that global warming will have profound effects and that whole societies may fall victim to increased desertification, ever more violent storms, and more widespread flooding and forest fires, with ramifications for health, disease, and health systems. The three sciences of medicine (basic, clinical, and HSS) will need to respond accordingly. For example, greater consideration of the socio-ecological determinants of health and increased training in disaster planning and management may become more routine in health professions education and practice.

3. Distributed knowledge

7:45 a.m., MAY 15, 2041; IN TRANSIT TO BLOCK 43:
As the virtual meeting continued and the team members got closer to their destination, a student training to become a public health social media specialist revealed her impressions. She had been monitoring the major and minor social media streams for select keywords most associated with this type of outbreak. Her impressions, bolstered by augmented intelligence, were that the

outbreak was in the northwest corner of Block 43 among people with first- or second-degree connections to a day care center in a local house of worship that simultaneously met the needs of all religious groups in an atmosphere of peaceful coexistence and mutual respect. (These publicly supported houses of worship and day care centers had been set up across the globe after the widespread religious wars of the previous decades.) This day care center was not exclusive to those who were religious and was used by many families in the area.

In light of this information, Dr. Bella contacted the day care center and a local pediatrician in a small private practice who provided care for many of these children. The pediatrician sent out an alert to the families in her care and asked for permission to pass on information to the health care team that was coming to their area. The day care center, which had already started for the day, did not close. Rather, it sent out an alert to families and asked permission for the team to provide vaccinations and treatment, if appropriate. Drones that traveled near the speed of sound were already taking off and on their way with the refrigerated medications from a regional pharmaceutical supply depot.

The rise of the Internet, along with social media and innovative movements in medicine, such as shared decision making and the OpenNotes movement (which allows patients to see and even take part in their electronic health record documentation),[8] has increased access to health information for patients. This in turn has expanded the role of patients as partners in care. This movement is supported by a variety of developments, such as patient-facing medical information and patient support groups via social media. Patient-facing information systems are designed to provide a wide range of computer or Internet-based services that support patient interactions with the health care system.[9] The current trends in distributive knowledge are likely to expand further with advances in communication modalities and augmented intelligence. Such advances will not only affect doctor-patient communication but may change the structure of interaction, the balance of power, and the nature of decision making in clinical medicine.

4. Advances in science, technology, and the humanities

8:30 a.m., MAY 15, 2041; ARRIVAL AT BLOCK 43:

The team meets at the house of worship in Block 43. The day care center had parent/guardian permission for the team to see 60% of students. The remainder will be seen later that day.

Medical student Alex will administer vaccines. Dr. Bella will treat those showing signs of infection. Chris, a student in genetic and proteomic counseling, is testing children for a particular gene and protein profile. A tiny minority will not be vaccinated because the vaccine would not protect them. Diane, a student in medical engineering with a specialty in 3-D printing, will create custom tools as needed. Her job is especially critical since child-size bodies may not necessarily fit standard equipment.

The team sets up a small instant clinic at the day care center. The self-contained solar- and helium-powered clinic was delivered by hovercraft and has everything they need for a small to medium-size outbreak. They will contact later that day the families of children without parental or guardian consent for treatment or vaccination.

But then Alex notices an alert on his personal device about the possibility of infection elsewhere. The social media public health specialist confirms it. There is another case on the other

side of Block 43. Alex alerts the public health network, and the team, for the moment, keeps its focus on the day care center.

The next century is expected to bring unprecedented advances in science, technology, and the humanities that will have profound influences on our lives, on our health care, and in turn on HSS. Dramatic developments in the basic sciences (e.g., genomics and proteomics) are already being applied to the clinical sciences, and new technologies continue to emerge, such as 3-D printing, machine learning (a computer's ability to learn on its own by analyzing data and tracking recurring patterns), and the Internet of Things (IoT—the concept that all technological devices can be connected to the Internet and to each other in union between the physical and digital worlds). The humanities and social sciences are also advancing with greater understanding of everything from communities and the social nature of health and health care to structural racism and its effects on health to the role of empathy and forgiveness. These developments will most likely change both the existing HSS domains and the HSS competencies necessary for functioning in the future health care environment, as well as creating new critical HSS topics.

5. Glocalization

Glocalization is a linguistic hybrid of globalization and localization and is used to describe a global outlook adapted or modified to better fit local conditions. In business, this has been used to refer to a product or service that is developed and distributed globally but is adjusted to accommodate the user or consumer in a local market.[10] This concept is a refinement of the concept of *globalization,* which is considered as involving cultural homogenization with the subsequent domination of one culture or method of doing things over another.

Glocalization entails the interconnectedness of global and local levels. In health care, glocalization recognizes the necessity to tailor relationships, treatments, and messaging to local needs—whether talking about Ebola epidemics or quality control. Such tailoring in health care will require the application of multiple HSS skills and an alteration in worldview that accepts the requirement of fitting approaches to local conditions.

B. System trends

1. Systems citizenship

10:00 a.m., MAY 15, 2041; CITY 11, BLOCK 43, DAY CARE CENTER:
Although Alex is only in his first year of medical school, he is very familiar with the concept of systems citizenship, as are the other members of the team. Alex is administering vaccines, and he knows he has to administer as many as possible in a short amount of time. He won't be able to do that without the help of the day care staff and the members of his team.

He continues to administer vaccines. Alerts keep sounding about additional cases, but he keeps his focus on the task at hand. Other teams are automatically contacted, organized, brought up to speed on the latest developments in the outbreak, and dispatched to the field.

With the evolving understanding of HSS as a core domain of learning and practice, HSS will and must impact the professional identity formation of today's and tomorrow's physicians and other health care professionals—an identity as a systems citizen. The concept of systems citizenship describes a major evolution that needs to occur to realize the potential of HSS. This evolution pertains to the professional identities of trainees and the environment in which they learn and practice and recognizes the unprecedented interdependence and mutuality in professional lives. Representing a departure from the traditional "sovereign physician" identity in medicine, systems citizens embody both the motivations and behaviors embodied in the systems-based practice competency. Originally articulated by Peter Senge, systems citizens build genuine partnerships across boundaries, see patterns of interdependency, discern how a system is functioning, and connect with others to engage in a process aimed at achieving outcomes.[11] This conceptual framework translates to learners who become fluent in the language of teams, are knowledgeable across the full spectrum of HSS, and apply systems thinking skills in the process of collaborating, advocating, learning, and leading. They not only care for individual patients, but also know how to perform in developing systems of care and embody the motivation to grow and contribute to the emergence and evolution of the health care system itself. These sensibilities and skills must be nurtured at each level of training and in all health care settings.

2. Addressing social determinants of health

10:30 a.m., MAY 15, 2041; CITY 11, BLOCK 43, DAY CARE CENTER:
As the clinic progresses, the team notices a pattern. The children most likely to have received quick permission to be vaccinated or treated are those with parents with easy access to technology, either because they are not working outside the home or have jobs that permit personal access during work hours. It appears that the children most likely to be infected are from low-income families who do not speak any of the five most common languages in the area and who have inadequate access to nutritious food. The team is concerned that those who need the help the most may be least likely to get it. They agree that, after the initial batch of children is vaccinated or treated, they will huddle to identify strategies to get vaccines or treatments to children who most need it.

Over the past decade there has been an explosion of interest in the social determinants of health and an acknowledgment of their profound impact on health outcomes and disparities (see Chapter 12). The realization that the health and well-being of individuals, families, communities, and populations is determined far more by variables such as zip codes than medical care has led to new realizations and calls to action. This in turn has led to the founding of a myriad of projects and programs that aim to screen, measure, and intervene in reducing health disparities. Organizations at the local, state, and national levels—from the Robert Wood Johnson Foundation to the Centers for Medicare & Medicaid Services—are rushing into this domain. Multiple tools now exist for screening social determinants; however, the ability to intervene in response to the findings from these assessments—especially when they are in more than

one dimension, such as the lack of good housing and education plus inadequate food—remains elusive. In the future, these goals will be achieved through greater collaboration between health and service agencies and more sophisticated social determinant delivery systems. Some projects, such as the Practical Playbook,[12] already highlight examples of partnerships that simultaneously engage primary care and public health in efforts improve population health.

3. Incorporation of technologies

11:00 a.m., MAY 15, 2041; CITY 11, BLOCK 43, DAY CARE CENTER:
As the team continues to work, the local pediatrician contacts them because an incredibly sick child infected with this virus has just arrived in her practice. This child is now considered the index case for this outbreak. The team hones its focus to the children who spent the most time with this child.

The day care center also adjusts its security cameras to be more sensitive to body heat, tachycardia, and tachypnea, three newer biometric measures affected by this disease. This allows them to screen on a mass scale the people on site for fever. The team responds as appropriate.

Technology is being incorporated into care processes across the spectrum of health care and across all settings—from homes to tertiary care hospitals. For example, information capture is being augmented by wearables, home systems, facial recognition tracking patterns (dietary, activity, medication), and other means. The nearly ubiquitous use of electronic health records is expanding from health care providers to include patients and their families as patient portals and open notes become more routine.[8] Such innovations will require alterations in HSS elements such as workflows, information flows, and communication. Each technology will have its own challenges, and HSS solutions will be required. Examples of technologies affecting HSS are described in Box 17.1.

• BOX 17.1

Examples of Technologies Affecting Health Systems Science

Electronic health records (EHRs)

As described in Chapter 10, EHRs are rapidly expanding their capabilities in areas that will directly affect health care systems and health systems science (HSS). These include EHRs' rapidly increasing capacity to integrate and abstract records from multiple sites of care to patient safety features (e.g., drug allergies and drug-drug interactions) to data analytics and patient access to records.

However, there are major gaps in particular EHR capabilities that, unless addressed, may deleteriously affect HSS. For example, there is an urgent need for greater EHR accommodation of clinical workflow, interprofessional teams, and decision support tools. In addition, EHRs could benefit by including system-level variables in addition to the routine categories such as history, physical, allergies, problems, and medications. An example of such a system-level variable might be site of care. This item could focus

on whether the care was provided at the right place and time for the patient. Such dilemmas arise frequently in clinical practices regarding ambulatory sensitive conditions. Was the patient with disease or complaint *X* seen appropriately or inappropriately in the emergency department, or could their issues have been better addressed in a primary care or similar setting? A next-generation EHR might alert the care team and suggest transferring the patient to the appropriate setting. Similarly, an EHR program for rural hospitals might assist with decisions regarding the need to transfer particular patients to tertiary and quaternary care settings. Other EHR developments might include interactive holograms, natural language processing, and augmented intelligence.[34] Hardware and software developments now make possible the incorporation of wearable technology and smartphone applications into patient care. Further developments are nearly limitless and will affect HSS at every turn.

Nonetheless, it is becoming increasingly apparent that the near-ubiquitous penetration of EHRs into clinical settings is having broad effects on the communication skills that must be incorporated into health professions education. Health professions schools, however, are lagging in their adaptation of the teaching of communication skills to new settings and new forms of interaction.[35] When computers are used in provider-patient encounters they essentially become the "third party" in the consultation room,[36,37] yet students and trainees rarely receive training in how to optimize communication in these settings or how to actively engage patients in the EHR. EHRs can be seen as affecting all six domains of clinical competency introduced by the Accreditation Council for Graduate Medical Education.[38,39] This area is ripe for further guidelines, research, and HSS curriculum development, since it has implications for learning across the full educational continuum.

Big data

The ever-growing capability of clinical information systems to gather, store, and analyze vast amounts of data for individual patients, physician patient panels, or populations opens up infinite possibilities. Aided by advances in the science of data management and analysis, these advances should enable everyone from students to physicians to organizations in converting these vast resources into information and knowledge.[40]

Augmented intelligence (AI)

AI has been defined as the theory and development of computer systems able to perform tasks that normally require humans, such as visual perception, pattern and speech recognition, and decision making. Unlike other tech tools, AI systems have the capacity to evolve via deep learning. AI offers the opportunity to augment human intelligence; physicians who integrate well with this technology will be most effective. Most immediately there are issues regarding accreditation, liability, informed consent, and bias that need to be addressed.[41]

C. Health care provider trends

1. Triple aim/quadruple aim

1:00 p.m., MAY 15, 2041; CITY 11, BLOCK 43, DAY CARE CENTER:
The team continues to work even though they have surpassed the maximum number of hours allowed. In order to prevent burnout, physicians and other health care professionals, including students, are restricted in the number of hours they can work and the number of patients they can see. These restrictions have been suspended in this outbreak.

There has been a growing realization in the United States that the Triple Aim[14] of improving the health of populations, improving the patient's experience of care, and reducing costs is not sufficient to address the major issues in medicine. Although widely accepted as a road map to optimize health system performance, the Triple Aim neglects to recognize that

> physicians and other members of the health care workforce report widespread burnout and dissatisfaction. Burnout is associated with lower patient satisfaction, reduced health outcomes, and it may increase costs. Burnout thus imperils the Triple Aim. This article recommends that the Triple Aim be expanded to a Quadruple Aim, adding the goal of improving the work life of health care providers, including clinicians and staff.[15]

More recently it has been realized that although personal interventions such as mindfulness training can be helpful, burnout requires structural systematic approaches, not just strategies focused on the individual.

2. Shifting preferences in learning approaches

Learning preferences of students are likely to be recognized further as education and training become more individualized, building on the:

- Differing experiences of students prior to medical education
- Millennial students being accustomed to short bursts and immediate access to information
- Demand for more tailored learning and individualized pathways
- Improved educational information technology platforms that can evaluate, measure, and attend to individual knowledge, skills, and competencies
- Shifts in medical education structure

Health professions education is leaving the confines of the brick and mortar classroom. Online capabilities and advances in information technology have facilitated the expansion beyond the walls of health professions schools and teaching hospitals for the last few decades. This expansion will accelerate. Some, like the editor of *JAMA,* have suggested that the future of medical education in the United States includes, "No walls, no classes."[16] Such liberation will allow training to occur in varied settings, wherever learning and health care can occur. Students have already voted with their feet in many

medical schools where lectures are recorded. Students often watch lectures at home, using higher speeds for sections more easily understood and multiple, slower viewing of sections that are more difficult to conceptualize. Some medical schools accelerate further devolution of the classroom by recording lecturers in studios, without students present.[17] The online learning explosion (from local productions to MOOCs—massive open online courses) and the "flipped classroom," as well as the expansion and diversification of educational platforms and forums, will likely accelerate in the future. Recently the University of Vermont Larner College of Medicine decided to transition away from lectures to "100% active learning."[18] Such trends will influence the methods and content of learning, including HSS. Similarly, health professions training, to remain aligned with health system needs, will increasingly follow health care wherever it occurs in the community, including in patient's homes. The evolution of clinical care for patient populations beyond the hospital and usual clinic settings to accountable care organizations, patient-centered medical homes, community health teams, and the use of telemedicine and other technologies may further hasten the movement beyond conventional medical school walls. The University of North Dakota School of Medicine and Health Sciences is leading in this area by enhancing medical education through advanced simulation and telemedicine technologies to teach interprofessional competencies along with rural health care skills. Some medical schools are already following in this direction, and more will likely follow.

3. Ensuring readiness for roles

In order to ensure readiness of health professions students for roles in the health care system, formal education and role modeling in both educational and clinical settings must be routinely required and provided. To reach the intended audiences in a systematic manner will require both expanding current educators' skills and recruiting a new cohort of educators, especially interprofessional clinicians, as well as creating validated assessment tools for HSS. Such assessment tools may include the gamut of current medical education evaluation methodologies, such as competencies, milestones, and entrustable professional activities. Uses of competency-based educational outcomes[19] range from guiding learning to feedback, evaluation, and certification. Assessment tools must emphasize the key tenets of HSS, encourage lifelong HSS learning, and be translatable into professional behaviors. Proposed competencies for optimizing health care delivery and systems science have been put forward by Lucey,[20] and the authors and editors of this textbook have also proposed new competencies. Finally, attention needs to be paid to potential metacognition and cognitive pitfalls in order to devise strategies to help learners overcome them.

4. Collaborative orientation (interprofessional education)

A desire for collaboration, especially in the workplace, is one of the key characteristics of millennials, the generation born from 1980 to 2000 that comprises the majority of the current medical student population and younger physicians.[21] By 2025, the millennial generation will comprise 75% of the workforce, including the health care workforce.

This is a generation that is generally more comfortable working in groups than individually. They tend to be less hierarchical and are not as limited by set ideas about roles. This means they are particularly well suited to work in the interprofessional teams that are increasingly central to the modern health system. Millennial physicians and other health care professionals also are better positioned for more collaborative relationships with patients. They are more likely to ask their patients to come in with their own research, whereas older physicians from other generations may be more dismissive of patient research.

While the current generation of medical students, and in turn the latest generation of physicians, is more interested in teamwork, they are also interested in recognition of the diverse roles within teams. This all means that teamwork and team science will be more important than ever.

5. Structural competency and addressing structural bias and racism

Structural competency refers to a medical education and clinical paradigm that recognize the influence of structural-level determinants, biases, and inequities in shaping health. It acknowledges the role that pathologies in social systems have in shaping individual outcomes and encourages learners to actively think about and engage with those broader structural factors. Structural competency encompasses systemic racism, societal stigma, structural violence, and other structural mechanisms. It takes trainees beyond the traditional cultural competency framework, which focuses on provider-patient cross-cultural differences in race, religion, social class, sexual orientation, or other characteristics and misses the broader structural context of marginalization and disparity. Five core components of structural competency have been articulated by Metzl and Hansen[22]: "(1) recognizing the structures that shape clinical interaction; (2) developing an extra-clinical language of structure; (3) rearticulating 'cultural' formulations in structural terms; (4) observing and imagining structural interventions; and (5) developing structural humility." Traditionally, clinicians are trained to listen to and act on individualized stories, but structural competency demands the recognition of structural forces impacting a patient's presentation and interventions on individual, systems, and societal levels. A social medicine case series by the *New England Journal of Medicine* illustrates how structural competency can be integrated into medical education and clinical care.[23]

The last few years have witnessed an increased awakening and engagement around diversity issues in the health professions and in health professions training. Part of this includes greater recognition and acknowledgement of structural bias and racism and their effects on workforce diversity, patient care, and outcomes. Race has often been perceived as a biologic variable in the basic and clinical medical sciences, but this understanding is being challenged as more critical thinking emerges. A major driver of these changes can be traced to the power and influence of broader social movements such as Black Lives Matter and #MeToo.

Structural bias and racism in health care impede efforts to promote diversity in the professional workforce and in academia. There is so much further to go in addressing these issues in health care. The statistics remain egregious. The share of African

American men entering medicine has hit historic lows,[24] and women remain woefully underrepresented in positions of power in health systems. In the United States currently,

> only 3% of health care CEOs are women, 6% are department chairs, 9% are division chiefs, and 3% are serving as chief medical officers. This is despite women comprising 80% of the health care workforce and evidence that having women in upper management and on corporate boards is associated with improved financial performance and enhanced accountability.[25]

Active discussion of race, ethnicity, gender, and culture in health professions education and in medicine is expected to increase over the next decade. This increase will not just be focused on the current "isms"; rather, the emergence of other dimensions and domains of diversity is expected. Some of these are just in the discussion phase, such as socioeconomic status of medical school applicants, sexual identity/preferences, and the use of pronouns. Others are present in other disciplines and fields but have yet to enter the health professions discourse, such as generation gaps, personality types, digital experience, first languages, and life experiences.

6. Admissions to medical school

As HSS becomes more established as the third science of medicine, health professions schools may rethink their admissions processes and standards to ensure that applicants have the capacity to acquire the knowledge, attitudes, and skills required for success in this field. For example, future requirements for admission may include experience working in teams and information technology skills, as well as courses in health economics and advanced communication. Admission criteria might also include the ability to function in complex adaptive systems, to tolerate uncertainty, and to maintain resilience. In addition, applicants may be screened to ensure they have a modicum of social responsibility and the capacity to be change agents. Tools that have sufficient reliability and validity to select such students will need to be developed. The multiple mini-interview format[26] may be an example of a method that could be amplified in its reach. It has already been employed by an increasing number of medical schools, starting with Michael G. DeGroote School of Medicine at McMaster University in Canada, to help identify desirable behaviors, such as communication skills.[27]

III. Health professions students and trainees as master adaptive learners and change agents

3:00 p.m., MAY 15, 2041; CITY 11, BLOCK 43, DAY CARE CENTER:
As the day progresses, Alex has applied his skills at delivering vaccines rapidly in a difficult situation. He has also learned how to screen out people already sick and send them to Dr. Bella.

The team is now huddling to determine how to get to those who have not yet received vaccines or other care, but they don't have much time. The tornado is still on the way, and they have to get out of the neighborhood within 3 hours or else they will be spending the night. They decide to target children they have not yet reached but who had close, direct contact with the sickest child in the care of the local pediatrician. This is a time-intensive approach. They have to go to people's homes, but the list is short. They use augmented intelligence to create a map of homes to go to and ways to get there. They start with the closest one, and they will proceed until they are out of time.

Change is ubiquitous and unavoidable in health care. Traditional approaches to education that emphasize only the basic and clinical sciences do not prepare health professions students, trainees, and practitioners for their future careers. Health professions student trainees will need to become master adaptive learners and change agents in HSS in order for them to survive and thrive in the future health care environment and to ensure that individuals, families, communities, and populations receive the best possible care. The Master Adaptive Learner (MAL) concept "describes a metacognitive approach to learning based on self-regulation that can foster the development and use of adaptive expertise in practice."[28] This means health care professionals must be able to rapidly access and interpret constantly evolving data and understand how to use the new information to provide the best care possible to patients and populations.

The creators of the MAL model believe everyone involved in the health professions must develop critical analytic lifelong learning skills in gaining competency in all areas of the medical sciences, including HSS—the right knowledge, attitudes, and skills at the right time and the right place. To achieve this, those behind the MAL model suggest the integration of learning with work processes and the adoption of their model. Learners have been and will continue to be major change agents for health care and health professions education, including HSS.

Students can and do contribute to improvements in patient care. Medical schools around the country have been developing value-added roles for students and trainees that lead to achievement of the Triple Aim. As suggested by Lin and colleagues,[29] change "is desperately needed to translate education into better health outcomes for Americans today." Both Lin and colleagues[29] and Lucey,[20] as well as others, advocate for "value-added medical education" where students' experiential learning experiences can measurably improve health care system processes of care and patient outcomes, adding both value and capacity to the health care system.

An example is the novel academic program at Penn State College of Medicine, detailed earlier, that utilizes medical students as patient navigators. This program is a "win-win" for students and patients since the former learn how to navigate the complex health care system through the patient's eyes while the latter are helped to overcome hurdles that include insurance issues, medication concerns, and follow-up.[30] At UCSF, where much of the pioneering work on value-added medical education began, there are programs to improve patient outcomes through medical education,[31] leveraging the talents and commitments of students to add value to the care of patients today. Though these efforts must be supervised to ensure that patients and students truly benefit, they hold promise for further student engagement in the health care system. Another value-added role for medical education involves faculty development. The Brody School of Medicine at East Carolina University (ECU) has established a comprehensive longitudinal core curriculum in patient safety, quality improvement, population health, and team-based care.[32] To execute and facilitate these curricular changes, ECU has established its Teachers of Quality Academy to provide faculty development in the new competencies. Faculty who are trained in this academy in turn train students. They will both be able to bring their quality improvement projects back to their health systems where implementation should improve patient care for individuals and populations.

Future health care professionals must be able to engage in practice-based improvement and systems-based improvement if they are to serve as change agents for the health system. Such experiences have been relatively common in student-run clinics, 96 of which are said to be operating in the United States according to the Society of Student Run Free Clinics.[33] However, other opportunities should be encouraged to facilitate students gaining experience in this important HSS domain. The innovative programs noted at Penn State, UCSF, and ECU are just a few examples of what is possible. The new University of Texas Rio Grande Valley School of Medicine places medical students at health centers in impoverished rural settlements in unincorporated areas along the United States–Mexico border. Students are taught strategies to support information exchange and empathetic interactions with individuals and diverse groups in multiple settings for numerous preventive health, health maintenance, and health care delivery purposes. This new medical school is in one of the most medically underserved areas of the United States, and its transformative program will improve local practices and health systems, along with educating the next generation of physicians to be effective in such settings.

IV. Future directions for health systems science

Since the first edition of this textbook was published in 2016, thousands of copies have been sold around the world, and it has been implemented at dozens of institutions, including medical schools, other health profession schools, and business schools. The *Health Systems Science Review* book has been published to help educators create HSS assessments and students prepare to take them. The American Medical Association has launched the Health Systems Science Learning Series, a set of online modules. Beyond the products that are a direct result of this textbook, HHS is increasingly viewed as the third science, critical to undergraduate, graduate, and continuing medical education.

This textbook must always be a living document evolving with the shifts in the social, scientific, and economic context of health systems and health professions education. The authors envision that students, faculty, and patients will engage in thoughtful dialogue that will spur the further evolution and development of HSS that will be beyond what the authors ever could imagine.

Other individuals and groups also will work to influence the content and direction of this third science. Stakeholders range from social activists and social movements to trainees, physicians, other health care professionals (including interprofessional care groups), social and behavioral scientists, and, of course, patients. All are welcome as HSS develops.

V. Chapter summary

5:00 p.m., MAY 15, 2041; CITY 11, BLOCK 43, IN THE NEIGHBORHOOD:
The team spends the rest of the afternoon going to people's homes. Some are more amenable to their approach than others. For those who are most resistant, they contact a teacher at the school to have a video conference with the family. This is usually enough to convince them that the team is legitimate.

Finally, the alerts of new cases stop coming. Their work and that of other teams has had the desired effect. The outbreak has been contained. No one died during this one, and it is time to go home.

This chapter has attempted to provide the rationale for viewing HSS as a dynamic and evolving domain and field of inquiry as well as articulate several future trends and their possible implications for the health system and for health professions education. This chapter also examined the role of learners as change agents—for patients, the health care system, and the future of HSS.

Efforts to foretell the future of health care and health professions education in the United States and the world are pervasive in academia, business, and politics. However, despite prognostications and predictions about the future, many developments will occur that cannot even be imagined now. In these, as in all scientific investigations, "Chance favors the prepared mind" (Louis Pasteur), and a firm grounding in the three sciences of medicine—basic, clinical, and health systems—will provide sound preparation. Whatever happens in the future, it is crucial that these three sciences be integrated in as seamless a manner as possible into the training and lived experience of learners and practitioners, who engage in lifelong learning. Careers and the future of patients, communities, and populations depend on it.

Questions for further thought

1. In what ways is health systems science a dynamic, rapidly changing field?
2. What are some of the trends in US health care that currently affect what should be taught in US medical schools?
3. What do you see as the future of the US health care system in 10, 20, and 50 years, and what new knowledge, attitudes, and skills will be required in terms of health systems science?
4. What is "value-added medical education?" What meaningful roles can students play in health care systems to facilitate their learning while contributing to improving health system processes and patient care outcomes?
5. What are the potential benefits to physicians and to the health of patients and populations if all health care professionals master the knowledge, attitudes, and skills in the various domains of health systems science?

Case study 1

You are a second-year medical student who has decided to set up a free clinic in the underserved community near your medical school. You've pulled together a committee of 20 enthusiastic students and 6 primary care attendings. You and your clinic receive free space from a local community agency and plan to operate three evenings a week, with students from the medical, nursing, and social work schools in the area, as well with the help of faculty who will volunteer their time.

1. What health system issues must you and your colleagues consider and resolve prior to opening and operating the free clinic?
2. What knowledge, attitudes, and skills must you ensure are acquired by students working in the free clinic?

Case study 2

You are working at a large academic health center in the Midwest that has operated under a fee-for-service model for the last 50 years. During this time, it established large, costly, resource-intensive, specialized medical and surgical services focused on organ transplantation and joint replacements. These units have been profit centers for the academic institution, supporting much of its teaching and research mission. In the meantime, the health center developed only a rudimentary primary care network, leaving this to a nonacademic rival across town. In the new health care environment, all the insurers in the state move to value-based care with set per-member per-month payments, supplemented by a quality indicator incentive.

1. How might these changes affect the resource-intensive services that suddenly become cost centers? How will the academic health center need to change to ensure its future viability?
2. What population health strategies should be considered?

3. Consider the different roles you may have in this health center. How might these changes affect you, depending on your role?

Case study 3

You are a young attending physician who has been charged with integrating a new promising technology into your health system. The technology has the potential to reverse end-stage congestive heart failure but has only been used in experimental trials.

1. What health systems science domains must you consider?
2. What should be the first steps in areas such as training, implementation, quality, safety, and finances?

Exercise

Identify one trend in health care that you believe will be particularly important in the near and distant future. Write a paragraph or a list of bullet points about how it will impact you and how you will ensure that the impact is beneficial rather than detrimental. Consider how one or more of the core components of health systems science will impact this trend. Discuss with colleagues—and look for alternative interpretations.

Annotated bibliography

Bodenheimer T, Sinsky C. *From Triple to Quadruple Aim* care of the patient requires care of the provider Ann Fam Med 6, 2014;12: 573-576.

This article builds on the Triple Aim of enhancing the patient experience, improving population health, and reducing costs—tenets that are widely accepted as guideposts to the optimization of health care system performance. The authors believe the Triple Aim is insufficient since physicians and other health care professionals report widespread burnout and dissatisfaction, which is associated with lower patient satisfaction, reduced health outcomes, and increased costs. This article recommends that the Triple Aim be expanded to a Quadruple Aim, adding the goal of improving the working lives of physicians and other health care professionals.

Lin SY, Schillinger E, Irby DM. *Value-added medical education* engaging future doctors to transform healthcare delivery today J Gen Intern Med 2, 2014;30: 150-151.

Medical student education typically ignores current problems in health care delivery and does not address the pressing societal challenges. Change is desperately needed to translate education into better health outcomes for all people. The authors advocate for "value-added medical education," whereby powerful experiential learning experiences add value and capacity to the health care delivery system. Medical students can be trained and can become involved in a variety of targeted patient care tasks.

Lucey CR. *Medical education* part of the problem and part of the solution JAMA Intern Med 17, 2013;173: 1639-1643.

High-quality health care requires that medical educators accept a social contract to reduce the burden of suffering and disease through the education of doctors. "Medical schools and residency programs must restructure their views of basic and clinical science and workplace learning to give equal emphasis to the science and skills needed to practice in and lead in complex systems. They must also rethink their relationships with clinical environments so that the education of students and residents accelerates the transformation in health care delivery needed to fulfill our contract with society.".

Tierney MJ, Pageler NM, Kahana M, Pantaleoni JL, Longhurst CA. *Medical education in the electronic medical record (EMR) era* benefits,

challenges, and future directions Acad Med 6, 2013;88: 748-752.

This article reviews the effects of EMR use on medical learners through the lens of the six core competencies for medical education promulgated by the Accreditation Council for Graduate Medical Education. The authors examine educational benefits and risks of EMR use, discuss factors that promote successful use when implemented in academic environments, and identify areas for optimization and future research on the EMR's role in medical education.

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Glossary

Accountable care organization (ACO) An organization that brings together groups of doctors, other health care professionals, and a varying range of health care delivery facilities (e.g., hospitals, nursing homes, home care) to provide coordinated care, generally with financial incentives and careful attention to quality and outcomes. An ACO usually contracts with Medicare, Medicaid, or private payers, or a combination of these to share in savings achieved while quality goals are maintained or exceeded.

Accountable care teams Those working with an ACO to maintain or exceed quality goals while reducing health care expenditures. Teams may include physicians, physician assistants, nurses, nurse practitioners, pharmacists, case managers, medical assistants, hospitals, ambulatory care centers, urgent care centers, retail clinics, administrators, and other types of professionals or health entities.

Accreditation Council for Graduate Medical Education (ACGME) competency domains ACGME's six core competency domains that every physician should have are medical knowledge, patient care, professionalism, interpersonal communication, practice-based learning/personal improvement, and system-based practice/system improvement.

Active failures or active errors Errors involving frontline personnel and occurring as the result of an individual's action. These errors occur as the result of mental lapses, errors in judgment, or procedural violations. Examples include administering the incorrect medication, performing surgery on the wrong site, or ignoring an alarm.

Adverse drug event Harm caused by a drug. It may or may not be the result of an error.

Adverse event Harm caused by medical treatment. It may or may not be the result of an error.

Afferent limb Part of a rapid response system. Usually composed of bedside clinicians empowered to use predefined criteria to trigger the rapid response team, bypassing the traditional hierarchy, in order to expeditiously deliver necessary expertise and equipment to a patient.

Affordable Care Act The Patient Protection and Affordable Care Act of 2010, a federal statute also known as "Obamacare."

Antitrust laws Federal and state statutes or regulations, enforced by the US Department of Justice, the Federal Trade Commission, state attorneys general, or private lawsuits, or a combination of these, that preserve market competition in the private economy.

Artificial intelligence/augmented intelligence Artificial intelligence is the use of computational methods to perform tasks normally requiring human intelligence. A more appropriate term in health care is *augmented intelligence,* reflecting the enhanced capabilities of human clinical decision making when boosted by computational methods.

Authority gradient The psychological distance between a worker and a supervisor.

Beveridge system System where health care services are financed by taxes.

Bias An inclination of temperament or outlook. A personal and sometimes unreasoned judgment. Can be helpful or harmful. A systematic departure from the truth due to design or measurement characteristics.

Biomedical and health informatics The discipline devoted to the efficient storage, acquisition, and use of information in biomedicine and health. The subset focused on informatics in health care is clinical informatics.

Biopsychosocial (BPS) model of medicine A conceptual model and systems approach developed by George L. Engel that incorporates biologic, psychological, and social factors and their complex interactions in understanding health and illness in context.

Bismarck system System where health care services are financed on the basis of insurances provided by sickness funds or insurers.

Block grant payment system Payment system where a fixed amount, per period per provider, is used.

Blunt end The many layers of a health care organization that are removed from direct patient contact but directly influence what happens to a patient.

Bundled payments Incorporating expected costs for a typical encounter or episode of care into a single payment.

Case law (also called common law) Law created by federal or state judges in the course of deciding a lawsuit.

Case management A collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and a family's comprehensive health needs. May include the provision of services and goods not traditionally provided in the health care setting that may improve a patient's health.

Case manager Health care professionals who help provide an array of services to assist individuals and families to cope with complicated health or medical situations in the most effective way possible.

Clinical data warehouses Central repositories of data where information is integrated together from disparate sources. Typically maintained at the institutional level.

Clinical decision support (CDS) A component of health information technology that provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to

enhance health and health care. CDS tools include computerized alerts and reminders to care providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information, among other tools.

Clinical informatics The subset of informatics focused on health care.

Clinical pathways Standardized, evidence-based clinical decision tools developed to guide practice at the local level.

Cognitive science The study of how decisions are made.

Common Rule A term used to describe federal statutes and regulations that set forth a consistent ethical framework for most research involving human subjects in the United States.

Communication and Resolution Program (CRP) An organized response to medical error that prioritizes transparency, immediate assistance to patients and families, timely compensation for unreasonable care, safety improvement, and caregiver support.

Community health needs assessment (CHNA) A collaborative process between health care organizations and community residents and organizations that uses quantitative and qualitative methods to systematically collect and analyze data to understand health needs within a specific community.

Comparative effectiveness research Designed to inform health care decisions about drugs, medical devices, tests, surgeries, or ways to deliver care by providing evidence on the effectiveness, benefits, and harms of different options.

Computerized provider order entry (CPOE) The act of entering medication orders or other physician instructions electronically instead of on paper charts.

Constraint A limitation in a system requiring an individual to slow down at a critical juncture and complete certain steps or goals in order to proceed with the intended action. Intended to create situational awareness and a recognition that an event has increased potential for harm and all focus should be on preventing such harm.

Core Entrustable Professional Activities for Entering Residency (CEPAER) Activities defined by the Association of American Medical Colleges that residents should be able to perform on the first day of residency without direct supervision, regardless of specialty choice.

Cost-sharing In health insurance, money that insured individuals must pay out-of-pocket as deductibles, copayments, and co-insurance obligations, in connection with receiving covered services.

Critical period A limited time window in an individual's life during which an exposure can have adverse or protective effects on development and subsequent disease outcome.

Damages Money demanded by a private party under law as compensation for injury,

whether or not the injury consists of money lost or forgone, or as punishment for reckless or intentionally harmful conduct.

Data analytics The extensive use of data, statistical and quantitative analysis, explanatory and predictive models, and fact-based management to drive decisions and actions.

Determinants of health The multiple factors influencing an individual's health and the health of populations. Determinants can be behavioral, genetic, social circumstances, environmental exposures, or health care, or a combination of these.

Diagnostic error The failure to establish an accurate and timely explanation of a patient's health problem(s) or to communicate that explanation to the patient.

DRG Diagnosis-related group.

DRG-based payment model Model using DRGs primarily to remunerate health care costs.

Efferent limb The part of a rapid response system that responds to a situation when alerted by bedside clinicians (the afferent limb). Team composition varies based on the local needs. Most rapid response teams do not include a physician and are usually led by advanced practice providers, nurses, or respiratory therapists.

Electronic patient portal A secure online tool that gives patients 24-hour access to personal health information.

Error Not completing a planned action as intended or using the wrong plan to achieve an aim.

Event analysis A structured method used to analyze serious adverse events. A central tenet is to identify underlying issues that increase the likelihood of errors while avoiding focusing on the mistakes of individuals. May also be referred to as *root cause analysis.* Event analysis is becoming the more common term because adverse events may have more than one cause.

Evidence-based medicine or evidence-based practice The intersection of best available evidence, best clinical judgment, and the patient's values.

Fee-for-service model Paying physicians and other health care professionals a fee for each service provided.

Fiduciary duties In certain relationships (parent to child, physician to patient, lawyer to client), the legal and ethical obligations to a dependent person by the person depended on.

Flattening the hierarchy Creating an environment in which all members of the team feel safe providing input, are valued for speaking up, and are not deprecated for doing so.

Formulary system An ongoing process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best

serve the health interests of a given patient population.

Fraud and abuse Conduct involving delivery of or billing for services that violates the rules of government health insurance programs such as Medicare and Medicaid.

Health care delivery system An organization of people, institutions, and resources that delivers health care services to meet the health needs of target populations.

Health care improvement A broad term that encompasses traditional process and quality improvement and patient safety efforts to close gaps aligned with the six Institute of Medicine dimensions of quality.

Health care market failures Impediments for efficient, effective, and socially acceptable allocation of health care services.

Health care team A team of health care professionals who provide diagnostic and therapeutic procedures to a patient.

Health disparities Differences in health and health outcomes among groups of people.

Health equity Attainment of the highest level of health for all people.

Health information exchange (HIE) The mobilization of health care information electronically across organizations within a region, community, or hospital system. HIE may also refer to the organization that facilitates the exchange.

Health Leads An online instrument developed at Boston Medical Center with support from the Robert Wood Johnson Foundation to lead patients to community and health system resources related to the specific needs that they express.

Health policy A law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions. Decisions, plans, and actions that are undertaken to achieve specific health care goals within a society.

Health systems science The principles, methods, and practice of improving quality and patient experience, outcomes, and costs of health care delivery for patients and populations within systems of medical care.

Heuristic A pattern or "rule of thumb" used to approach a problem.

High-performing system A system performing dramatically better than other systems as measured by one or more criteria.

High-reliability organizations (HROs) Organizations that operate in complex, hazardous environments making few mistakes over long periods of time. A key aspect of HROs is a focus on teams.

HIPAA Regulations adopted under the Health Insurance Portability and Accountability Act of 1996 that constitute the principal federal health care privacy law in the United States.

Hospitalist An inpatient physician who works exclusively in a hospital.

Individual factors Aspects of an individual that impact how a patient interacts with the health care system or how a physician or other health care professional provides

care.

Informed consent In both medical treatment and research involving human subjects, the ethical and legal obligation to disclose risks, benefits, and alternatives of proposed interventions and receive permission to proceed.

Institute of Medicine (IOM) A division of the National Academies of Sciences, Engineering, and Medicine. The Institute of Medicine was renamed the National Academy of Medicine in July 2015.

Institutional context External regulatory agencies, the medicolegal environment, and financial constraints that impact an institution.

Institutional Review Board (IRB) A self-governing body mandated by federal law to evaluate, approve, and monitor research involving human subjects.

Integrated health care system A health care system that aligns the incentives of health care professionals in order to deliver value-based care for its patient population. The integration can be vertical or virtual.

Interdisciplinary team A team of health care professionals from a variety of disciplines who coordinate care and base professional relationships on shared goals, shared knowledge, and mutual respect.

Interoperability The ability of two or more systems or components to exchange information and to use the information that has been exchanged.

Interprofessional practice When multiple physicians and other health care professionals from different disciplines and specialties work together with patients, families, caregivers, and communities to deliver the highest quality of care.

Joint Commission The accrediting body for health care organizations.

Just Culture A work culture that allows every employee to advocate for an environment where safety concerns can be addressed in a nonpunitive manner with willingness to address underlying causes.

Lapse When an action is missed or an individual forgets to do something.

Latent failures or latent errors Errors that result from system or design flaws occurring away from the bedside. Errors may include equipment design flaws, decreased staffing for fiscal reasons, and software interface issues.

Lean A systematic method of eliminating waste focused on activity that adds value. Originally developed by Toyota.

Learning health system A system characterized by a clear shared vision and professionalism. The presence of standardized interoperable data and systems that not only lead to improved direct care of patients but also to secondary use or reuse of clinical data for quality measurement and improvement, clinical and translational research, and public health.

Machine learning The area of computer science that aims to build systems and algorithms that learn from data.

Malpractice An instance of negligence or incompetence on the part of a professional.

Mandatory reporting systems Systems that receive error reports from a designated individual who often is not directly involved in the error. Reports are typically required for serious events, including death, retained foreign object after surgery, radiation overdose, or transfusion error.

Medicaid A program of public insurance financed jointly by federal and state governments and administered by states in accordance with federal law. Covers most poor children and pregnant women and, in many but not all states, substantial numbers of other persons with limited financial means.

Medical staff A voluntary, self-regulating group of physicians who hold admitting and practice privileges at a hospital.

Medicare A program of public insurance financed and administered by the federal government that covers nearly all persons age 65 and over and a few special populations regardless of age (e.g., persons with end-stage renal disease).

Metadata Data points used to identify data (e.g., who authored a particular clinical note), how data are linked together (e.g., vital signs from multiple records that represent a single patient), or how data have been utilized (e.g., data access and audit logs).

Miller's pyramid A figure designed by George Miller, a highly respected medical educator, to help faculty and education program leaders understand the progressive and developmental acquisition of clinical competence and how different assessment tools may be applied.

Mistake When someone does something he or she thought to be correct, but it was not.

National Board of Medical Examiners (NBME) Independent, nonprofit organization that develops and manages the United States Medical Licensing Examination (USMLE).

Near miss An unplanned event or close call that does not reach the patient or cause injury or damage to the patient.

Negligent adverse event A preventable adverse event that satisfies the legal criteria for negligence where the care provided to the patient does not meet the standard of care an average physician would provide.

Never event A largely preventable action, such as wrong-site surgery or retained sponges, that should never occur.

Normalization of deviance Deviation from standards and policy on a recurrent basis without resistance.

Nurse care manager A registered nurse with the educational qualifications and clinical experience to manage and coordinate the care of complex patients within patient-centered medical homes and accountable care organizations, as well as health plans.

Objective structured clinical examinations (OSCEs) Hands-on examinations designed

to test competence in skills such as communication, clinical examination, medical procedures/prescription, and other skills required for clinical practice.

Organizational factors Policies and processes at a health facility or system related to leadership, education, supervision, and availability of equipment or supplies that impact care provided to patients.

Patient factors Aspects of a patient, such as personality, language, culture, and illness complexity, that have a direct impact on communication and bias.

Patient handoff Transferring a patient from one health care setting or professional to another.

Patient Protection and Affordable Care Act Federal statute passed in 2010; also known as the Affordable Care Act or "Obamacare."

Patient registry An organized system using observational study methods to collect data to evaluate specific outcomes for a population of patients.

Patient safety A discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery.

Pay for performance Payment based on meeting quality measures in care delivery.

Personal health record (PHR) The patient-controlled portion of the electronic health record (EHR), which may be tethered to one or more EHRs from health care delivery organizations.

Persons approach An approach that focuses on the errors of individuals at the bedside, such as the physician, nurse, or other caregiver in contact with the patient.

Physician Orders for Life-Sustaining Treatment (POLST) An approach to end-of-life care that involves facilitating advance care planning conversations among health care professionals, patients, and families and recording the results of those discussions as orders for emergency responders and subsequent caregivers.

Plan-Do-Study-Act (PDSA) cycle Part of the Institute for Healthcare Improvement's Model for Improvement. Steps in the PDSA cycle:
Step 1: Plan—Plan the test or observation, including a plan for collecting data.
Step 2: Do—Try out the test.
Step 3: Study—Set aside time to analyze the data and study the results.
Step 4: Act—Refine the change, based on what was learned from the test.

Population health An approach that focuses on interrelated conditions and factors that influence the health of populations over the life course, identifies systematic variations in their patterns of occurrence, and applies the resulting knowledge to develop and implement policies and actions to improve the health and well-being of those populations.

Population management Management of and payment for health care services for a defined population.

Population medicine The design, delivery, coordination, and payment of high-quality

health care services to a defined group of people.

Precision medicine Formerly referred to as personalized medicine. Identifying which approaches will be effective for which patients based on genetic, environmental, and lifestyle factors.

Predictive analytics Branch of data mining concerned with the prediction of future probabilities and trends.

Preventable adverse event An adverse event attributable to error.

Process map A visual representation of a process showing how a sequence of events leads to a given outcome.

Process measures Measures of the specific steps in a process that lead—either positively or negatively—to a particular outcome. The process is what links the input to the outcomes.

Provider network The hospitals, physicians, and other health care providers that enter into contracts with health insurers to provide services to insured individuals on specified terms regarding qualifications, service delivery, and payment.

Public health What society does collectively to assure the conditions in which people can be healthy.

Quadruple Aim Includes the three aspects of the Triple Aim (improving the patient experience of care, improving the health of populations, and reducing the per capita cost of health care) with the addition of health care professional wellness.

Quality improvement The combined and unceasing efforts of health care professionals, patients, their families, researchers, payers, planners, and educators to make changes that will lead to better patient outcomes, better system performance, and better professional development.

Rapid response system A tool implemented in hospitals and designed to identify and respond to patients with early signs of clinical deterioration on nonintensive care units with the goal of preventing respiratory or cardiac arrest.

Registry A collection of data about patients with a similar disease or therapeutic process.

Regulation Law adopted by a federal administrative agency, such as the Food and Drug Administration, or a state administrative agency, such as a department of health or insurance.

Relational coordination The coordination among team members that occurs through frequent, high-quality communication supported by relationships based on shared goals, shared knowledge, and mutual respect.

Reliability The consistency or reproducibility of an assessment result and whether the same result would occur if the assessment were administered at some future time or in different circumstances.

Rights Claims by individuals on the government to assure particular aspects of well-

being (positive rights) or to refrain from restricting particular forms of conduct (negative rights).

Root cause analysis A structured method used to analyze serious adverse events. A central tenet is to identify underlying systemic causes that increase the likelihood of errors while avoiding focusing on mistakes by individuals. May also be referred to as *event analysis* because adverse events may have more than one root cause.

SBAR Stands for Situation, Background, Assessment, and Recommendation. A tool to structure conversations at critical junctures in care.

Second victims Physicians and other health care professionals involved in an adverse event, even if they are not primarily responsible.

Self-referral A practice, typically restricted by fraud and abuse laws and professional ethics, whereby a physician orders or recommends services (e.g., imaging, laboratory testing, ambulatory surgery) from which the physician will derive financial benefit because of an ownership interest or compensation arrangement.

Self-regulated learning The means by which learners adjust their behaviors to achieve learning goals. Key elements include goal setting, self-efficacy, attributions of learning outcomes, self-assessment, feedback seeking, and reflection.

Self-regulation Collective action by a private group, such as a licensed profession, to create and enforce standards that substitute for or supplement legal requirements set by government.

Sensitive period A time period in an individual's life when an exposure has a stronger effect on development and disease risk than it would at other times.

Sentinel event A patient safety event that reaches a patient and results in death, permanent harm, or severe temporary harm. These events signal the need for immediate investigation and system improvement to prevent further harm.

Shared savings Financial incentives to physicians, other health care professionals, health systems, and medical practices to improve quality while reducing costs. Any savings achieved are shared between the payer and provider once a certain threshold is met.

Sharp end The part of a patient care process that is closest to the patient when harm occurs. This is the person doing the task, such as the nurse giving the medication or the surgeon doing the surgery.

Situational awareness Knowledge of the changing clinical status or environment that enables physicians and other health care professionals to adapt to the emerging situation. Also involves maintenance of a shared mental model, allowing team members to work toward the same goal.

Slip An action that does not occur as planned.

Social determinants of health (SDOH) The conditions in which people are born, grow, live, work, and age. Five key areas include economic stability, education, social and community context, health and health care, and neighborhood and built

environment.

Social gradient of health The concept that health and wealth are typically correlated in a linear, stepwise fashion at all levels of income and class.

Socioeconomic position (SEP) The social and economic factors that influence what positions individuals or groups hold within the structure of a society.

Socioeconomic status (SES) The social standing or class of an individual or group. Often measured as a combination of education, income, and occupation.

Statute Law enacted by Congress or a state legislature.

Swiss cheese model Recognizes that error is inevitable and that every step in a process has the potential for failure, with each layer of the system serving as a defensive layer to identify and catch the error before harm reaches the patient.

Systems approach Focuses on improving and redesigning the environment and care processes rather than the behavior of a few individuals.

Systems thinking Recognizing and understanding the complex interdependencies and relationships within a functional system such as health care. Allows the formation of linkages among disparate areas of activity in health care to improve outcomes, patient experience, and value in health care.

Task factors Components of an action that affect its outcome, such as the availability and use of clear protocols.

Team science An understanding of teams, their structures, and critical elements.

Teamwork Cooperative or coordinated effort on the part of a group of persons acting together as a team or in the interests of a common cause.

Telehealth/telemedicine The delivery of health care when the participants are separated by time, distance, or both.

Third medical science Health systems science. Basic and clinical sciences are the first two medical sciences.

Tort claim A legal claim, usually under state law, asserted by a private party (the plaintiff) against another party (the defendant) for harm not associated with a contract between them.

Transitions of care Times when patients are moved from one setting of care or practitioner to another.

Triple Aim A framework developed by the Institute for Healthcare Improvement describing an approach to optimizing health system performance. It includes the following improving the patient experience of care (including quality and satisfaction), improving the health of populations, and reducing the per capita cost of health care.

USMLE United States Medical Licensing Examination.

Validity A determination as to whether the results of an assessment method provide

accurate information about what is being measured.

Value-based health care Services of measurable quality and effectiveness delivered at reasonable cost (often contrasted with "volume-based" care delivery, emphasizing fees for individual services that may or may not substantially benefit patients).

Value-based payment systems Payment system where payment is dependent on value/performance of the service.

Violation A deliberate, illegal, or otherwise unsanctioned action.

Voluntary reporting systems Systems that receive error reports from physicians and other health care professionals who willingly report adverse events.

Workplace factors Issues in the health care setting that contribute to a physician's or other health care professional's ability to carry out a task.

Wrong surgery Procedure performed on the wrong patient or the wrong site, or the wrong surgery was performed. This is a never event.

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