

Health Law and Ethics

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MHA 633

Patient Autonomy - Confidentiality

Lecture 7



In the previous Lecture: Doctor – Patient Relationship

Introduction

Duties of a good doctor

Doctor competencies

7 Principal elements that are essential to the relationship

Etiquette Based Medicine

Communication skills

Consultation styles

Four Models of Decision Making

Patient Education

Improving Doctor-patient relationship

In this Lecture: Patient Autonomy - Confidentiality

Patient Autonomy

Informed Consent

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Modes of Consent

Capacity to consent and special consideration

Patient Rights, Privacy and confidentiality

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What is Confidential?

Conditions to breach confidentiality

Chapter

Patient autonomy and consent to treatment



Elements of consent

Capacity/Competence

- Understanding the given information
- Appreciation of risk associated with decisions
- Memorization: Ability to retain study-related info after consent

Disclosure

- Relevant information
- Appropriate format

Consent

Voluntariness

- Free from coercion
- No undue influence

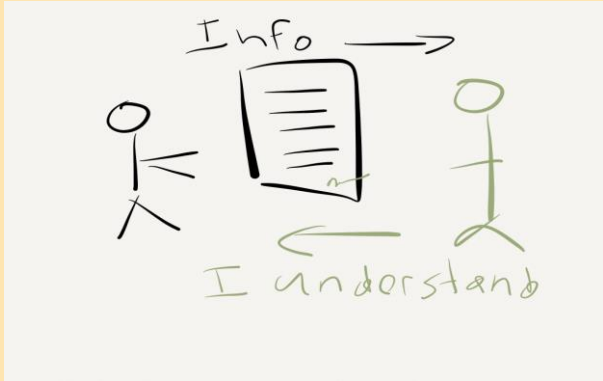
Documentation

- Witnessed (verbal)
- Signed (written)

Components of IC:

1. **"Disclosure"** refers to the provision of relevant information by the clinician and its comprehension by the patient. This refers to the process during which physicians provide information about the proposed research to the participant
2. **"Capacity"** refers to the patient's ability to understand the relevant information, to appreciate those consequences of his or her decision that might reasonably be foreseen, and to remember these information for adequate period of time.
3. **"Voluntariness"** refers to the patient's right to come to a decision freely, without force, coercion or manipulation.

Informed Consent to Treatment

CAPACITY	VOLUNTARINESS	DISCLOSURE
•The patients has the ability to: • <u>Understand</u> medical information • <u>Appreciate</u> the risks • <u>Memorize</u> the information • <u>Communicate</u> the decision	•Freedom from undue influence: • Financial • Social pressure •Physical restraint 	•Information: •Diagnosis • Possible prognosis • Benefits and risk of treatment • Expected outcome • In a language understood by the patient

- **Article 19**

- No medical intervention may be performed except with the consent of the patient, his representative or guardian if the patient is legally incompetent.
- As an exception, a healthcare professional must in cases of accidents, emergencies or critical cases requiring immediate or urgent medical intervention to save the patient's life or an organ thereof or to avert severe damage that might result from delay, where the timely consent of the patient, his representative or guardian is unattainable – intervene without waiting for such consent.
- Under no circumstances may the life of a terminally ill patient be terminated even if so requested by the patient or his family.

المادة التاسعة عشر

يجب ألا يجرى أي عمل طبي لمريض إلا برضاه، أو بموافقة من يمثله أو ولي أمره إذا لم يعتد بإرادته هو واستثناء من ذلك يجب على الممارس الصحي - في حالات الحوادث أو الطوارئ أو الحالات المرضية الحرجة التي تستدعي تدخلاً طبياً بصفه فورية أو ضرورية لإنقاذ حياة المصاب أو إنقاذ عضو من أعضائه أو تلافي ضرر بالغ ينتج من تأخير التدخل وتعذر الحصول على موافقة المريض أو من يمثله أو ولي أمره في الوقت المناسب - إجراء العمل الطبي دون انتظار الحصول على تلك الموافقة ، ولا يجوز بأي حال من الأحوال إنهاء حياة أي مريض ميؤوس من شفائه طبياً، ولو كان بناء على طلبه أو طلب ذويه .

اللائحة:

1-19 تؤخذ موافقة المريض البالغ العاقل سواءً كان رجلاً أو امرأة أو من يمثله إذا كان لا يعتد بإرادته قبل القيام بالعمل الطبي أو الجراحي وذلك تماشياً مع مضمون خطاب المقام السامي رقم 2428/4م وتاريخ 1404/7/29هـ المبني على قرار هيئة كبار العلماء رقم 119 وتاريخ 1404/5/26هـ.

Chapter

Consent to Treatment



Modes of Consent:

- **1. Implied Consent**

The patient is presumed to minor operations e.g x rays

- **2. Express written consent**

Whenever possible , this should be obtained for all patients undergoing procedures involving an anesthetic complex treatments with significant risks or side effects, or as part of research.

Written consent is not legal proof that adequate consent was obtained at the time the document was signed.

- **3. Express verbal consent.**

Should be obtained if it is not possible to get written consent and witnessed by an independent health care professional, and documented in the notes accordingly, for simple procedures with minimal risk of harm.

What is an informed consent?

- ❖ **Informed consent** is the process by which a fully informed patient can freely (without undue influence) participate in choices about his/her health care.
- ❖ **Informed consent** is a consent obtained freely, without threats or improper inducements, after appropriate disclosure to the patient of adequate and understandable information in a form and language understood by the patient.

❖ الموافقة المتبصرة هي عملية تواصل بين المريض والفريق العلاجي يشارك فيها المريض في القرارات التي تخص جسده وصحته بعد اطلاعه على المعلومات الكافية والمقدمة له بلغة يفهمها وطريقة يقبلها وتكون قراراته غير متأثرة بأي إغراء أو تهديد أو أي نوع من الضغوط

Why to Take Consent?

- ❖ **Ethically:** it reflects the ethical principle of respect of **autonomy**. It establishes trust in the healthcare providers. مطلوب أخلاقيا كتعبير عن احترام حقه في اتخاذ القرار
- ❖ **Legally:** It expresses the right of people to make informed decisions about health treatment. It is against the law to interfere with people's bodies without their consent.
- ❖ مطلوب قانونيا لأن النظام يمنع التدخل في جسم إنسان بدون إذنه
- ❖ **Professionally:** All guidelines and codes request healthcare professionals to obtain their patients' consent
- ❖ **Fiqhi:** In Shariah, every adult has his/her competence (*Zimma*) to take permissible (*Mobah*) decisions related to his/her life, unless there are genuine causes to assume the opposite. شرعا لأن الأصل هو أن الناس مؤهلون ليقرروا ما لم يثبت العكس ولأن الشرع يحمي نفوس الناس من التغول عليها

Patient's Consent (Saudi Code of Ethics)

- The adult conscious patient's permission (consent) should be sought (whether the patient is male or female), or from his/her representative in case the patient is not competent to decide, before any medical or surgical intervention.
- This is because the human's body and soul are from the person's privacies that no one should deal with unless with prior permission.

When is Consent Needed?

Consent would include any procedure undertaken for the purpose of treatment

الضابط هو أن الأصل أن أي تدخل مع المريض بغرض العلاج يكون بإذنه الصريح أو الضمني:

1. Anesthesia التخدير
2. Fluid infusion إعطاء السوائل الوريدية
3. Blood transfusion نقل الدم
4. Any form of medical/ surgical treatment العمليات الجراحية

Conditions for a Consent to be Valid?

الأهلية Capacity

Understand فهم
المعلومة

Appreciate تقدير
الخطر

Remember تذكر
المعلومة

Communicate القدرة
على التعبير عن القبول أو
الرفض

المعلومات Disclosure

Relevant
information المعلومات
المناسبة

Understandable
بطريقة مفهومة

Without
misrepresentation
or fraud أو
تضليل

الطوعية Voluntariness

Free from undue
influence عدم التأثير
عليه

No coercion عدم
الضغط عليه

Principles of consent

- ▶ Every person is presumed to be capable of
 - (a) giving or refusing consent to treatment; and
 - (b) making a health care directive, until the contrary is demonstrated.
- ▶ Authority to give consent includes authority to refuse consent or revoke a consent previously given
- ▶ Every patient who is capable of giving or refusing consent to treatment has the right
 - (a) to give consent or to refuse consent on any grounds, including moral or religious grounds, even if the refusal will result in death;
 - (b) to select a particular form of treatment from among those proposed by a health practitioner on any grounds, including moral or religious grounds;
 - (c) to be assisted by an associate; and
 - (d) to be involved to the greatest degree practicable in case planning and decision making.

What we should tell our patients to get their consent

ما هي المعلومات التي يجب إخبار المريض بها قبل أخذ الإذن الطبي؟

Patient must receive information on the:

- ❖ طبيعة التدخل الطبي Nature and the process of the intervention
- ❖ طبيعة العلاج Nature of the treatment
- ❖ التشخيص والتنبؤ المرضي The diagnosis and the prognosis
- ❖ الفوائد المتوقعة من العلاج Expected benefits of the treatment
- ❖ والمخاطر المتوقعة من العلاج Material risks of the treatment
- ❖ الآثار الجانبية المتوقعة side effects Material and possible undesirable
- ❖ البدائل العلاجية الأخرى إن وجدت Alternative course of action
- ❖ Possibilities, benefits and risks of alternative interventions
فوائد ومخاطر الخيارات الأخرى
- ❖ ما قد يترتب على عدم العلاج Likely consequences of not having the treatment



Patient's Consent (Saudi Code of Ethics)

- For a patient's consent to be considered valid; the following conditions must apply:
 1. The healthcare practitioner should present enough information in a language that the patient can understand
 2. The patient should be able to understand and appreciate the information that he/she has been provided so that he/she decides with full consciousness, awareness and conviction.
 3. The patient's consent should be made voluntarily without pressure or coercion.
 4. The consent should be written at the time the healthcare practitioner will perform any intervention

Patient's Consent (Saudi Code of Ethics)

- **Woman's Consent:** The conscious adult woman has the right to give consent to any medical interventions that is related to her, including surgical operations, except for what is related to reproduction, like the use of family planning methods, hysterectomy or other procedures.
- In such procedures, the acceptance of the husband must be obtained too. In emergency and life-threatening conditions, the woman's consent is sufficient.

Patient's Consent (Saudi Code of Ethics)

- **Incompetent Patient's Consent** If the patient cannot give an informed consent, for example in case of unconsciousness, or children, or the insane; his/her legal guardian should be the person to give this proxy consent.
- If there is potential loss of life or severe harm to the patient, then the healthcare practitioner can do these interventions without consent.

Capacity to consent:

To give informed consent, a person must have the capacity to understand and communicate what they are agreeing to.

People who lack capacity:

1. Children
2. Mentally Incapable
3. Living Will
4. Pregnant Mother (baby)
5. Emergency Situations



Special Considerations:

1. Emergencies

Treatment can be provided without consent where a patient is experiencing a severe suffering, or where delay in treatment would lead to serious harm or death or consent can not be obtained from their patient or their substitute decision maker.

NB: However, you must respect any valid advance refusals that you know about or are drawn to your attention.

2. Mentally Incapable Patients

Assess patient's competence to make an informed decision.

If unable to decide, and provided they comply, treatment may be instigated that is judged to be in their best interest.

Special Considerations:

3. Advanced Statements/ Living Will

A/S made by patients before losing their capacity of informed consent must be respected.

Provided:

- Decision is applicable to current situation
- No reason to believe that they may have changed their decision.

*the known wishes of the patient should be taken into consideration if an A/S is unavailable.

4. Pregnancy

The right to autonomy applies equally to pregnant women. It includes the right to refuse treatment that is intended to benefit the unborn child.



Special Considerations:

5. Children

Under 16 – Parents or Guardians would see at the best of interest of the child. However, may give their own consent, if they are judged to understand what is involved.

Over 16 – regarded as young adults and have capacity to decide.

*Age 6 - 15 can give assent. If child refuses that parent cannot force participation

*Unlike adults if competent child refuses treatment, a person with parental responsibility or a court may authorize treatment deemed in the child's best of interest.

*Emergencies applicable in same manner as adults



Consequences of Failure To Obtain Valid Consent:

❖ Treatment without consent = BATTERY
Including **NO** consent or **WRONG** procedure.

❖ Treatment with **poor** or **invalid** consent =
NEGLIGENCE .

Including misinformation about diagnosis or surgery

Tips to Disclosure قواعد إيصال المعلومة للمريض

In carrying this information physician should:

- ❖ Avoid technical terms تحاشى المصطلحات الطبية والفنية المحضة
- ❖ Attempt to translate statistical data into everyday probabilities ترجم له الأرقام بأشياء مشاهدة في حياته
- ❖ Enquire whether patient understand the information اسأل المريض باستمرار ما إذا كنت تتحدث بطريقة مفهومة له
- ❖ Use language appropriate to the patient's level of understanding in a language of their fluency تحدث إليهم بلغة يفهمونها
- ❖ Pause and observe patients for their reactions توقف وتابع ردود أفعال المريض
- ❖ Invite questions from the patient and check for understanding ادع المريض ليسألك وتأكد من فهمه لك

When consent isn't needed

- It may not be necessary to obtain consent if a person:
- **requires emergency treatment to save their life, but they're incapacitated** في حالات التدخل الطارئ المنقذ للحياة
- **immediately requires an additional emergency procedure during an operation** حدوث طارئ أثناء العمليات الجراحية
- **with a severe mental health condition** – such as schizophrenia, bipolar disorder or dementia – الإختلال العقلي أو النفسي الشديد وعندها يؤخذ الإذن من وليه
- **is a risk to public health** (notifiable disease) الإبلاغ عن الامراض الواجب التبليغ عنها
- **Complementary procedures** (مثل) الإجراءات المكملة أثناء الكشف على المريض (مثل قياس ضغط الدم)

Challenges to informed consent

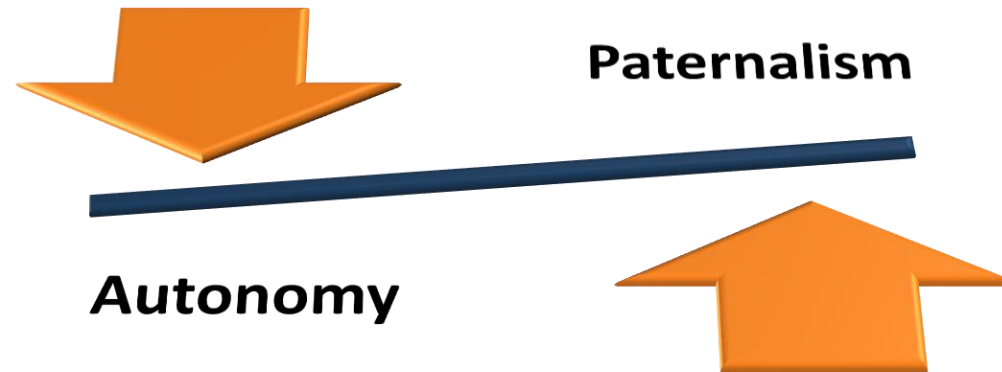
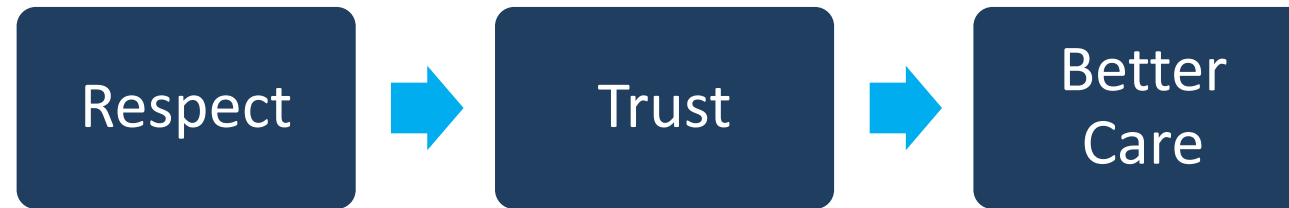
- Doctors' paternalism (doctors know best)
- Uncertainties about many medical conditions
- Difficulty in explaining/translating some medical information
- Telling how much information is enough
- Some patients prefer verbal consents & refuse to sign forms

Chapter
6

Patients' Rights: consent, privacy, & confidentiality



Ethical basis



Islamic guidance

1. Relieved patients from some religious commitments: خففت عنهم التكاليف الدينية:

* (وَإِنْ كُنْتُمْ مَرْضَىٰ أَوْ عَلَىٰ سَفَرٍ أَوْ جَاءَ أَحَدٌ مِنْكُمْ مِنَ الْغَائِطِ أَوْ لَامَسْتُمُ النِّسَاءَ فَلَمْ تَجِدُوا مَاءً فَتَيَمَّمُوا صَعِيدًا طَيِّبًا)

* (فَاقْرَءُوا مَا تَيَسَّرَ مِنَ الْقُرْآنِ عَلِمَ أَنْ سَيَكُونُ مِنْكُمْ مَرْضَىٰ) سورة المزمل 20

* (فَمَنْ شَهِدَ مِنْكُمُ الشَّهْرَ فَلْيَصُمْهُ وَمَنْ كَانَ مَرِيضًا أَوْ عَلَىٰ سَفَرٍ فَعِدَّةٌ مِنْ أَيَّامٍ أُخَرَ) سورة البقرة 185

* (فَمَنْ كَانَ مِنْكُمْ مَرِيضًا أَوْ بِهِ أَذًى مِنْ رَأْسِهِ فَفِدْيَةٌ مِنْ صِيَامٍ أَوْ صَدَقَةٍ أَوْ نُسُكٍ) سورة البقرة 196.

* (لَيْسَ عَلَى الضُّعَفَاءِ وَلَا عَلَى الْمَرْضَى وَلَا عَلَى الَّذِينَ لَا يَجِدُونَ مَا يُنْفِقُونَ حَرَجٌ) سورة التوبة 91

2. Visiting them is a duty (on everybody, not only doctors). جعلت عيادتهم حقاً واجباً.

3. Referred to their health, mental, and social requirements نبهت على مسائل

يحتاجونها: صحياً ونفسياً واجتماعياً.



Professional/Legal requirement

- *Patient's Bill of Rights and Responsibilities (KSA)*
<http://www.moh.gov.sa/en/HealthAwareness/EducationalContent/HealthTips/Pages/Tips-2011-1-29-001.aspx>
- *Law of Practicing Healthcare Professions:*
- **“Article 5:**
- Healthcare professionals shall serve the best interest of individuals and society within the framework of respecting human right to life, safety and dignity and shall observe customs and traditions prevailing in the Kingdom, and eschew exploitation.”



Rights of Patients & Their Families

1. **Knowing Patient and Family Rights and Responsibilities**
2. **Getting Health Care**
3. **Privacy and Confidentiality**
4. **Safety and Protection**
5. **Respect and Appreciation**
6. **Participation in the Healthcare Plan**
7. **Refuse Treatment**
8. **Participation in Research Studies**
9. **Organ and Tissues Donation Policies and Procedures**
10. **Health Insurance and Financial Policy**
11. **Clear and Comprehensive Declaration Forms**
12. **Complaints and Suggestions Policies and Procedures**
 - **Child Patient Rights**
 - **Elderly Patient Rights**
 - **Psychiatric Patient Rights**
 - **Special Needs Patient Rights**



Participation in decision-making

Receive Relevant Information

Diagnosis

Treatment

Prognosis

Post-Discharge Care

Hospital policies

Consent to Treatment

Relevant facts explained

Patients are free from undue influence

Patients assign Substitute decision maker (SDM)

Right to Refuse Treatment

Relevant alternatives explained

Risks explained, and consent taken



Right to Privacy & Confidentiality

Privacy :

- Is the right of an individual to have personal, identifiable medical information kept out of reach of others.



**RESPECTS PATIENT'S
BODY**

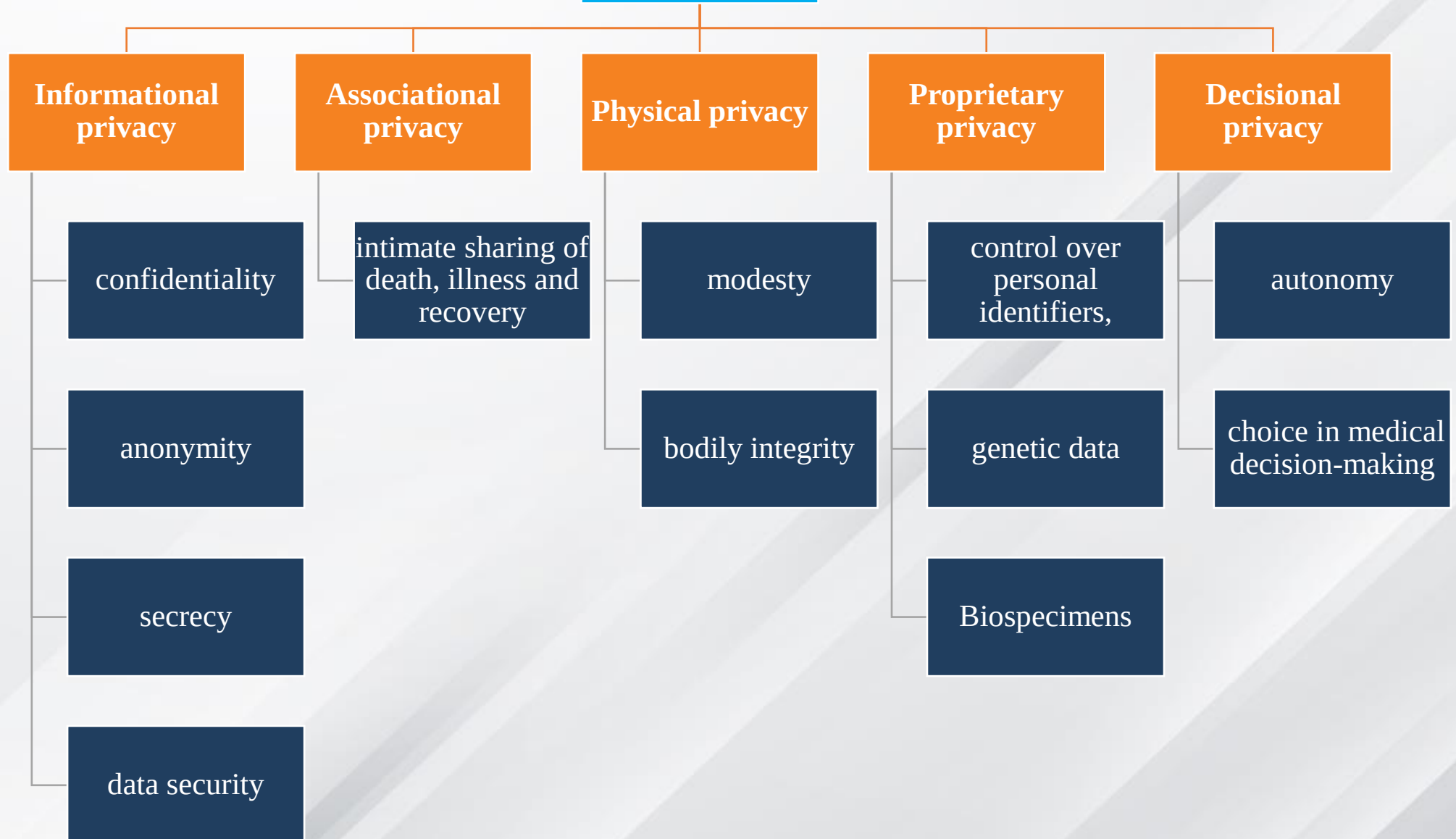
Confidentiality :

- A right or expectation to not be interfered with
- Be free from surveillance
- A moral right to be *left alone*.



**RESPECTS PATIENT'S
INFORMATION**

Privacy



Physical privacy

- Patients have expectations that they will not be needlessly touched, crowded, gawked at or imaged.
- Many individuals understand bodily modesty as a moral virtue, and act accordingly. Under some religious traditions, such as those of Muslims, Orthodox Jews and the Amish, **bodily modesty** is a requirement of faith. Being asked to disrobe, even for a good reason, may impose the cost of going against principle or desire (Kato and Mann 1996).

Measures to Protect Privacy *(KSA guidelines)*

1. Make sure examination takes place in isolation from other patients, unauthorized family members, and/or staff
2. Provide gender-sensitive waiting and examination rooms
3. Provide proper clothing for the admitted patients
4. Make sure patients are well covered when transferred from one place to another in the hospital
5. Make sure your patient's body is exposed ONLY as much as needed by the examination or investigation
6. Patients should have separate lifts and be given priority



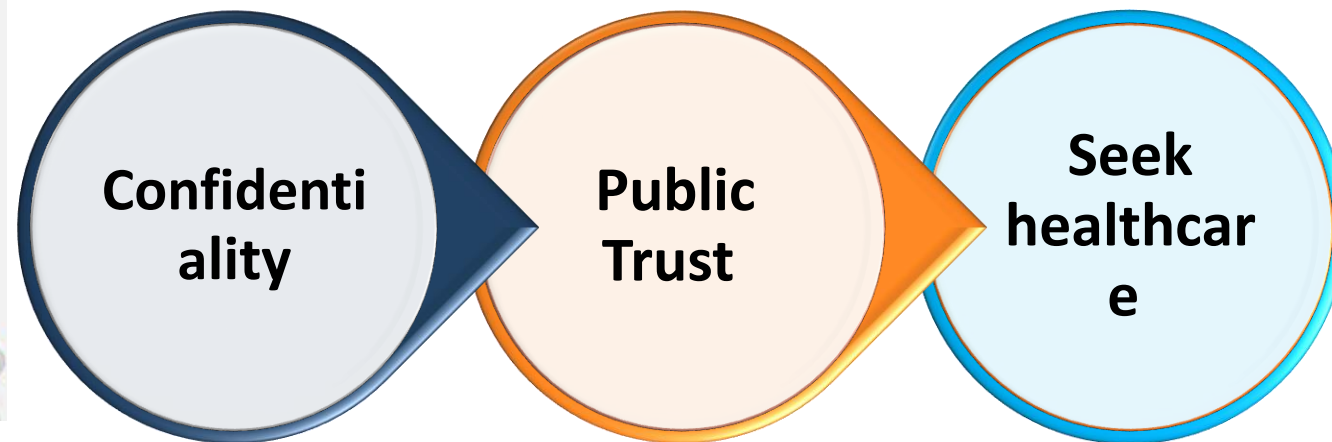
Measures to Protect Privacy

7. Make sure there is another person (chaperone, nurse) of the same sex as the patient present all the time of the examination
8. Always take permission from the patient before examination
9. Ensure privacy when taking information from patients
10. Avoid keeping patients for periods more than required by the procedure.
11. It's prohibited to examine the patient in the corridors or in the waiting area.
12. During examination, no foreign person unrelated to the patient allowed
13. Give patients enough time to expose the part with pain
14. Only relevant personnel are allowed to enter the examination room



Why is there a Duty for Confidentiality?

- **Trust** between patients and health professionals.
- Patients give information about their health in **confidence**.
- Individuals will be **encouraged to seek appropriate treatment** and share information relevant to it.



Proficiency (Medical) Secret

- **Medical secret** is defined as “Any medical information that comes to the knowledge of the practitioners as a result of their work whether directly obtained from the patient, or otherwise”
- **It includes** any information that the doctor (or treatment team) knows about the patient (alive or dead), directly or indirectly that a patient may deem its disclosure undesirable or harmful to his/her health, reputation, financial, social or professional status.
- **It includes** any information about the patient’s identity, condition, diagnosis, investigations’ results, treatment, and/or prognosis (whether chances of cure, disability, or death)



What is Confidential?

- All identifiable patient information, whether written, computerized, visually or audio recorded or simply held in the memory of health professionals, is subject to the duty of confidentiality.

It covers:

- Past, present or future physical or mental condition,
- Individual diagnosis or treatment;
- A picture, photograph, video, audiotape or other images of the patient;
- Who the patient's doctor is and what clinics patients attend;
- Anything else that may be used to identify patients directly or indirectly
- The past, present, or future payment

Confidentiality Measures

1. Limit the accessibility to the medical records
2. Do not discuss the patient's medical information with unauthorized family members
3. Do not disclose patient's information without his/her consent, or in established exceptions (below)
4. Do NOT collect information not related to the provision of care
5. Set policies that regulate access to medical information and how any breach to confidentiality is managed
6. Limit sharing of information with other staff, unless in cases of consultations and second opinion



Conditions to breach confidentiality

1. Approval from the patients or their substitute decision maker,
2. If the information is required by judiciary
3. Consultation or second opinion
4. Notification of events of public health interest/threats (birth, death, notifiable diseases, etc.)
5. Prevent individual/personal threats (e.g. prevent crimes)
6. If needed by the doctor to defend him/herself before judges, or discipline committee
7. If the patient consciously and truly admits committing a crime on which another person was accused/punished

Remember: Disclosure should be only to the concerned party & not beyond the needed limits

الضابط في ستر أو كشف الطبيب عن سر المريض هو منع ظهور المفسدة

The patients have the right to:

- ❖ Receive uninterrupted care from his/her doctor.
- ❖ To be referred to other health care providers when necessary.
- ❖ Receive a second opinion when the patient or his/her doctor requests one.
- ❖ The second opinion must be provided by a qualified health care professional within the same organization.

Compassionate EOL Care

The patient have the right to:

- ❖ Have her physical pain assessed and managed
- ❖ Have Advance Directive Plan (Living Will)
- ❖ Assign a family member to be the SDM
- ❖ Have her/his emotional and spiritual needs addressed



Appeal and Complaint Submission



The patient have the right to:

- ❖ Be told on how to process her problems or complaints
- ❖ Voice his/her concerns about the care she/he receives
- ❖ Ask questions and express concerns about hospital health care and services, without fear of reprisal
- ❖ Have his/her complaint responded to in a timely and satisfactory manner



Additional Rights for special groups

Children

- Examined by specialized team.
- Appropriate environment
- Assign a companion
- Report any violence against children to the concerned authority.
- Avoid isolating the patient unless it's medically necessary.

Elderly

- Meet their special needs in the health facility.
- Provide needed health and treatment services to the patient.
- Facilitate making appointments and having their medical reports

Additional Rights for special groups

Psychiatric

- Protect psychiatric patients from harm.
- Ensure the patient's freedom of movement and shouldn't isolate him/her unless it's medically necessary.
- Allocating mental health clinics
- Provide suitable education and rehabilitation methods

Special Needs Patient

- Respect the patient's dignity, independency in addition to his/her personal decisions.
- Provide specialized equipments and tools for special needs patients.
- Assist the patient in moving
- Provide suitable aisles and bathrooms.
- Allocate parking spaces for special needs patients.

Conclusion....Key messages

- ❖ Make sure you and your patients know your and their rights
- ❖ Train your colleagues on patient's rights
- ❖ Knowing and providing these rights protects you professionally and legally
- ❖ Patient rights guide you to achieve your ethical and professional goals of availing the best service to your patients
- ❖ **Rights are rights!** They are required by LAW, needed for accreditation, and not gifts that you may or may not give.



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Thank You