

Health Law and Ethics

Prepared by Dr. Aya Mohamed

MHA 633

Terminally incurable diseases
and end-of-life decisions

Lecture 9



In the previous Lecture : Truth telling & breaking bad news

- ❖ What do we mean by breaking bad news (BBN)?
- ❖ Which news is 'bad' in clinical practice?
- ❖ Why should we care about BBN?
- ❖ BBN as part of the Communication Cycle/Pathway
- ❖ Practical approaches to BBN: (SPIKES, ABCDE, BREAKS, & Calgary-Cambridge framework for breaking bad news)



In this Lecture: Terminally incurable diseases and end-of-life decisions

- About death and dying: Definitions and basic questions
- Withdrawing treatment
- Deciding not to resuscitate (DNR orders)
- Refusal of treatment and advance directives
- Euthanasia and physician-assisted suicide
- The goals of medicine in palliative care
- Decisions at the end of life
- Ethical Issues in Health Research



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Chapter
8

Terminally incurable diseases and end-of-life decisions



Patient Monitoring Equipment



A Final farewell



Reflection and Loneliness



death

- Death is an intrinsic part of life
- Modern techniques/technology/services led to:
 - longer lives through prevention and cure of many previously lethal conditions (BUT is it a better one?)
 - greater degree of control over the processes of dying
- **Traditionally/medically:**
 - When their breathing and heartbeat had permanently stop
 - A conception of death as “**whole brain death**” involving the destruction of the entire brain—including both the brain stem and the neocortex
 - **Brain death** is cessation of all functions, including blood circulation in the brain. Brain death is diagnosed based on clinical criteria, and laboratory and radiological confirmatory tests. Brain death can be total brain death if it involves the whole brain, or can be brain stem death if it affects the vital centers of the brain stem. By consensus, brain stem death is considered clinical death; this is also a legal definition of death.

death

- **Religiously:** “the departure of the soul out of the body” (differ on what happens after)
- **Philosophically/ethically:**
 - Christopher Pallis conceived human death as a “state in which there is irreversible loss of the capacity of consciousness combined with the irreversible loss of the capacity to breath” (cf. linguistic old observation of linking “nafs” (soul) with “nafas” (respiration))
 - Winston Chiong proposes a view of death as a “**cluster concept**” composed of a variety of human functions that normally go together but that can be disaggregated in some circumstances that call for nuanced policy judgments based upon the nature of the decision at hand, such as transplantation, the continuation of treatment, or burial.

Islamic View(s) to death

- The Fatwa of the The Islamic Fiqh Academy of the Organization of Islamic Conference (October 1986) incorporated the concept of brain death into the **legal definition of death in Islam**:
[A] Person is pronounced legally dead and consequently, all dispositions of the Islamic law in case of death apply if one of the two following conditions has been established:
 - (1) there is total cessation of cardiac and respiratory functions, and doctors have ruled that such cessation is irreversible;
 - (2) there is total cessation of all cerebral functions and experienced specialized doctors have ruled that such cessation is irreversible and the brain has started to disintegrate

Why is it hard to agree on a definition?
Why is it important to define it in the first place?

Permanent vegetative state PVS

- **Permanent vegetative state (PVS)** patient's higher brain functions and capacity for conscious awareness have been permanently destroyed by cardiac arrest or traumatic brain injury, but the brain stem remains intact, thus leaving the patient in a state of “**wakeful unresponsiveness.**”
- Patients reach a PVS after suffering a pathological process that has produced widespread damage to cerebral cortical neurons, thalamic neurons, or the white matter connections between the cortex and thalamus, but that largely spares the brain stem and hypothalamic neurons.
- Some advocates of a “higher brain” conception of death claim that patients who are permanently vegetative should be considered dead

Concepts Involving End-of-Life Care

- **Full Resuscitation:** Aggressive ICU management up to and including full resuscitative attempts.
- **Withholding Resuscitation:** Aggressive ICU management up to, but not including Cardio-Pulmonary Resuscitation (CPR).
- **Withholding Life Support:** Decision not to institute a medically appropriate and potentially beneficial therapy, with the understanding that the patient will probably die without the therapy in question.
- **Withdrawing Life Support:** Cessation and removal of an ongoing therapy with the explicit intent not to substitute an equivalent alternative treatment. is terminating futile artificial life support measures in a terminally or critically ill patient, or in some cases in patients who are clinically or brain-dead, but still on life support.
- **Palliative Care:** Prevention or treatment of suffering, including the administration of drugs such as narcotics and sedatives.
- **Do Not Resuscitate (DNR) order:** An order stating that in case of cardiac arrest or respiratory arrest, cardiopulmonary resuscitation will not be undertaken by any means. It is an advance medical decision not to undertake extreme artificial life support measures like intubation for patients in terminal illness who develop cardiopulmonary arrest.
- **Do Not Treat (DNT)** is an advance medical decision to withhold futile therapeutic intervention from a terminally ill patient; however, palliative and symptomatic treatments can continue.

Concepts Involving End-of-Life Care (EOL)

- **Terminal illness**, also called maradh al maut (مرض الموت) an illness from which recovery is not expected. Death is not an ON/OFF event. It is a process that has a timeline, and can be quite lengthy.
- There reaches a **z-point** in the timeline that is called the point of no return, and the illness is then called terminal because it is expected to soon end in death. Some illnesses can be called terminal way before the z-point because they have a predictable course; a good example is multiple sclerosis.
- The definition of terminal illness is not always accurate; some patients who were told they were going to die have lived for years, but such anecdotal cases are few in actual practice.
- **Palliation** consists of measures taken to make the remaining life of a terminal patient as comfortable as possible and includes pain relief, support (psychological, social, and spiritual), nutrition, hydration, etc.
- Palliative care starts when the hope for cure of the disease disappears.
- **Euthanasia**, also called medically-assisted death, or physician-assisted suicide, consists of measures that lead to the death of a terminal patient to spare him or her from further pain and suffering.
- If acts of commission deliberately bring about death, it is called active euthanasia. If acts of omission lead to death, it is called passive euthanasia.

Concepts Involving End-of-Life Care

- **Autopsy examination** is the dissection of a dead body to determine the cause of death. The dissection could cover the whole body or could be selective. Specimens for further analysis are usually taken during a postmortem. Post-mortem examination can be carried out for legal forensic purposes to obtain evidence needed for criminal prosecution, or may be carried out for educational purposes, to enable doctors to make better diagnoses in the future.
- **Organ harvesting** is surgically removing organs such as the heart, lungs, and the kidneys for subsequent transplantation into another patient.
- It can be carried out after death of the patient, but in this case, the organs could have already deteriorated. In most cases, it is carried out in patients who are braindead but still have blood circulation to keep the organs alive.
- Artificial life support for circulation and aeration may be carried out in clinically dead people to keep the organs alive until the arrival of the surgical team that will do the harvesting

Ethical issues at EOL Care

- **The continuum of care**
Deficient **decision making capacity**.
- What **interventions can be made** (nutrition, hydration, pain control, treatment for infection?)
- **Pain control** may cause respiratory depression, pain may be eliminated altogether, but the patient is left semiconscious and unable to interact with the family. Less analgesia will leave the patient socially active, but with some level of pain.
- **Futility**: overall health outcome are not worth the side effects
Should not be denied nutrition, hydration, and general supportive care without discrimination.
- They also require **psychosocial and spiritual support** to allay their anxiety.
- Terminal patients should also be **reminded about their religious duties**, such as paying zakat, and their liabilities, such as settling debts. Health care workers may remind them about concluding their wills

Decisions for the terminally ill

• Serious decisions with irreversible consequences might have taken by or on behalf of terminal patients.

1. To **withhold or withdraw aggressive treatment** that has no net benefit that would last for a reasonable time.
To **withhold resuscitation** in case of cardiorespiratory arrest for patients who cannot get a net benefit from CPR and who would succumb again and have to undergo resuscitation.
2. **DNR order is a physician decision**, but the family must be informed (without seeking their involvement in the decision). For patients on artificial life support, a decision must be made about when to withdraw support.
3. If brain stem death can be ascertained, the **decision to withdraw life support** is easy because brain stem death is accepted as a definition of legal death.
4. If the patient is in an irreversible coma with intact brain stem function, the decision to withdraw life support is more complicated.

Decisions for the terminally ill

- Serious decisions with irreversible consequences might have taken by or on behalf of terminal patients.
- 5. **Withdrawal on the basis of low quality of life** and the continuing expense of intensive care are not usually ethically acceptable reasons because of the overriding concern of preserving life, *hifdh al nafs*
- 6. Life support could be **withdrawn in cases that are definitely futile**, but this is not an easy decision and is usually a cause of dispute between the family and the health care workers.
- 7. The families of terminal patients may be approached for **consent to harvest their organs** as soon as clinical death is ascertained.
- 8. A **prior decision (advance directives)** taken by the terminal patient while still competent will make the work of the organ transplant team easier. the terminal patient may be competent in some matters, but not in others.
- 9. The **proxy decision maker** decides in two ways, based on (a) what he thinks the patient would have decided if competent, and (b) the best interests of the patient.

Advance directives

- ❑ Documents written during the period in which the patient is competent, and are part of prospective autonomy.
- ❑ They enable the patient to control what is done to him after losing consciousness, or even after death.
- ❑ The common term “living will” is often used to refer to an advance statement.
- ❑ **Benefits:**
 - The patient is assured of his prospective autonomy;
 - the physicians are relieved of the burden of looking for a decision maker, and of making the decision themselves in the absence of a decision maker.
 - The family is relieved from the tension of looking for consensus and making difficult decisions when their state of mind is not at its best because of the patients illness.

Advance directives

- ❑ The **ADs can cover any aspect of care** that the patient is entitled to decide on during terminal illness and after death.
- ❑ The patient's decisions are respected even if not logical, but they must not contradict the Sharia. The AD **deals with major decisions** like DNR.
- ❑ An AD must preferably be **written and witnessed**. It is best that each institution develops a specific format to make sure that all legal requirements are fulfilled.
- ❑ An oral directive properly witnessed is effective, but **should be avoided** because doubts could arise about its authenticity.

Chapter
9

Ethical Issues in Health Research



Main ethical issues in research

Before

Benefit/harm analysis
Vulnerability (Risk-Vulnerability Matrix)
Fair selection of participation
Conflict of Interests (COI)

During

Informed Consent
Privacy and confidentiality
Risk to researchers
Risk to participants

After

- Sharing results
- Sharing benefits
- Integrity & publication ethics

Core ethical principles/issues in research

(Source: WHO Training manual: Ethics in research, surveillance and patient care in epidemics, emergencies and disasters, WHO (2014))

Ethical principle/issue	Definition ¹	Examples of guidelines
Respect for people's autonomy	The duty to respect people's ability to make decisions on issues related to their health and their body, if they are competent to make such decisions; and the duty to protect individuals with impaired or diminished autonomy	CIOMS, General principles TCPS, article 1.1 Belmont Report

Core ethical principles/issues in research

(Source: WHO Training manual: Ethics in research, surveillance and patient care in epidemics, emergencies and disasters, WHO (2014))

Ethical principle/issue	Definition ¹	Examples of guidelines
Beneficence	The moral duty to pursue actions that promote the well-being of others and the ethical obligation to maximize benefit and to minimize harm	CIOMS, Belmont Report,
Non-maleficence	The moral duty not to cause harm to others through interventions	CIOMS, DOH (articles 16–18)
Justice	Primarily distributive justice, which requires equitable distribution of benefits and burdens, i.e. distribution such that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it	CIOMS (guidelines 10 and 12) DOH (articles 16–18) TCPS (article 1.1 and Chapter 4)

Core ethical principles/issues in research

(Source: WHO Training manual: Ethics in research, surveillance and patient care in epidemics, emergencies and disasters, WHO (2014))

Ethical principle/issue	Definition ¹	Examples of guidelines
Vulnerability	A status in which some people may struggle to protect their interests or be at greater risk of being exploited. This situation is usually linked to specific physical, financial, educational or social circumstances. Groups considered as vulnerable vary by guideline, but children, mentally retarded and handicapped people, prisoners, refugees, terminally ill patients and women are often cited as the prime vulnerable groups.	CIOMS (guidelines 13–16), DOH (articles 19 & 20) Common rule, subparts B, C and D TCPS (Chapter 9)
Privacy	The right or expectation not to be interfered with or to be free from surveillance or, more generally, a moral right to be left alone. In practical terms, privacy is for instance concerned with the setting in which a person's health-related information is acquired.	TCPS (Chapter 5), DOH (article 24)

Core ethical principles/issues in research

(Source: WHO Training manual: Ethics in research, surveillance and patient care in epidemics, emergencies and disasters, WHO (2014))

Ethical principle/issue	Definition ¹	Examples of guidelines
Confidentiality	The principle that ensures that identifiable information is kept out of reach of others. All identifiable information about individuals, whether recorded (written, computerized, visual, audio) or simply held in the memory of health professionals, is subject to the duty of confidentiality.	CIOMS (Guideline 18), TCPS (Chapter 5)
Research ethics review	A process by which a group of experts in research, ethics and other disciplines decides whether a research protocol fulfils the ethical standards of research before being undertaken	CIOMS, Guidelines 2 and 20; Common Rule, subpart A, (articles 46.107, 46.108 and 46.109); DOH (article 23); TCPS (Chapter 6)

What is IC?

- A process whereby potential research **participants decide** whether they want to participate in the proposed study **after receiving information** about it.
- Decisions must be made **free from coercion**, by a competent person who can understand the information given and appreciate the associated risks.
- The information given to the participant **should be in a language and format suitable to the participant's** ability to comprehend it.

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 and to appreciate those consequences of his or her decision that might reasonably be foreseen.
3. "**Voluntariness**" refers to the patient's right to come to a decision freely, without force, coercion or manipulation.

Eight Required Elements

[45 CFR 46.116(a) & 21 CFR 50.25]

1. Statement that study in research and information on purposes / duration / procedures / experimental procedures
2. Reasonably foreseeable risks or discomforts
3. Reasonably expected benefits
4. Alternative procedures
5. How confidentiality will be maintained
6. Information on compensation for injuries (unless minimal risk)
7. Contact persons for information on research, injury, subject's rights
8. Voluntary participation, no penalty or loss of benefits for refusal or withdrawal

Waiver of Informed Consent

Conditions to waiver IC:

- ❖ Poses no more than Minimal risk
- ❖ Waiver or alteration will not adversely affect the rights and welfare of the subjects
- ❖ Research could not practicably be carried out without the waiver or alteration
- ❖ Does not involve a therapeutic intervention
- ❖ Subjects will be provided with additional pertinent information

All of the above must apply

Documentation of Informed Consent

- ❖ Written consent document
- ❖ Language understandable to the subject or the subject's Legally Authorized Representative (LAR), or
- ❖ Signed by subject or subject's LAR
- ❖ Copy SHALL be given to subject
- ❖ Opportunity to read before signing

Principles for Providing Information to Participant:

- ❖ Make it clear; avoid jargon
- ❖ Use language appropriate to the participant's level of understanding in a language of their fluency
- ❖ Invite questions from the patient and check for understanding
- ❖ Summarize the imparted information
- ❖ Provide contact information (and other resources)

2. Capacity:

Refers to *the presence of a group/set of functional abilities a person needs to possess in order to make a specific decisions*

(Griso and Applebaum, 1998).

These include:

- ❖ To **UNDERSTAND** the relevant information
- ❖ To **APPRECIATE** the relatively foreseeable consequences of the various available options available.

3. Voluntariness:

- Refers to a participant's right to make participation decisions free of any undue influence.

Influences include:

- Physical restraint or sedation
- Coercion involves the use of explicit or implicit threat to ensure that the treatment is accepted
- Manipulation involves the deliberate distortion or omission of information in an attempt to induce the subject's participation

Chapter

Conflicts of Interest (COI)



What is an interest?

- An interest may be defined as a commitment, goal, or value held by an individual or an institution.
- **Examples** include a research project to be completed, gaining status through promotion or recognition, and protecting the environment.

What is COI?

- COI exists when two or more contradictory interests relate to an activity by an individual or an institution.
- Conflicts of interest are “situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator’s judgement in conducting or reporting research.” AAMC, 1990
- “A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might therefore, in actuality or appearance compromise the integrity of the research.”

What comprises COI?

- Stock ownership
- Paid employment Board membership
- Patent applications (pending or actual)
- Research grants (from whatever source)
- Travel grants and honoraria for speaking or participation at meetings
- Gifts
- Membership of lobbying organizations
- Relationship with the National Research Ethics Review Committee, or with possible reviewers of the paper
- Relationship with organizations and funding bodies
- Membership of a government advisory board

Levels of COI

1- Researchers

- The REC should assess the likelihood that the researcher's judgment may be influenced, or appear to be influenced, by private or personal interests (TCPS, 2000)

2- Conflicts of Interest by REC Members

- It is of the highest importance that members of the REC avoid real or apparent conflicts of interest .
- E.g.: their research are reviewed by their REC or when they have been in direct academic conflict or collaboration with the researcher whose proposal is under review.

3- Institutional Conflicts of Interest

- Situations may arise where the parent organization has a strong interest in seeing a project approved before all ethical questions are resolved.
- The REC must act independently from the parent organization.
- Institutions must respect the autonomy of the REC and ensure that the REC has the appropriate financial and administrative independence to fulfill its primary duties.

Why to worry about COI?

COIs may result in:

1. Loss of objectivity
2. Reordering of priorities towards applied research
3. Degradation of the *nature of science as a collegial enterprise*
4. Exploitation of trainees
5. Transfer of time and interest to commercial ventures

Practical Steps to resolve COI

- Disclosure / transparency
- Stringent analysis of COI,
- Review of contracts between funders and researchers
- Close external monitoring
- Blinding of study, when possible
- Restrict review of colleague's work
- Peer review of manuscripts

What is Ethical Review?

- It is a process by which research proposals are reviewed for their compliance and accordance with the national/international ethical principles & guidelines for research involving human subjects.

All research involving living human subjects by collecting identifiable information or materials including:

- Research with human remains, cadavers, tissues, biological fluids, embryos and fetuses.
- Interviews, surveys and questionnaires.
- Secondary data analysis of data from living human subjects.

Chapter

Research Misconduct (FFP)



Types of research misconduct

(Adapted from: Committee on Publication Ethics. The COPE Report, 2000. 2000. & Research Misconduct, F.J. Gilberta and A.R. Denison, 2002)

- Fabrication
- Falsification
- Plagiarism
- Failure to get ethical approval
- Not admitting that some data are missing
- Ignoring outliers without declaring it
- Not including data on side effects in a clinical trial
- Conducting research on humans without informed consent
- Publication of post hoc analyses without declaring it

Types of research misconduct (2)

(Adapted from: Committee on Publication Ethics. The COPE Report, 2000. 2000. and Research Misconduct, F.J. Gilberta and A.R. Denison, 2002)

- Gift authorship
- Not attributing other authors
- Redundant publication: “Shotgunning” & “Salami-slicing”
- Not disclosing a conflict of interest
- Not attempting to publish completed research
- Failure to do an adequate search of existing research before beginning new research

Research Misconduct (FFP)

Research misconduct is defined as **fabrication, falsification, or plagiarism** in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication** is making up data or results and recording or reporting them.
- **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.
- Research misconduct includes the destruction of, absence of, or accused person's failure to provide research records accurately documenting the questioned research.

How to maintain research ethics and avoid scientific misconduct?

Before conduct of research

- Develop clear research plan (who will do what when and how)
- Submit protocol to ethical review
- Prepare (communicate) well with your research community
- Agree on authorship

During conduct of research

- Follow the approved protocol
- Gain consent
- Involve the community
- Protect yourself, your team, & your participants
- Regularly check your data

After research

- Share your study report(s) with
- Return 'something' back to the researched community
- Publish following publication ethics
- Use Reference Management Software

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Thank You