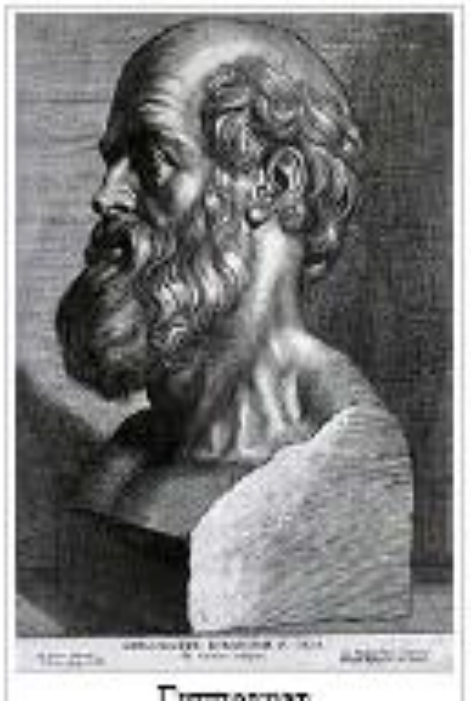
BIRZEIT UNIVERSITY

Ethics of Clinical Decision Making: Informed Consent

SPAU234 Ethics and Legal Issues

In the old days….

- In the Hippocratic tradition:



- I will apply dietic measures for the benefit of the sick according to my ability and judgement.

- I will keep my patients from harm and injustice

Who is responsible in decision making process- Doctor or Patient?

Why?

Clinical Decision Making

- Realization of individual person's future plans may be dramatically affected by some medical interventions such as surgical operation, chemotherapy, long lasting stay in hospital.

- In the past only doctor was responsible for decision making in such cases, in nowadays principle of respect of patients' autonomy is highlighted

Informed Consent

Informed Consent

- Definition: the consent of a patient, his/her relative or legal representative on the conduct of necessary for the patient medical intervention after explaining the risk to his/her health and life related to that intervention.

Informed Consent

- In the contemporary bioethics rule of 'informed consent' is originated from the principle of respect of patient/individual autonomy.

- Patient's Autonomy - the patient's right to decide independently all issues related to providing him/her a medical care.

Informed Consent

- The term “informed consent” first appeared 10 years after Nuremberg process and was developed by the 1972.

- The aim of informed consent is to protect patients against unfair and irresponsible actions from the specialist.

- And to provide the minimal health risks, social and psychological welfare, respect of moral values during biomedical experiments and medical manipulations.

Informed Consent

- Maintenance of this principle requires from the doctor to deliver thorough information to the patient before the starting of treatment.

- Information concerning patient's:
  - Health condition
  - Possible outcomes
  - Prognosis
  - Explanation of possible risks
  - Warning about unfavourable results

- Also to permit right to change own decision.

Informed Consent

- Informed consent should always be specific to:

  - The individual patient
  - The clinical situation
  - The recommended plan of care
  - The recommended treatment or procedure

Why Apply Informed Consent?

1. To provide respectful attitude towards patient or person involved in bio-medical experiment, as to the autonomous individual, who has right of liberal choice, to hold control of all procedures and manipulations, which are performed on his body during treatment or medical trails.

2. To minimize chance of moral and economic impact, which may be caused by dishonest treatment or experimentation.

3. To facilitate rise of awareness about responsibilities of doctors and researchers to protect moral and physical well-being of patients.

Constituent elements of Informed consent

I Pre-requisite elements:

- 1. Competence or ability to understand and making decision;
- 2. Self-dependence (in the process of decision making).

II Information elements:

- 3. Procedure of delivering important information;
- 4. Offering recommendations (action plans)
- 5. Process of understanding

III Consent element:

- 6. Making decision (according of certain plan);
- 7. Authorization (certain plan).

How to transfer informed consent?

- In those cases while medical intervention, or clinical trial bears certain risk for patient's health or life only one action is optimal - written informed consent.

- In other cases while serious risk is not anticipated, it is preferable for patient to transfer information in verbal form during conversation

Examples of Mandatory Informed Consent

1. All surgical operations, except minor manipulations;
2. Abortion
3. Surgical contraception – sterilization
4. Catheterization of main blood vessel
5. Hemo-dialysis and peritoneal dialysis
6. In vitro fertilization
7. Genetic testing
8. Gene therapy
9. Radiation therapy
10. Chemotherapy
11. In that cases while medical service provider considers to accept written consent
12. Also informed written consent is necessary to accept from the legal representative of incapacitated patient

Consent for Multiple Treatments

- When the plan of care for a given diagnosis involves repeated treatments or procedures- practitioners do not need to obtain consent for each individual episode.

Blanket Consent

- Informed consent for a planned course of multiple repeated treatments based on a specific diagnosis is very different from practices sometimes referred to as “routine” or “blanket” consent.

- Blanket Consent: Asking a patient to agree at the outset of care to “any treatment your doctors think is necessary” or “routine procedures as needed” is **ethically problematic.**

Refusing Treatment

- The right to refuse unwanted treatment , even potentially life saving treatment is central to health care ethics.

- How should practitioners respond when a patient declines intervention that practitioners believe is appropriate and needed?

- Depends on the patients decision making capacity and the particular circumstances of the treatment decision.

Persons Unable To Give Consent

- ‘Sometimes while legal representatives refuses to give consent;
- And physician or other provider is of the opinion that the intervention is in the interest of the patient,
- Then the decision must be refereed to a court or some form of arbitration’.

Case Study

- Suzanne is a 3 year old child who is suspected to have speech/language delay. Suzanne's parents are divorced. She is currently living with her Mom.

- Sarah's mom seeks a speech language pathologist to assess and treat Sarah. This was done without Sarah's dad approval/consent.

- What is best to do in this case?

Case Study

- Jack is a 54 year old coal miner. He underwent laryngectomy and his physician is requesting speech evaluation. Jack is illiterate.
- How the speech pathologist can obtain consent?
- Could this be problematic if the patient later denied his consent? What to do?

How to Judge if someone is able to give informed consent?

- It is the responsibility of the audiologist or speech-language pathologist to determine if a person is capable of consenting to the proposed service.

- A person is capable with respect to a service if the person:
  - Understands the information about the proposed service that is being presented.
  - Is able to appreciate the reasonably foreseeable consequences of either making a decision or not making a decision.

Case Study

- An audiologist recommends a hearing aid for a 10 year old child with a moderate hearing loss. The audiologist explains what a hearing aid does, and its risks and benefits in a language that is appropriate for the child. The child appears to understand this information, but refuses to consent to using a hearing aid. The child bases his decision on the cosmetics of the device, but does not appreciate the effects that not using amplification will have on his language development and academic performance.

- Is this child capable of giving informed consent?

Decision Making During Emergencies

- A decision on the medical intervention during the emergency and dangerous for life conditions of incapacitated patients is made only with taking into account the patient's interests

Case Study

- John, a 32 year-old lawyer, had worried for several years about developing Huntington's chorea, a neurological disorder that appears in a person's 30s or 40s, bringing rapid uncontrollable twitching and contractions and progressive, irreversible dementia. It leads to death in about 10 years.

Case Study

- John's mother died from this disease. Huntington's is autosomal dominant and afflicts 50% of an affected parent's offspring. John had indicated to many people that he would prefer to die rather than to live and die as his mother had. He was anxious, drank heavily, and had intermittent depression, for which he saw a psychiatrist. Nevertheless, he was a productive lawyer.

Case Study

- But when he went home, he ingested all his antidepressant medicine after pinning a note to his shirt to explain his actions and to refuse any medical assistance that might be offered. His wife, who did not yet know about his diagnosis, found him unconscious and rushed him to the emergency room without removing the note.

- What should the care team at the emergency room do?

Validity of Consent

- If a client signs a consent for a particular procedure, and a different procedure had been proposed.

- Case study:

- A profoundly deaf patient (bilaterally) signed a consent for to undergo cochlear implantation on the right ear. After the patient gave his consent, he travelled to America for a vacation. In the meantime, a donation was made for this patient to have 2 implants on both ears. The ENT and the Audiologist arrange for this patient to receive 2 implants.