AIETI High Medical School

Paradigm shift of Hippocratic Paternalism vs. Respect of Autonomy of Patients'

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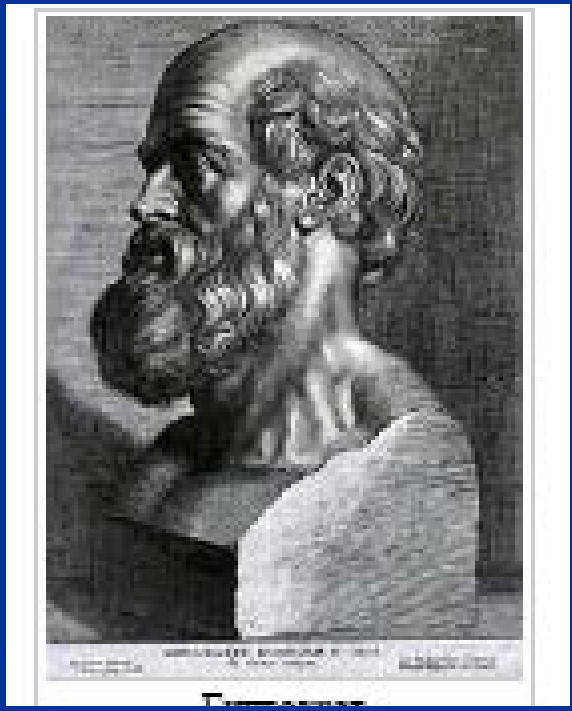
Ethics vs. Bioethics

- In the **Hippocratic tradition**
- I will apply dietic measures for the benefit of the sick according to my ability and judgment;
- I will keep them from harm and injustice. [‘primum non nocere’]



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

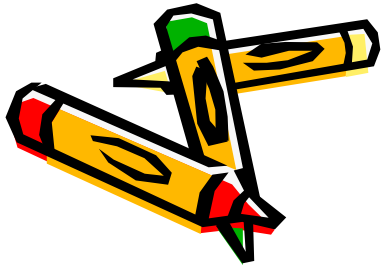
- Realization of individual person's future plans may be dramatically affected by such medical interventions as surgical operation, chemotherapy, long lasting stay in hospital.
- If in the past only doctor was responsible for decision making in such cases, in nowadays principle of respect of patients' autonomy is highlighted.

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

And vice versa principle of autonomy is reflected in the informed consent rule.

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

Law of Georgia on Health Care
Article 3.a)



Term ‘informed consent’ first appeared 10 years after Nuremberg process and was developed by the 1972

- **Informed consent is proposed and applied for providing respectful attitude towards patients’ or volunteers’ as to an individual persons;**
- **To protect them against unfair and irresponsible actions from the specialist,**
- **As well providing them minimal health risks, social and psychological welfare, respect of moral values during bio-medical experiments and medical manipulations.**

‘Informed consent’ was implemented initially in 70-80’s of XX century

- Opposite to the formerly practiced method of paternalism changing attitude towards understanding of human rights in the context of their autonomy, means that patients are considered as a partner and co-author of all decisions taken or more precisely suggested by the doctor.
- 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 unfavorable results, offer of real alternative treatment, to permit right to change own decision and etc.

Patients' Autonomy is leading in Bioethics, as only autonomous person possesses liberty of choice, thus dealing with responsibilities and applying ethical actions is possible in those cases, while liberal choice is permissible.

- Action is considered as autonomous, while person who performs it, acts intentionally, i.e. according to his/ her own intentions, plans, decisions.
- While realizing or understanding the action;
- Without external influence, which may determine outcomes of action or its flow.

Patients decision is refereed as received self-dependently while accepted by the patient without external violated force; coercion, constraint:

1. Direct pressure obliging for taking exact decision;
2. Authoritarian enforcement measures
3. Manipulation with the information

- „Autonomy became a central moral right of competent patient, while at the same time informed consent is now considered as mandatory requirement not only in cases of experimental procedures, but during routine medical practice“.

E. Pellegrino

US Administration of Hospitals for the first time in medical history adopted "Patient Bill of Rights“ in 1973.

- In this Bill was initially announced about the main right of patient - right of informed consent, i.e. patients' **conscious** and **deliberated** choice to agree or disagree, accept or decline proposed or administered course of treatment.

According to bioethics classic authors Beauchamp, Childress in medical practice and in bio-medical experiments there are 3 reasons to 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).

- Informed consent anticipated all medical intervention and manipulation.
- „For providing medical service mandatory term is patients informed consent“

Currently informed consent is acknowledged norm for those patients involved in medical treatment, clinical trials, or bio-medical experiments.

Definition:

- Informed Consent - 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.

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:

e.g. Georgian Law on Health Care Article 8.1

Law of Georgia on Health Care Chapter II. Citizens' Rights in Health Care

- **Article 8.**
- 1. The verbal or written informed consent is the necessary condition for participation of the patient in curative, diagnostic, rehabilitation and preventive processes. A list of medical interventions requiring written consent is determined by Georgian legislation.
- 2. The rights of a patient or a healthy volunteer participating in scientific research are protected by Georgian legislation and internationally recognized norms regulating the conduct of biomedical researches on humans.
- 3. The verbal informed consent is the necessary condition for patient's participation in the medical educational process.

Written consent is mandatory is following states:

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.

Chapter XIX. Biomedical Research

- **Article 108.**
- Prior to a planned biomedical research with human participation, a comparative study of the risk and the expected positive results of the research is to be made. During the performing of the biomedical research the interests and well-being of the person as a subject of the research, are more important than the interests of science and society. The risk of the research should be minimized. It should not exceed the expected benefit of the subject of research and/or the importance of the goals of research.

whether minors are obliged to obey without expression of their consent it is morally unfavorable action.

Nevertheless they will be involved in the decision making process to the fullest extent which their capacity allows.

'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'.

- **Article 12.**
- 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.

Chapter II.
Citizens' Rights in Health Care

- **Article 14.**
- The patient has the right to choose or change the medical personnel and/or medical institution in correspondence with the conditions of insurance agreement; the agreement should provide the possibility of choice.

Chapter II. Citizens' Rights in Health Care

- **Article 7.**
- All citizen's of Georgia have the right to receive in an understandable form comprehensive and true information, to seek for second opinion on his/her health condition, except for the cases specified in Article 41.
- **Article 41.**
- A physician is obliged to provide patient with full information on his/her health condition, except for the cases when the physician is sure that this information will significantly harm the patient.

Article 9.

- A patient has the right to refuse any kind of medical intervention, except for the case stipulated by Georgian legislation and the Article 75 of this Law. A patient also has the rights to refuse the participation in scientific research and medical educational process.

Article 75.

- On the basis of the recommendations elaborated by the Ministry of Health Care the state leads:
- a) compulsory immunization and quarantine measures;
- b) relevant curative and preventive measures taken for citizens with the high risk of development of communicable diseases;
- c) the protection of different entities from contamination and disinfection of contaminated units;
- d) fight against carrying agents in an antiepidemic situation;
- c) the provision of arrangements necessary for providing the antiepidemic readiness of medical personnel.