Obtaining the informed consent of the patient in the process of communication with the specialist - from the obligation to the art to the elimination of the risk

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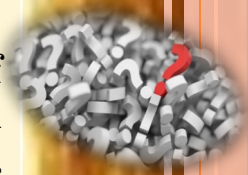


DEFINITION AND APPROACH TO CONSENT
DEFINIREA ŞI ABORDAREA CONSIMŢĂMÂNTULUI

- Informed consent is an expression of the individual's self-determination.
- This procedure describes how to inform patients and their patients, about their rights as a patient and insured person, their obligations as a patient of this hospital, as well as the medical services offered, the treatment applied and any direct or indirect intervention. of the staff employed.
- Expressing the need for protection of vulnerable persons, in order not to be exploited (eg children, comatose patients), the interests can be expressed at least by proxy when they cannot be expressed personally.

DEFINITION AND APPROACH TO CONSENT

Consent - a basic criterion in assessing useful risk.

Prior information - a right of the patient and an obligation of the specialist:

- the balance between the provision of risks and their assumption (useful/excessive warning);
- not to give the feeling of "**misleading**" nor "**over-clarification**";
- essential in the prophylaxis of judicial proceedings;
- mal praxis - canceled/diminished

REGULATIONS APPLICABLE TO PROCEDURAL ACTIVITY

Primary legislation

SR EN ISO 9000: 2006 - „Quality Management Systems. Essential principles and vocabulary ”

SR CEN / TS 15224: 2009 - ”Health services. Quality management systems. Guide for using EN ISO 9001: 2000 ”

Law no.95 / 2006, on health reform Title VII "HOSPITALS"

Law no. 46/2003 on patient rights

Law 42/2008, regarding the removal and transplantation of organs, tissues, and cells of human origin, for therapeutic purposes

LAW No. 584/2002 regarding the measures to prevent the spread of AIDS in Romania and to protect the people infected with HIV or AIDS patients

REGULATIONS APPLICABLE TO PROCEDURAL ACTIVITY

- **Order 946/2005 -** for the approval of the Code of internal control, comprising the standards of management / internal control at public entities and for the development of managerial control systems - republished.
- **Order no. 1389/2006** regarding the modification and completion of the Order of the Minister of Public Finance no. 946/2005 for the approval of the Internal control Code, comprising the internal management/control standards for public entities and for the development of managerial control systems
- **WHO 1500/2009** on the functioning and organization of ATI
- **National Guide** to the rational therapeutic use of human blood and blood components 2007
- **Ordinance No. 137/2000** Repealed on the prevention and sanctioning of all forms of discrimination

REGULATIONS APPLICABLE TO PROCEDURAL ACTIVITY

Other documents, including internal regulations of the hospital

- Internal Regulations
- Regulation of organization and functioning
- Job description

THE ART OF GETTING CONSENT

- it must be equidistant from "professional hypocrisy" and "moral blackmail";

- both dehumanize the patient-medical relationship..

CONSENT STANDARDS

"Patient standard"

the quality of the information will be judged from the point of view of a prudent patient

"The standard of the professional"

from the point of view of the prudent medical personnel.

PARTICULARITIES OF OBTAINING CONSENT IN SPECIAL SITUATIONS

1. OBTAINING EMERGENCY CONSENT

- The particularities of the emergency medical document do not always allow obtaining consent after detailed prior information

- it will act to the maximum interest of the patient (when the problem of a life-saving intervention is raised)

- The medical emergency does not exempt the doctor from informing the patient about his health and the procedures to be applied to improve the medical charges.
- As long as the patient is able to communicate and is aware and able to make a decision, the information needs to be made.
- The refusal of a patient to participate in a therapeutic act must be respected, but if this is not in his best interest, he assumes, in writing, the responsibility of his decision.

2. OBTAINING CONSENT FOR PARTICIPATION IN THE TEACHING EDUCATIONAL PROCESS

- the healthcare process is doubled by the educational process, and the data from the FO general clinic will be processed statistically.
- within the limits imposed by decency and common sense, he/she participates in the educational process with respect for confidentiality regarding his / her identity, but this should not affect the quality of the medical care.
- has the right to refuse the photographing of the body, except for the medical documentation photographs that it authorizes provided the essential elements of the physiognomy are masked, in order not to be recognized

- According to **article 19 of Law no. 677/2001** for the protection of persons regarding the processing of personal data and the free movement of these data, modified and supplemented, the appropriate technical and organizational measures are applied to protect personal data against, accidental or illegal destruction, loss, modification, disclosure or unauthorized access.
- As a result, the Hospital takes all the security measures according to **Order no. 52/2002** regarding the approval of the Minimum security requirements for the processing of personal data.
- According to **Law no. 677/2001**, patients benefit from the right of access and intervention on personal data.

3. OBTAINING CONSENT IN PEDIATRICS

- ✓ The consent of the minors must be viewed from the point of view of the principle of self-determination over the age of 18 (legal majority).

- ✓ Under this age, consent is obtained from parents / legal guardians, except in emergency situations, where - if the family contact (mandatory) failed - recourse is used for life-saving purposes.

4. OBTAINING CONSENT IN ONCOLOGY

- The purpose is to have double protection - of the patient and the medical staff.

- If one of the goals is achieved in the absence of the other, the task of consent is only partially fulfilled. It must provide patients with the information necessary to make a fair choice.

5. GETTING CONSENT FOR BLOOD TRANSFUSION / BLOOD PRODUCTS

- Explaining the meaning of the patient and/or legal practitioners, both the risks and benefits of blood transfusion and those of alternative therapies (erythropoietin, etc.).
- In the absence of the family members or if the urgency of the situation does not provide time for receiving the agreement, the decision to administer the component with the argumentation of vital indications will be made only after the decision of the medical council (no less than 3 doctors) who will make the respective registration in the patient's file.

LAW NO. 282/2005 REGARDING THE ORGANIZATION OF THE ACTIVITY OF BLOOD TRANSFUSION, BLOOD DONATION AND BLOOD COMPONENTS OF HUMAN ORIGIN, AS WELL AS THE ASSURANCE OF THE QUALITY AND THE SANITARY SECURITY, FOR THEIR THERAPEUTIC USE, CONSOLIDATION 2008

CHAPTER VI. Therapeutic use of blood and human components

Article 30

(1) Human blood and blood components may be administered only on the basis of a medical prescription, resulting from a complete medical examination and for therapeutic purposes only.

(2) ***The responsibility of prescribing and administering human blood and blood components lies with the patient's attending physician.***

(3) Clinical indications of blood transfusion and human blood components shall be established on the basis of the National Guide for the rational therapeutic use of blood and human blood components, approved by the order of the Minister of Health.

(4) For the purpose of administering transfusion therapy, the attending physician shall provide the patient with information about this medical document and obtain his / her written consent.

(5) Following the transfusion therapy, the patient is informed in writing about the transfusion act performed.

6. OBTAINING CONSENT FOR THE COLLECTION OF ORGANS IN BRAIN DEATH

- The collection of organs, tissues, and cells of human origin, for therapeutic purposes, can be performed by elderly people in life, having the psychic ability, after obtaining their written, free, prior and express consent;
- The consent is signed only after the donor has been informed by the doctor, about the possible risks and consequences on the physical, mental, family and professional level, resulting from the act of withdrawal.
- The donor can return to the consent given, until the moment of collection

7. OBTAINING CONSENT FOR SURGICAL INTERVENTIONS

- Performing a surgery is **the obligation of the surgeon** to give all the medical information to the hospitalized patient and/or his / her family members about the purpose, benefits, and risks of performing / not performing the surgery, as well as the unforeseeable risks (**including the risk of death**) the consequences of the intervention surgical.

8. OBTAINING CONSENT FOR ANESTHESIA

- Performing the anesthesia necessary for the surgical intervention consists in the **obligation of the anesthetist doctor** to give all the medical information to the hospitalized patient and/or his / her relatives about the purpose, benefits, and risks of performing the anesthesia, as well as of the unforeseeable risks (**including the risk of death**), the consequences it implies performing anesthesia.

9. OBTAINING THE AGREEMENT OF THE LEGAL REPRESENTATIVE OF THE PERSON WHO CANNOT EXPRESS HIS WILL, OR WITHOUT DISCERNMENT

- In the case in which a patient is discharged without emergency and without an attendant, brought by ambulance usually, the consent for major/surgical interventions will be granted by ***the medical team present at the hospitalization through the signatures from FOCG, the team constituted according to the legal procedure.***

- The team members will sign in place of the legal representative.

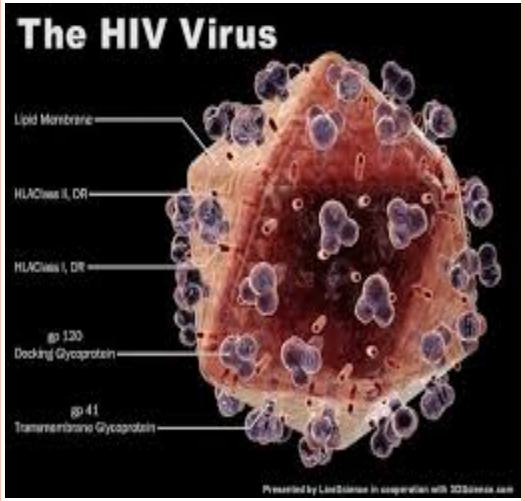
10. OBTAINING CONSENT IN PSYCHIATRY

- Patients affected by mental disorders to the limit of "normality" may be considered fit for informed consent.
- They have the same rights as patients with physical problems, and their hospitalization is voluntary.

11. OBTAINING CONSENT FOR ANALYSIS IN ORDER TO DETECT HIV INFECTION

- confirms the agreement for carrying out an analysis for the detection of HIV infection and for collecting the blood needed for it
- it can be changed at any time after harvesting to complete the sample

- ***note that the analysis cannot be performed in the absence of a fully and correctly completed declaration of agreement.***



DECISION No. 1342/2004 regarding the approval of the National Strategy for the surveillance, control, and prevention of HIV / AIDS cases

- ✓HIV testing is voluntary, and/or anonymous, with the guarantee of confidentiality and pre- and post-test counseling, both in the state and in the private sector.
- ✓Implementation of a system of disqualification and/or penalization for persons or managers of hospitals that violate universal precautions.
- ✓Including employer and trade union organizations in the national coordination mechanisms for HIV / AIDS;
- ✓Develop and promote policies to prevent HIV transmission to workplaces with potential occupational risk.

HIV / AIDS CONSUELING AND TESTING

Objective

- Increasing access to the general population and vulnerable populations to HIV / AIDS counseling and testing

Strategies

- Increasing counseling capacity by introducing the obligation of HIV / AIDS counseling to perform any voluntary test;
- Multiplication at the national level of programs that facilitate access to testing and counseling for vulnerable groups, respectively: persons involved in commercial sex, drug users, homosexuals, street children;
- Capacity development to ensure universal access to counseling and testing of pregnant women;
- Conducting periodic sentinel studies to estimate the incidence of HIV in population groups at risk.

MEDICAL RESPONSIBILITY RELATED TO INFORMED CONSENT

- The existence of the consent does not release the medical personnel from the responsibility for the mistake.

- Even if, without the consent, the medical personnel will bring the risky act to an end, they may still be accused of not complying with the consent request and may be sued on these grounds.

RULES FOR PROFILAXY OF RISKS

- *full competence* = professional honesty;
- *careful,* conscientious care, according to the latest scientific acquisitions;
- *rational caution,* according to the therapeutic arsenal;
- *the ability to make decisions* in difficult conditions involving accepting risks in the patient's interest;
- *permanent devotion* to the medical profession

RISK-BASED RESPONSIBILITY

- the possible risks incriminated, presume the mistake;
- prophylaxis of unknown risks (defensive medicine).

Risk posology (sharing of therapeutics = study of drug doses and their mode of administration), risk assessment in relation to the disease (intolerance reactions) - timely/inappropriate risk.

Abstention - medical error by refraining from taking risks.

RISK EVALUATION

Risk assessment is a complex process that is permanently related to the expected results, the spontaneous evolution of the disease, the technical conditions and the competence of the specialists through a statistical evaluation (it is not equivalent to the evaluation of the individual case), so that the risk:

- it is accepted only in *the interest of the patient;*
- to be accepted *freely and clearly* by the patient;
- not to have *negative human effects;*
- be *useful and socially justified;*
- it is accepted only *in the absence of an alternative;*
- must solve *the problem of medical necessity*

CONCLUSION

- Currently, there is a real creation of a patient's desire for information about the medical record. This is leading to the emergence of computerized consent, a process has not yet been private as a bureaucratic stage and is not part of a therapeutic act.

- Information provided through consent for the computational variant of the simple complex and the respect of the patient's need for information as well as their limit of understanding must be tailored to each individual.

- Informational consent must become a valid and real expression for a patient to the will that must respect the patient of an individual autonomous individual decision and by this principle to determine self-determination.


Dr Bill
THANK YOU!