

LAW AND ETHICAL REASONING ON THE INFORMED CONSENT

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INTRODUCTION

Ethics is the study of morality – careful and systematic reflection on the analysis of moral decisions and behavior, whether past, present and future (WMA, 2005). Ethics was closely linked to medicine since ancient times. Hippocrates was the exponent of an ethical medical act, the principle of beneficence being underlined in Hippocrates Oath. Nowadays, medicine changed dramatically, and thus the patient-doctor relationship changed also. Modern medical ethics is based on human rights. Medical ethics is also closely related to law. European laws related to human rights and patients' rights are well known. But ethics and law are not identical. Quite often ethics prescribes higher standards of behavior than does the law, and occasionally ethics requires that physicians disobey laws that demand unethical behavior (Jones, 1931).

Hippocrates said in his quotes: "Life is short, the Art long, opportunity fleeting, experience treacherous, judgment difficult. The physician must be ready, not only to do his duty himself, but also to secure the co-operation of the patient, of the attendants and of externals". (Jones, 1931).

What is the informed consent? According to the Medical Dictionary, the informed consent is the voluntary agreement

to medical procedures/treatment given by a patient after the potential risks, hazards, and benefits of the treatment have been explained (Mosby, 2005).

In the WMA Declaration on the Rights of the Patient it is written: "The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient on the consequences of his/her decisions. A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the

information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent."

There are many national and international official documents that describe the informed consent, such as: Romanian Law No. 46/2003 on Patient rights, Romanian Law 95/2006 on Health Reform, completed with Order no. 1170/2014, Code of Medical Ethics of the College of Physicians in Romania, the European Convention on Human Rights and Biomedicine, Charter of Fundamental Rights of the European Union, European Parliament, Council and Commission, AMM (WMA) Declaration of Lisbon on the Rights of the Patient, 34th World Medical Assembly, Lisbon, Sept/Oct 1981, modified by the 47th WMA General Assembly, Bali, Indonesia, Sept 1995 and revised by the 171st WMA Council Session, Santiago, Chile, Oct 2005, European Convention on Human Rights, Charter of Fundamental Rights of the European Union.

Is it a legal demand or a moral one? The Romanian Law in force, in Chapter III, stipulates that any medical intervention needs the consent free and uncorrupted, obtained from the patient, previous to medical services, being an expression of freedom of any person. The patient has the right to refuse or to stop the medical intervention, thus assuming, in writing, the responsibility for his decision. Moreover, the patient has the legal right to medical information, on his own medical status, the right to health care of the highest quality (Law 95/2006, Law 46/2003).

The procedure regarding the clinical decision-making within the Romanian hospitals includes special forms that the patient has to sign prior any medical/surgical intervention, after the correct information of the patient.

Clinical Bioethics makes the clinicians to face many ethical dilemmas, every such case being different and raising multiple questions to solve.

MATERIAL AND METHODS

One question, including a virtual ethical problem, was addressed to a lot of medical students from the first and second years of study, aged 19-45 years. The students responded to the question voluntarily and had enough time to decide their answers.

The ethical problem was the following: an old patient recently diagnosed with chronic lymphatic leukemia, advanced disease, admitted in the Hospital. The patient required chemotherapy in order to improve his prognosis

- without chemotherapy rapidly fatal. The old patient had his decisional capacity intact. His daughter, a doctor herself, insisted that the doctor shouldn't communicate the hematological diagnosis to her father. She almost threatened the doctors, and also asked the doctors to give his father the chemotherapy that could save his life, even without any information about the disease or treatment for her father.

The anonymous answers from the student lot were collected and analyzed.

It is important to mention that these students hadn't had their clinical training yet, thus having no experience in the doctor-patient relationship.

Table 1

Answers and ethical suggestions from the questioned lot

| |
|---|
| Complete information on diagnosis and treatment |
| Before telling the truth - previous psychological counseling; if he finds out later, it could be more serious |
| The patient must know the diagnosis, without his consent the doctor can't give him the chemotherapy |
| The patient decides for his own life, no matter what consequences. |
| Respect the autonomy of the patient; explain the patient all the benefices of the treatment. |
| The doctors must follow the law in force regarding the patient's rights – the right to information and to informed consent. |
| The principle of autonomy must take prevail over the principle of beneficence. |
| In spite of all his daughter's insistences, the doctor must communicate the medical truth |
| Ignore the patient's daughter opinion |
| The doctor can't start the treatment without the patient's informed consent, even if the patient's daughter is threatening the doctor |
| The patient must be carefully examined in order to establish his decision-making capacity |
| The doctor can't start the chemotherapy without the patient's decision, because, even if we know that the treatment would save his life, the patient could decide that he didn't want the chemotherapy |
| The doctor must obey the law and the ethics principles, and not the patient's relatives wishes |
| Respect the human rights |
| The doctor must communicate the diagnosis, otherwise he can't get the accept for the treatment |
| Communication of diagnosis can be a little delayed, in the meanwhile the doctor can have another discussion with the patient's daughter |
| Communicate the diagnosis in a proper way |
| Communicate the diagnosis step by step |
| The doctor must provide medical care at the highest level possible |
| First talk to the patients daughter, inform her correctly |
| The patient has to be sustained by his family. If the truth is hidden, finding it out after a while could affect the family relations. |
| Ask the patient's daughter to explain herself the medical status to her father, the final decision being the patient's one |
| Even if the patient's daughter is a doctor, her emotional involvement in this situation could affect her decision-making |
| The doctor can talk with the patient's daughter again, and give her a period of time (no longer than ½ hour) to take a decision, otherwise the doctor transmits the diagnose to the patient |
| The doctor tells the patient that he has a serious disease and that his daughter doesn't want him to know the truth. Afterwards the patient can be asked to talk to his daughter himself and reach a decision together. |
| Give the patient the chemotherapy but tell him that he is given another kind of treatment, so saving his life without telling him the truth. |
| Consider the consent for chemotherapy the patient's daughter consent. |
| Respect the patient's daughter wish |
| The doctor can tell the patient that he is severely ill, without telling him the real diagnosis, thus the patient is constraint to accept the treatment |
| The doctor should start the treatment, thus respecting the <i>primum non nocere</i> principle. |
| Respect the daughter's wish, because she is also a doctor and she knows best his father and the way he could react to such a news. |

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| Respect the principle of beneficence, so start the treatment and inform the patient about the diagnose when he is emotionally ready to accept it |
| Establish a medical council that could help with a decision in this case. |

Table 2

Comparison between the decision-making choices in this case

| Tell the truth to the patient | Don't tell the truth to the patient and give him chemotherapy |
|-------------------------------|---|
| 92,4% | 7.6% |

DISCUSSIONS:

WMA is an international organization that seeks to represent all physicians, regardless of nationality and specialty, and it established general standards in medical ethics: Declaration of Geneva, International Code of Medical Ethics, Declaration of Helsinki, Declaration on the Rights of the Patient aso, periodically revised. Every case studied raise questions about physician behavior and decision-making – not scientific or technical questions such as how to treat chronic lymphatic leukemia, but questions about values, rights and responsibilities. Physicians face these kinds of questions just as often as scientific and technical ones (WMA, 2005). The art of medicine involves the application of medical science and technology to individual patients, no two of which are identical (WMA, 2005).

In every day medical practice, many clinical ethical cases are difficult to be solved, many times the doctor needs to call for the help of other colleagues or the local ethical committee. There are ethical issues, for example asking for the patient's consent in a clinical trial, for which there is a well-developed consensus on the right way to act in that situation (WMA, 2005).

The ability to make decisions should be the quality possessed by everyone. The ability to make the correct decisions should be one of the most predominant assets of all those whose decisions change the lives of other people (Keidar, 2005). The decision comes after examining all the factors that can influence the case, the subject in case and involves the knowledge, the feelings of each part. The onco-hematological patient is part of a special patient category, who lays all his life in the doctor's hand; the hematological diagnosis change not only the patient's life, but also the patient's family life and his immediate environments. The doctor's firm decision – and especially when the doctor stands for it – inspires self-confidence and increases the trust in doctor-patient relationship.

In clinical decisional bioethics, the questions that can be asked in an ethical case are:

- Is the case an ethical problem?
- To what ethical principle is the case referred to?
- Which are the key aspects?
- What is the real problem?

- Who is implicated in the case?

After we synthesized all the data from the study lot, meaning their personal opinion on the case, we analyzed the case from an ethical point of view.

Is the case an ethical problem?

The answer is yes, we face an ethical problem. The hematological decision was correct, but the specialist can't continue the medical interventions because of the ethical conflict.

To what ethical principle is the case referred to?

This case refers to the principle of beneficence – *primum non nocere*, and to the principle of autonomy – the patient decides for himself. The doctor faces a hematological patient, correctly diagnosed who requires chemotherapy. The first medical duty is to do the best for the patients. On the other hand, there is the principle of autonomy that stops the doctor judge the medical act solely through his own concepts, as in paternalistic eras, and take seriously into consideration the patient decision, whatever it could be. Are the two principles in conflict? Sometimes they seem to be in conflict, but modern medicine comes with another important concept, that of quality of life. On the basis of this concept the patient, for example, can choose to refuse the treatment in order to have a short but satisfactory quality of life instead be given chemotherapy that could raise multiple side effects and thus alter his quality of life.

Who is implicated in the case?

- The patient: the severely ill person
- The doctor: having the responsibility for the patient's life and health
- The patient's daughter: close relative to the patient, also a doctor

Who is implicated besides the three?

- The hospital: through internal procedures and regulations; the doctor is an employee of the Hospital

Which are the key aspects?

The key aspects can be considered the following:

- The Romanian law comprises Law no.97/2003 – the Law for Patients Rights. This Law stipulates that one of the patients rights is the right to information and to the informed consent.
- The patient has a severe disease that requires chemotherapy in order to improve the prognostic (avoid death).
- The patient has its decisional capacity unaltered.
- The patient's daughter is a doctor, so a colleague of the doctor in charge for the patient.
- The local hospital rules require an informed consent for every treatment given to the patient.

What is the real problem?

Defining the problem is a difficult task. It comprises avoidance of a hasty decision, finding all alternatives, avoidance of formalistic reasoning during the process of situation appreciation, avoidance of ready-made solutions (Keidar, 2005). Correct and complete acquisition of data is part of a correct decision-making. Sometimes it is necessary a collective decision making, when the time to involve other colleagues is long enough.

Determination of objectives: the aim and the benefits accruing from it is another important step in ethical reasoning. At last, preparation of alternatives after a decision has been reached – in case it can't be implemented.

In this case, the real problem seems to be to inform the patient correctly regarding the disease. To obtain the patient's informed consent for chemotherapy. Without an informed consent, the chemotherapy can't be given.

Of course, many ethical questions arise from every case, once it is deepened. The students noted it and tried to give their personal opinion on solving it. The majority went for telling the truth to the patient, and supported this in several ways such as: respecting the patient's rights, respecting the patient's dignity as a person. They underlined the importance of a proper information on the disease and the treatment to be given, the importance of a previous psychological counseling.

Ethical medical dilemmas must take into account that the "case" it studies is a human being, and, moreover, a vulnerable one – a patient, having his own fears, feelings, changes of mood. In this regard, the students made good observations on how the diagnosis could be communicated: step by step, in a proper way, the manner of communication being personalized for each patient. The students also noted another important aspect that the doctor has to take into account: the patient's family. The patient's family has in general a crucial role for the patient, supporting him even from the beginning – communication of diagnose etc. The remarks were that the doctor should have another constructive discussion with the patient's daughter, explain to her again all the situation or even let her talk about the malignant diagnosis with her father. Even she is a doctor and thus she should know the patients rights and the Hospital

requests, her judgment could be altered because of her emotional involvement.

Part of the students choose not to tell the truth to the patient, thus respecting the principle of beneficence solely. Part of them considered the daughter's consent as sufficient for giving the therapy. If the patient has his decisional capacity unaltered, then the choice is always his, the official forms require his signature on the informed consent.

The subjects' decisions (and the doctors' decisions) are influenced by their own personality, their outlook on life, their own codes of values and beliefs, their social group ethical norms, their logical judgment, professional experience. The process of choice could be essentially mathematical, on an algorithmic structure or based on a heuristic method, in which the correct decision is spontaneous (Keidar, 2005).

In the decision-making process, the cognitive and emotional features of decision can occur. The emotional element, often hidden and imperceptible, consists of emotional outlooks derived from personal experiences, worldliness, education and attitudes. It can distort sometimes the rational judgment (Keidar, 2005).

CONCLUSIONS:

As a consequence of this study case, we drawn some practical conclusions that could help in ethical decision-making. First the consultation of authoritative sources such as Laws, internal rules, ethical codes and respected colleagues. Respecting the Law is the first request. Then the proposed solution is to be discussed with those whom it will affect. Balance the outcomes of the choice, the short-term and long-term aftermaths of the decision. Afterwards, making the decision and acting on it, with sensitivity to others affected, is the next step. Always evaluate the decision and be prepared to act differently in future (WMA, 2005).

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