MEDICAL LAW AND ETHICS

Sunčica Ivanović1, Ćedomirka Stanojević1, Sladana Jajić2, Ana Vilà3, Svetlana Nikolić4

The subject of interest in this article is the importance of knowing and connecting medical ethics and medical law for the category of health workers.

The author believes that knowledge of bioethics which as a discipline deals with the study of ethical issues and health care law as a legal discipline, as well as medical activity in general, result in the awareness of health professionals of human rights, and since the performance of activities of health workers is almost always linked to the question of life and death, then the lack of knowledge of basic legal acts would not be justified at all.

The aim of the paper was to present the importance of medical ethics and medical law among the medical staff.

A retrospective analysis of the medical literature available on the indexed base KOBSON for the period 2005-2010 was applied. Analysis of all work leads to the conclusion that the balance between ethical principles and knowledge of medical law, trust and cooperation between the two sides that appear over health care can be considered a goal that every health care worker should strive for.

This study supports the attitude that lack of knowledge and non-compliance with the ethical principles and medical law when put together can only harm the health care worker. In a way, this is the message to health care professionals that there is a need for the adoption of ethical principles and knowledge of medical law, because the most important position of all health workers is their dedication to the patient as a primary objective and the starting point of ethics. Acta Medica Medianae 2013;52(3):67-72.

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Bioethics and medical law

The term bioethics was mentioned for the first time in 1971 in the book "Bioethics - Bridge to the Future," in which Professor Van Rensselaer Potter II used a prefix (Greek: bios=life) and the term ethics, and thus emphasized that the growing biological knowledge at the same time needs to be under the watchful eye of the moral, human values. The emergence of bioethics itself necessarily had to happen due to increasingly more complex requirements when making medical decisions and their connection with ethical problems, both for health workers and for laymen involved in the decision-making process, for whom the traditional interpretation of medical ethics was "too close" to give satisfactory answers.

Bioethics is not only about the issues on the so-called classical medical ethics, such as abortion, euthanasia, medical secrecy, relationship with the patient, but also on issues such as cloning, organ transplantation, treatment of patients with AIDS, contemporary issues like disthanasia (the process of purposless extending of life), artificial insemination, surrogate motherhood, manipulation of the human genome, genetically modified foods, and religious and ethical issues on respect of rights of the members of Jehovah's Witnesses in case of blood transfusion (1).

"Medical law is a legal discipline, a subject restricted area of law, which regulates the relationship between the patients and the medical staff pursuant to legal norms as well as medical activity in general" (J. Radišić). By these legal norms, an external control over the conduct of medical professionals is being established in the name of the community, aimed at protecting the rights and interests of not only patients, but also the community as a whole (2). Medical ethics and law are complementary; pursuant to the rules of medical ethics the courts recognize the legal force as well, and any failure of health professionals which is not in accordance with the set rules shall be subject to sanction, so it is...
indisputable that medical ethics is the source of medical law (3). When ethical principles and rules of conduct in the medical area are regulated by legal norms, an overlap i.e. a kind of symbiosis of bioethics and medical law happens, and in so doing it is the least significant whether bioethics has become a part of medical law or is it vice versa (3).

Medical ethics is closely related to law, but law and ethics are not identical. Many times, ethics provides a higher standard of behavior than laws. In addition, laws vary from country to country, while ethics applies regardless of national boundaries. In order to respond to the expectations of patients, health professionals should know and practice the core values of medicine, and especially care for/about a patient, ability and autonomy in their work. These values, together with respect for the basic human rights, are the basis of medical ethics (4).

"Medicine and Law have a lot in common, and sometimes overlap...medicine takes care of the life and health of people in one way, and law does the same in the other way...lawyers and doctors during their studies study a common doctrine: Forensic and Legal Medicine" (J. Radišić). It could be said that the medicine used to, with regard to law, have a privileged position in comparison with other professions. It was regarded that such an audit, except in some upmost basic issues, was not necessary as far as society or the state were concerned. Furthermore, the opinion was that a sufficient and successful control might be established and carried out only by the medical professionals themselves through their professional associations and chambers, using medical ethics. Let us recall that, from the very beginning of the development of medicine, and until recently, paternalism has ruled in medicine. Paternalism has put the interest of the health of a person in front of the interests of the person to decide for himself/herself what is best for him/her under the circumstances (Lat: salus aegrotisuprema lex). It has often been explained by the patient's lack of knowledge, which according to the doctor, was needed to make a rational decision about a medical procedure. The starting point was that the doctor knows best and knows how to protect the health and interests of his patients in the best way, knows how to treat them, and what to do on their behalf. It was not until the early twentieth century, when law began to interfere with the relationship between the patient and the physician (i.e. medical staff), as well as in medical activities (5).

The time we live in is marked by the development of science and its impact on society. To solve medical problems, it is necessary to have a comprehensive knowledge, and therefore it is right to say that raising the level of personal professionalism is something that we should work on a daily basis (6). Perhaps a number of the health workers would claim that knowledge of law is absolutely necessary for lawyers only, but it can be said that the knowledge of law can make the difference between a successful and unsuccessful man in the occupation he performs. Ignorantia juris nocet (ignorance of the law harms) is one of the fundamental principles of law. The logical conclusion is that the lack of knowledge of law brings health workers into situations that can do harm to them.

It is often difficult to measure something that is intangible and invisible to the human eye, and especially to control it. Sometimes, especially in today's global business environment, it is difficult to implement, as pointed out by Takala, the concept of ethics which in itself does include the idea of universality and equality in the applicability of the rules, for what is good for one may be bad for others (7). Health policy imposes an additional role on health care workers, too, to conduct social policy, and even to be keepers of the social wealth. Nowadays, there are different aspects of the moral responsibility of health professionals as far as designing and implementation of health policy are concerned.

These responsibilities are as follows:
- The health worker must respect the trust given to him and in his work to be guided only by the interests of patients;
- The health worker provides accurate and reliable information to those who create health policy. In this way the health worker participates in making decisions which are important for the organization of health services and the distribution of health dinars;
- The health worker, as well as all the others, has an obligation to work for justice and social interest;
- The health worker must take into account the prescribed legal and regulated rules and regulations in order to reduce medical costs. Thus, the desire of patients and assessment of doctors are correlated with socio-economic needs;
- The health worker is primarily a morally responsible individual (4).

In the recent years, ethics in health care has been heavily influenced by the improvement in human rights. In the world we live in, with lots of different moral traditions, it is international agreements related to the human rights that matters. They form the basis for medical ethics, which is acceptable to all, crossing national and cultural boundaries. Ethical and human rights have the same roots in many core values (Mann, 1997). These examples include respect for autonomy, beneficence, harmlessness and justice. Justice has many forms but all of them are relevant to health care workers. What is important in nursing practice is that by using the professional code of ethics one should remain aware of the social impact and consequences of their treatment. Nursing profession has reached a consensus on the ethical obligations which are contained in the Code of Ethics for Nurses.

The principles of justice and care are the points at which the issues of ethics and human
rights unite. Authors Falk-Rafael (2006) define "Nursing is a fundamental responsibility to promote health, prevent disease and alleviate suffering, it is a call to express the concern for humanity and the environment through political activism at the local, national and international level. This would mean that if there are no rules, there is a need and an obligation to fulfill them. For instance, the right of all the patients to have an equal treatment throughout the health care implementation, i.e. the nurses should provide fair and equal treatment of all patients. The Code of Ethics also obliges nurses to provide fair and equitable treatment respecting "the dignity, worthiness and uniqueness of every individual, unrestricted considerations of social or economic status, personal attributes, or the nature of health problems (8). Therefore, knowledge of medical law allows nurses easier, better and safer application of practical knowledge gained from everyday conduct of activities, and which is the result of responsible and dedicated approach to professional duties. This includes love of the profession, critical thinking, nursing knowledge and expertise. Nurses actively engaged in clinical situations with a sense of responsibility and commitment to the profession contributed to efficient implementation and improvement of specialized knowledge (9). Based on this, we can say that the health care that is congruent with the needs of patients, and within the available resources it is both righteous and attentive (8). Medical ethics rules are usually codified in a separate, national and international, ethical i.e. deontological codex.

The principles and rules of conduct are generally determined by the codes of ethics and deontology, which in the performance of their professional duties, and in order to preserve the dignity and reputation of the profession, health care workers and members of the individual chambers are obliged to abide by (3). The struggle for prestige and status of the profession come out of the in the Codex adopted and brought by the profession itself. In their class organization, health care providers express their professional integrity and identity through the creation and adoption of codes of ethics, rules of conduct and the desirable behavior which they consciously and in a disciplinary way comply to. On the other hand, medical law is not only composed of the regulations passed by the state but also of the regulations passed by the professional associations of health workers i.e. in this case, the regulations passed by the Chamber of health workers. (10)

We can say that medical law with its legal rules regulates medical activity, determines the status of people who conduct the activity and their relationship with the users of their services. This leads to the protection of human rights to health, health care and health insurance, as well as the rights and responsibilities of health workers and health organizations. This unity shows that medicine and law tend to have a common interest with an aim to preserve the human most precious resources of life, body, health and human dignity as integral and important parts of human rights protection (3).

**Safety and health promotion**

There is no doubt that in recent years the various legal aspects of occupational health services have been the subject of interest. In this context, they emphasized three arguments have been particularly emphasized:

a) First, every person needs health in order to be able to work normally and happily, to live alone or with his family. The state and the whole society are interested in human health (public health) out of many economic, social, cultural, defense and other reasons, as well as for reasons of humanity.

b) Secondly, the Republic of Serbia is going through a period of intense legal regulation of the health care system. Since the late nineties the normative action in this area, encouraged by the commitments under the Stabilisation and Association Agreement of the EC has resulted in adoption of constitutional law and numerous regulations related to health care.

c) Third, the stated interest stems from the desire which is based on the general well known idea - the principles of human rights under the Constitution of the RS, legislation, UN Convention, the EC legislation, the National Health Development Strategy (2006-2010), programs and directions that accompany medical care.

The Code of medical ethics and deontology has a special meaning to healthcare professionals and patients. It obliges all Chamber licencend health workers in the RS to independent practice.

Medical Ethics and Medical Law are particularly interested in the relationship between health professionals and patients concerning the provision of medical services. Strictly looking that ratio does not take place only according to legal rules, but also according to the norms of so called medical ethics.

Furthermore, ethical considerations are primary in this area: they form the legal obligations, determine their content and scope. Unless the ethical rules of conduct are sufficient to ensure a quality service, the right has to come to the rescue as a reserve. Because ethics and law are complement and they rely on each other, in the case of legal loopholes the ethical rules are worth, and where the legal rules are made, they are applied at the same time, or in the case of different solutions, they take precedence over the class rules (10).

The literature review shows that there is little that describes the implementation of the entire law on patients' rights, and just a bit of research on the application of patients' rights in the specific area of international field. In 2007, Länsimies-Antikainen published the results of a
Informed consent - a bridge to future and partnership with a patient

Informed consent, conscious consent, informed approval, informed or informed consent grasps wide bioethical area: respect for the patient's personality, patient care in medical procedures and biomedical researches, including family, relation to children, patients and people with impaired reasoning ability and communication between health care workers and patients.

Tom L. Ruth Faden and Beauchamp point out that the term informed consent was first mentioned in 1957. But not earlier than 1972, the debates on doctors and researchers duties, their relationship to the patient in a medical procedure and subjects in medical research began. That same year the right of patients to understandable information was declared and based on that the acceptance or rejection of a medical intervention (13).

Göran Hermerén, professor of medical ethics at the University of Lund in Sweden, the current president of the European Group on Ethics in Science and New Technologies (engl. The European Group on Ethics in Science and New Technologies - EGE) in Brussels, introduces three categories of questions, i.e. problems that appear in both the theoretical (pre) settings, as well as practical application in clinical practice into the contemporary debate on informed consent. These are:

- conceptual problems - try to explain the meaning and the (pre) conditions of informed consent;
- empirical problems - try to find out, for example, how much time doctors need to provide information in some specific conditions, and how the information provided is understandable to the patient or family;
- regulatory issues - to try to determine, when, how and by whose duty consider the informed consent (14).

The functions of informed consent in clinical practice

According to two prominent lawyers and bioethicists, Jay Katz and Alexander Capron, informed consent includes the following features:

1. promotes individual autonomy of the patients and subjects
2. encourages rational decision making,
3. eludes the interference of the public
4. refers physicians and researchers to ethical self-control,
5. reduces the risk of civil and criminal liability of doctors, researchers and their institutions.

Ivan Šegota points that the 6th function should be added here - communication, because informed consent is actually based on communication, one might even say that communication is the crucial problem. From the point of view of communications, in order to determine the validity
of informed consent the most important things to be considered are the following:

1. how well the information is given,
2. how much the patient understands it
3. how consent is truly voluntary,
4. how to get the consent from - the incompetent person, or person with reduced competence, as well as people exposed to hidden pressures (prisoners, soldiers, students ...)
5. how much time it actually takes to communicate with patients or subjects.

The Declaration adopted by the 33rd General Conference of UNESCO on 19 October 2005th issue of informed consent is processed through Articles 6 and 7 (15):

**Article 6 – Consent**

1. Any preventive, diagnostic and therapeutic medical intervention may only be carried out with the prior and free consent of the person which means the obtaining of sufficient information. When appropriate, the person has to give his consent, and he may also withdraw it at any time and for any reason without adverse consequences and damages.

2. Scientific research can only be carried out with the prior, free, expressed consent of the person based on the received sufficient information.

   The information should be adequate, provided in a comprehensible form and they should include modalities for consent withdrawal. Consent may be withdrawn by the person concerned at any time and for any reason without any negative consequences or damages. Exceptions to this principle may be made only in accordance with ethical and legal standards adopted by States, pursuant to the principles and provisions set forth in this Declaration, especially in Article 27 and International Human Rights Law.

3. In appropriate cases of research carried out on a group of people or community, an additional consent of the legal representative of the group or community is required.

   A collective agreement or consent of a community leader or other authority in any case it cannot replace an individual consent of each person received upon sufficient and relevant information

**Article 7 – People who are unable to consent**

In accordance with domestic law, special protection is given to people who are unable to consent

a) authorization to conduct research and application of medical practice should be obtained in accordance with the best interests of the person concerned in accordance with domestic law.

However, the person concerned should be involved as much as possible in the decision-making process of consent, as well as the process of consent withdrawal;

b) the research could be only carried out for the direct benefit to the health of the person concerned which is subject to the authorization and protection provided by law, and if there is no other alternative to the research and whose efficiency with that participant could be compared with other researches that the participant might agree with.

The research that does not have any potential direct health benefit may be taken as an exception with the maximum limitations and minimum risk and burden to which that person is to be incurred, and if these studies are expected to contribute to the health benefit of others of the same category they must comply with the conditions prescribed by law and be consistent with the protection of human rights of the individual person. Any refusal of such people to participate in research must be respected

**Responsibilities of health workers**

The principle of respect for autonomy includes the law on consent and refusal of treatment (16). The ability of human mind to choose the crucial factors determining the choice and the decision based on it represents autonomy, the ability to defend and protect the human personality and moral identity. Its guidelines suggest consideration of personal values, opinions, beliefs and perceptions, fundamental human rights, self-determination skills (17). Touching a patient without a consent is recognized in law as a violation or even an assault. Patient's consent must be voluntary, meaning that the patient has the ability or competence to make decisions and to be informed so that the consent is legally valid. Based on this the conclusion for the health care entities is that the consent is valid only after the patient's being previously informed about the procedure, and if the person understood properly the obtained information and based on all these voluntarily gave the consent (17).

The right to refuse is only the other side of the right to give consent and together they make a whole, and pursuant to the law, the patient’s decision must be respected even if he could in that way jeopardize his own life. Decision-making capacity is a key condition for the final approval/consent. Knowledge and understanding of the ethical framework as well as the law governing the right to refuse treatment and decision-making ability is very important. Law on mental capacity (Mental Capacity Act) 2005 evaluates the competency assessment, and it was created in order to demonstrate consider-ration of ethical issues in clinical practice and the application of ethical theory. Capacity Act (MCA) 2005 states that the patient must assume to have capacity unless there is a different proof. What this status provides is the guidance on assessing skills and
activities in the "best interests" of those who do not have the ability, with the primary goal of balancing the rights of potentially affected patients and their care. If it is estimated that the patient does not have adequate capacity of assessment, and needs to be involved further in the decision-making process as much as possible in order to strengthen his capacity to exercise autonomy. The conclusion that the patient lacks the capacity to give consent or refuses to undergo the treatment must be showing that the patient did not understand the information relevant for decision making, cannot keep the information, cannot perceive information as a part of decision-making process, or is incapable to communicate the decision in any way. The capacity act recognizes the ability of changing one's decision and it emphasizes that the assessment of capacity should be carried out just when the decision should be made.

It is particularly relevant when the care of patients in the early stages of Alzheimer disease is concerned. Beauchamp and Childress have developed frameworks for moral reasoning based on moral judgment, rules, principles and theories at different levels of moral reasoning. This approach does not solve the ethical problem but it aims to help decision-making in health care practice. At the level of principle, the authors have made four basic moral principles that can be applied in an ethical dilemma for the identification and importance of ethical issues. These principles refer to respecting the patient's autonomy, well-being or provision of procedures for the benefit of patients, not doing any harm or wrong, to being just and acting honestly and fairly. Health workers in this way receive guidance for decision-making in practice and thus protect the patient's right to self-determination and interests of vulnerable patients (16). These guidelines emphasize the requirement that a patient is the centre of decision-making, the patient should be told the truth, patient's privacy is to be respected, the information must be fully preserved and patient's personal beliefs should be respected; the consent for the proposed interventions should be obtained in accordance with the competence of the healthcare worker, to respond to all patient's questions so that he could make the final decision (17,16). Taylor said that modern society requires moral competences of health professionals and that they are aware of the full moral responsibility in order to work through ethical issues, because only health care workers who have moral competence can be trusted to act in ways that promote the interests of patients (18).

The way to solve the dilemma of health workers

Viewed from a practical perspective, the following information and knowledge can help health professionals in their daily work to solve the dilemma they have (19).

1. Communication and collaboration with ethicists, particularly in terms of establishing an ethical relationship with the patient;
2. Determinants of ethical documents binding for health care workers: national ethical Code Medical Association (chamber), and the Geneva Declaration and Helsinki Declaration, the International Code of ethics for medical professionals (including nurses);
3. Bioethics, which offers the approach to solve ethical dilemmas that they are faced with.

Discussion

In this paper, most attention is paid to the knowledge, learning and connecting of ethical principles and medical law and the importance of considering the provision of health services, functioning, and quality of health care as one of the priority issues for all citizens and health care professionals. The right to health care has been recognized in the Charter of Fundamental Rights of the European Community. The aim of all health professionals should focus on understanding and review of the existing solutions in an ethical, legal, social aspects by comparing it with the correct model of behaviour and work with patients, detection and determination of potential mismatches between regulations and their enforcement, the continuous monitoring of legislative changes being implemented in the direction which enables the most appropriate behaviour and dealing with patients, particularly when it comes to vulnerable patients, for instance, people with HIV, dementia or some infectious diseases. Errors in medicine are not rare and it is a reality that doctors should be aware of them worldwide.

Often the consequences of these errors are impairment, a disorder of some functions, and sometimes death of patients due to the failure or negligence of health care professionals. Given the undeniable dominance of litigation in relation to criminal matters, which for the subject include the actions of health care workers, and a high amount of monetary damages as well as an effort to avoid their payment, it has been concluded that the risk of liability of health professionals for the damage the patient may incur while treated is very large. To minimize the risks and amounts of awarded damages based on the responsibilities of health professionals, the institute insurance against liability of health professionals is being implemented. Insurance Institute has a role to improve the status of patients on the one hand, and health facilities and health workers on the other. The patient is obliged to prove the occurrence of damage caused by the activities of a health care professional, and if he succeeds to prove the guilt of the damage, he is eligible to claim compensation for damages from the insurer. Improved status of health workers is that through an insurance policy in case of liability they are released of obligation of potential claims of
patients that can reach amounts that would bring into question the future of health workers, and further investment in the health institution. Aspiration of the society should be reflected in an effort to support the idea of establishing accountability for health care workers, which enables that mistakes and accidents in medicine to be viewed in the light of their true nature and avoid the temptation to categorize them into the hidden practices of health professionals.

When you build equality, trust and cooperation between the two sides that appear in the process of health care, then this procedure can be considered to be the aim which each society should aspire to (20).

**Conclusion**

There is no doubt that the knowledge and linking of medical ethics and medical law for health professionals is especially important in the delivery of health care as it is important for citizens to be aware of legal rights and regulations and the quality of the health care which provides them with the possibility of mutual interference in the issues of health care and an easier recognition of situations in which these services are not satisfactory and legally impermissible. We have witnessed a number of problems that the medical staff is faced with in daily work. Also, the community has been reminded to consider the issues such as time engagement (overtime, shift work, irrational regime of work and rest, changing work schedules, pressure to do something for a very short period of time), a discrepancy between the demands of the workplace and what nurses can provide, the relationship between the number of staff members, excessive range of work and stress. These problems endanger the health of patients and lead to risky situations (21). It is also important to know that the performance of activities of health workers is almost always linked with the issue of life and death, and therefore not adopting, lack of knowledge and not linking of ethical principles and legal regulations are without any justification. According to recent sociological research conducted in the world, a health care professional vocation is at the top of the rankings by the social significance and this obliges all health professionals to act in the general social life in accordance with the highest status of their profession. In a way, this is the message to all health workers that there is a need to restructure the traditional knowledge of medical ethics and law, as the most important position of all health workers is their dedication to the patient as the primary goal and the starting point of ethics (22).

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ETIKA I MEDICINSKO PRAVO

Sunčica Ivanović, Čedomirka Stanojević, Slađana Jajić, Ana Vila, Svetlana Nikolić

Predmet interesovanja u ovom članku jeste značaj poznavanja i povezivanja medicinske etike i medicinskog prava za delatnost zdravstvenih radnika. Poznavanjem bioetike, kao naučne discipline koja se bavi proučavanjem etičkih pitanja i medicinskog prava kao pravne discipline, kao i medicinske delatnosti u celini, autor smatra da se postiže jačanje svesti zdravstvenih radnika o ljudskim pravima, a kako je obavljanje delatnosti zdravstvenih radnika gotovo uvek povezano sa pitanjem života i smrti, onda bi nepoznavanje osnovnih pravnih propisa bilo bez ikakvog opravdanja.

Cilj rada bio je utvrditi značaj medicinske etike i medicinskog prava u radu medicinskih radnika.

Retrospektivna analiza dostupne medicinske literature za period 2005-2010. godine na indeksnoj bazi KOBSON korišćena je u metodologiji. Analiza svih radova dovodi do saznanja da uspostavljanje ravnoteže između etičkih principa i poznavanja medicinskog prava, poverenje i saradnja između dve strane koje se pojavljuju u odnosu zdravstvene zaštite, ovaj postupak može smatrati ciljem kome bi svaki zdravstveni radnik trebalo da teži.


Ključne reči: bioetika, principi, medicinsko pravo, zdravstvena nega