

Hajrija M. Mujović-Zornić
Centre for Legal Research
Institute of Social Sciences
Belgrade
hmujovic@idn.org.rs

Challenges of Traditional Bioethical Principles in the Implementation of Contemporary Standards of Medical Law

Abstract: *The paper focuses on issues of development dimensions of Medical Law and its ongoing process of standardization and harmonization on one hand, versus the traditionally rooted and available principles of biomedical ethics, on the other. The collision of new legal institutes and the spread of human rights protections is evident. This paper follows the theory and practice of medical ethics and medical law. The theoretical aspect points out medical ethics as one of the sources of medical law. Legal theory makes a distinction between formal and autonomous sources of medical law. Even though ethics is morally much higher, law prevails because it has stronger sanctions and legal power. In its practical aspect, this paper gives examples of different situations of medical decision-making processes. Ethical rules are of the utmost relevance in the domain of confidentiality and options of medical treatment. But, in concrete medical procedures, where legal positions of patients are evidently very significant, law has a more distinct function. Therefore, explaining particular cases from medical malpractice, such as cases of penal, civil or professional liability have an ethical dimension as well. Members of medical professions in Serbia often find these cases unfair. Mostly this is the consequence of ignorance in this kind of medical law and ethics relations. A discussion about practical cases has in that sense a self-learning component, which could be developed to strengthen ethical reasoning and judgment.*

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Key words: *bioethical principles, medical ethics, medical law, legal standards, implementation.*

Medical law and bioethics

The issue of the relationship between bioethics and law is a rather ancient one, retroactively datable to the first philosophical speculations about the relation between law and science, as well as between law and medicine in particular. In an extreme synthesis, this is the question posed about whether law should be involved in bioethics to the extent that bioethics becomes subject to legal norms. The answers should not be taken for granted, as they influence the epistemological interpretation of bioethics itself. In general, the latter is considered as an interdisciplinary science, drawing from and contributing to the fields of medicine (intended as both research and practice), ethics, and law (Cannovo et al 2009: 111–113). Ethical norms of medicine as a profession are distinctive, very specific

and most often consider the human being, its life, health and dignity. Concerning medical ethics, it is in fact grounded in general ethical rules. The fundamental ethical principle of the medical profession is humanism, as the basis of medical ethics. At the same time, the basic assumption of the latter is that only a good man could be a good physician and that confidence in a physician is the basis of a physician-patient relationship, and also that a physician should treat both the illness and the patient (Radišić 1986: 54-57). Moreover, the medical profession has since ancient times been explained by a corpus of ethical attitudes, primarily developed for the patient's sole benefit. As a member of the profession, a physician is obliged to be aware of his responsibility: for patients, society, his colleagues, but also for himself. Here, it is the question of available standards of behaviour, defining the very essence of the conscience in a physician's work.

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A specific development of medicine, a decaying trust between physicians and patients, and an asymmetry of their positions have lately resulted in an increasing interweaving of professional rules (legally obliging the physicians to respect adopted principles of medical ethics) and legal regulations. As a rule, when an activity is sufficiently regulated by rules of medical ethics, no legal regulation is furthermore needed. In such a case, awareness of the physician's responsibility, willingness to be responsible for one's own deeds and their consequences could be developed upon the code of medical ethics and medical education. But if ethical rules of behaviour do not suffice to provide for quality of medical services, law has to come to the rescue as a reserve mean (Katzenmeier 2002: 69). Medical ethics and a physician's consciousness are undoubtedly indispensable values, never to be given up. It is impossible to simply replace such fundamental values with law. Sometimes ethical and legal duties of physicians are so closely tied that they can hardly be distinguished. On the other hand, professional and legal norms often complement each other: where there is a legal vacuum, ethical norms are applied, and where legal regulations exist, both are parallelly applied, or in the case of different solutions, legal regulations prevail over the professional ethical rules. This simply indicates that legal medical regulations should be supplemented with ethical norms. The complexity of the issue is well documented by legal analyses devoted to the specific methodology of ethical codes, which is a codification of ethics and the related problems. In that connection, a definition of clear ethical rules for medical professionals and patients is considered a priority, with the ethical code being a kind of 'ethical compass' for all parties. For their part, opponents of codification argue that it leads to simplification and impoverishment of ethical rules, considering codification as coming from 'the outside' instead from 'the inside', a characteristic of any ethics (Meulenbergs 2002: 5-9).

Rules of medical ethics

Nowadays codifying ethical principles of various professional groups is gaining importance. The growing tendency to underline professionalism, work quality

and efficiency, and professionally standardized procedures has inspired these developments. Medicine is no exception. Namely, medical professionals, above all physicians, have a professional ethics of their own, which stand as a statute of their profession. As a self-declaration of high ethical principles, this statute results from the very nature of their profession and professional autonomy. Called by many theorists “law at the crossroads” due to its interdisciplinary character, since it incorporates parts of other legal disciplines relevant for medicine, the importance of professional rules also points to another specific feature of medical law. Namely, the latter is comprised not only of state regulations (laws and rulings), but also of professional regulations (codes, professional guidelines, protocols, and standardized medical procedures). Many developed countries have their national codes of medical ethics, or codes of deontology. Some of them even elevate codification of professional rules on the level of law. For example, France adopted a special Act on Medical Deontology (*Code* 1979). The Netherlands also has its Medical Professional Act. In the field of biomedicine ethical principles have been incorporated in law thus giving them legal force, which is certainly a quite distinctive approach (HCP Act 2001). The concept of regulation of ethical codes could be in principle disputed. From the comparative point of view, there are at least two models of codification. The Anglo-Saxon model tends to be as brief as possible and reduced only to ethical principles. For example, the American Code of Medical Ethics has only nine principles which guide physicians in their work, although the original, a more detailed text from 1847, has never been overruled. On the other hand, codes in countries with a continental legal system, in Europe are thoroughly elaborated and detailed, and some take the form of laws, or have become incorporated within laws.

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In practice, various situations may present themselves in the course of working in the medical profession. So, ethical standards and legal standards could be identical for a concrete solution, and then a physician has a duty to treat. For example, duty to obtain *informed consent* from the patient. It may happen that the law is silent about a particular medical issue (one not regulated by law). Then, there is a gap in the law or something called *customary law*. The physician then proceeds as required by the principles of medical ethics: he fills the legal gap by resorting to interpretation in the spirit of these principles. An example of this situation in Serbia could be the medical treatment of a dying patient, and more specifically, passive euthanasia. Occasionally, there are cases where legal standards are different from what is an ethically acceptable opinion of practicing medical professionals. For example, this happens in the case of vital medical treatment refusal, in the case of attempted suicide, or a prisoner’s hunger strike. In those cases the physician has a duty to respect the patient’s will, according to legally adopted standards of patient rights, in spite of the ethical solution for the given situation, which could obviously be different. In rare cases, which the law allows, possible discrepancies between legal and ethical rules could be covered by a physician’s

right to use a *conscience clause*, for instance, in the case of late abortion. However, in all the other cases the coercive power of the state gives an advantage to legal regulations and demands strict respect of patient rights. The law has stronger powers than ethical reasoning and puts members of medical professionals at risk of liability lawsuits for the violation of these rights. The principle is that “unjust” laws may be changed, but only by the law, not by the will of any individual.

Ethics committees

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Ethics Committees (boards, councils) are a form of organized ethical decision-making that systematically and continually refers to the ethical dimensions of medical science, humanities, science and innovation in health policy (*Guide N°.1* 2005: 12). They often carry different names (bioethics, clinical, research, health care, counseling, etc.) depending on the tasks that they perform, but basically it means applying the team-work approach to each issue, that are not simple and factual but essentially normative. There are three levels of ethics committees—national, regional and local. The legal basis and ethical aspects of the bodies in health care institutions of Serbia in the past were mainly a result of those internal regulations, acts of self-government, and primarily the statute (*Kodeks etike* 1964: 51). Their legitimacy is generally derived from the time of the former state through the *General Act on the organization of health services* (1960), which provided guidelines for the adoption of codes of ethics for health workers, followed by an Act of Medical Societies of the Yugoslav Federation (Brajić 1991: 531). In the past, committees have been formed mainly within clinical centers and major health care institutions, especially those dealing with the most ethically sensitive procedures, such as oncology, transplantation and gynecology. Today, with the legal regulation of these issues, the establishment of ethics committees of professional bodies has become an obligation for every health care institution. The *Health Care Act of Serbia* (2005) includes a provision on professional bodies and ethics committees in health institutions (*ZZZ* 2009: Art.143–147). The provisions regarding the ethics committees, define an expert body that monitors the provision and implementation of health care in accordance with the principles of professional ethics. The Act provides significant regulation regarding research on human subjects, and ethical committees are now composed to provide complete and adequate review of each research. In this respect, Serbian positive law in this area is mostly harmonized with several important European and international treaties.

Fundamental rights

It is now widely accepted that human beings should be by nature free and able to autonomously determine their own actions. Therefore, they should also be granted the catalogue of fundamental rights, which safeguard their survival and permit their personal development in their natural and social environment. This

catalogue is initially signed in the form of rights designed to protect the individual against interventions by the state in the scope of constitutional provisions. These rights are based on the guarantee of human dignity as the “ground of fundamental rights”, and they represent the human being’s special status protected under the heading of dignity (14th Leg.Period 2002: 37). The wording of these provisions at the same time provides an answer to questions as to the extent to which fundamental rights that conflict with other legal interests may be curtailed without violating human dignity. This implies that it is possible to restrict fundamental rights. For instance, *The Constitution of Serbia* (2006) guarantees fundamental rights and health protection through its known principles: – human life is untouchable, Article 24; – human dignity is untouchable and everyone shall be obliged to respect and protect it, Article 23; – physical and mental integrity is inviolable, Article 25; – nobody may be subjected to torture, inhuman or degrading treatment or punishment, nor subjected to medical and other experiments without their free consent, Article 25; – protection of personal data shall be guaranteed, Article 42 (Constitution 2006).

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The fundamental rights derived from human dignity are related, on the one hand, to the ability of human beings to be the subject of their own thoughts, wishes and actions. This includes, first and foremost, the demand to recognize every person’s freedom to act in accordance with the ideas that an individual has determined to be good or binding. This fundamental freedom, without which human beings cannot be moral subjects, becomes manifest in the demand for the self-determination of each individual and in the demand for the free development of an individual’s personality. However, this freedom also includes the freedom of expression and conscience, as well as the freedom of individuals to practice religion of their own choice. Since in a science-based culture the freedom to be able to follow one’s own judgment also included the freedom of research, the rights associated with such a freedom are also protected as fundamental rights.

On the other hand, since the human being is a physical and social being, the fundamental claims ensuing from human dignity, as well as the fundamental rights derived from such claims, are designed to safeguard the physical and social conditions without which a being of that nature cannot maintain its way of life. These fundamental claims and the fundamental rights derived from them include, in particular, the claim to safeguard the integrity of life and limb, the claim to safeguard ownership of property, the claim to obtain social service and to safeguard a sound environment.

It can be assumed that all claims derived from an individual’s human dignity bear the risk of intrapersonal and interpersonal conflicts. When interpersonal conflicts arise with regard to any of the claims described above, the principle that applies is that any right claimed by an individual is necessarily limited by the fact

that another person may claim the same right. The only right that cannot be restricted is the individual's right to human dignity.

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Fundamental moral convictions are also manifested in the system of specific professional ethical norms that have evolved in medicine since ancient times. Such professional ethics is indispensable, especially in professions in which the very exercise of the profession can severely affect other human beings. In the case of medicine, the code of professional ethics includes a number of professional duties, such as not to harm patients (*nil nocere*), to gear all actions to the goal of curing patients (*salus aegroti suprema lex*), to exercise the profession in accordance with the state of the art, i.e. to use one's skill and available resources to cure patients and to attend further courses in order to preserve and update one's professional competence. For physicians, this means that they should empathize with patients, be truthful in the information they provide to patients, observe confidentiality and secrecy of third parties, etc. The primary duty of all doctors under their code of professional ethics, not affected by the inevitable asymmetry in the relationship between doctors and patients, is to respect the autonomy of patients, in particular when patients decide that they do not want any medical treatment. Any medical intervention must be legitimized not only by the rules of the art of medicine (medical indication), but also by the patient's will. For this reason, professional ethics stipulates that any medical intervention is subject to the patient's informed consent. This principle has also become the first of three or four principles that are essential parts of the ethical approach (autonomy, non-maleficence, beneficence, justice), developed in the United States and acknowledged worldwide (Beuchamp 2001: 39). The principles mentioned in the Council of Europe's Convention on Human rights and Biomedicine include not only the protection of human dignity, Article 1, the principles of professional ethics, Article 4, but also the principle of the patient's informed consent, Article 6 (Convention, internet). However, the Convention also contains provisions (which are subject to a controversial debate in Germany) according to which it is admissible to carry out research that consumes embryos and research for the benefit of others on persons not able to consent to such research (Nur. Code 1947). Physicians often have to weigh situations where ethical principles, prohibitions, interests or objectives conflict with one another, as in the case when patient confidentiality is opposed to the protection of third-party interests. In such cases, merely listing a doctor's duties under the code of professional ethics is as inadequate as citing the pertinent rules: there are limits even to sophisticated case histories.

What is therefore needed is ethical judgment on the part of the players involved. This should be the primary choice, rather than giving preference to one of the several conflicting values or combining all values with each other by means of a practical concordance, while sparing each of them as much as possible. This applies both to finding a practical norm in the event of conflicting moral intentions and

to weighing interests in a specific case. What is required from doctors in the latter case is not only their discriminating judgment but also their ability and willingness to assume responsibility. Beyond all norms and rules, professional medical ethics therefore relies on mindsets and attitudes (virtues).

There are numerous cases which are not dealt with in the same way by medical ethics and by law. Most of the medical issues have their distant roots in ethics principles, but their practical expression and forms are sometimes in contemporary conditions modified and therefore impose new solutions. It happens that the achieved standards of human rights move forward the medical practice in many countries and make a change through the current approach to problems. Important issues are abortion, euthanasia, and reconstructive medicine, because the legal aspect was not entirely accepted in the past. For example, according to the health legislation, woman-patients enjoy increasing legal protection in the reproductive area of contraception or abortion. The use of the abortion, “day after” pill effectively rejects the arguments against abortion for reasons of viability of the fetus and fetal pain, since it is not even formed yet. It is an established and undisputed institution of genetic counseling in gynecology practice. Legal systems also accept the right to adequate treatment for dying patients as a result of better definition of brain death, or legalizing of passive euthanasia as a more humane treatment in palliative care. So, advanced patient directives and patient wills in terminal health care in most countries became legally allowed. A similar situation occurs with other patient rights that have been developed for many years (as users of health services, patients ask for more possibilities of second opinions, or more privacy and confidentiality)—rights which were not even discussed in the past. Same with an individual right to physical integrity as one of the fundamental human rights. Namely, body parts and organs are integral parts of the human body, and in principle cannot be qualified as things. However, if they are separated by the medical authorities in the scope of some medical treatment or operation, they acquire a legal status of things. As such, they can be further used for therapeutic purposes. All these examples are new elements and significant demands for bioethics and law, where the stronger influence of current legal standards and legal statutes in the field of human health and biomedicine become evident.

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Conclusion

The relation of law and bioethics dates back to the first philosophical speculations about law and science, particularly law and medicine. From the legal standpoint there is no difference concerning what kind of ethics is in question (clinical ethics, applied ethics, research ethics etc.) because those are medical, not legal terms. Therefore, in legal theory *medical ethics* is usually used as a common term. In spite of medical law, which is characterized by customary law, legal norms and court practice, for medical ethics, ethical principles, ethical norms (rules), codes of ethics and ethical committees are essential.

The mutual connection between medical law and medical ethics sometimes appears as two “faces” of one problem. The main reason for that are the rules of medical ethics, which means identity, similarity or different applicability in accordance with legal provisions. Besides, ethical committees constitute a new form of an institutional ethical dimension of the decision-making process. In addition, the development of medical law includes the continuing process of standardization, unification and harmonization of law (national, regional, and international level). This process is sometimes opposed to the traditionally rooted and available principles of biomedical ethics and consequently in some situations provokes serious debates. Namely, standards of human rights are moved forward by new biomedical technology and everyday medical practice, and changes are made through the current legal approach to issues. Most of the issues in biomedicine find their basis in ethical considerations, but on many occasions situations change and require new solutions.

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The final remark could be that medical law and medical ethics (bioethics) overlap in many ways and influence each other by having a common goal: to represent and defend basic human values (life, health and dignity). Still, they are not identical and one should be aware of the differences that exist between them and of their different approaches to the same issues. There are terminological differences, because legal language is not colloquial, it is rather specific, pure and strict and its aim is to regulate a specific relation or resolve a specific dispute (for example, disputes regarding the defensive medicine, violation of patients’ individual rights, or disregard of ethical committees’ decisions).

Primljeno: 15. decembar 2012.

Prihvaćeno: 4. januar 2013.

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Hajrija M. Mujović-Zornić

Izazovi važenja tradicionalnih bioetičkih principa
u implementaciji savremenih standarda medicinskog prava

Apstrakt

Članak stavlja naglasak na razvojnu dimenziju medicinskog prava i pitanja u kojoj meri njegova standardizacija i harmonizacija, na jednoj strani, utiču na primenu tradicionalno ukorenjenih važećih principa biomedicinske etike, na drugoj. Teorijski aspekt članka upućuje na medicinsku etiku kao jedan od izvora medicinskog prava koji se smatra autonomnim izvorom. Iako je etika na višoj lestvici, pravo preteže jer ima pravnu snagu element prinude i jaču sankciju za postupanje protivno pravilima. U svom praktičnom aspektu ovaj članak stavlja naglasak na različite situacije pri donošenju medicinskih odluka, gde pravni položaj onog ko se leči (pacijenta) postaje veoma bitan, a pravo tu ima striktno određenu funkciju zaštite. Zbog toga, objašnjenje posebnih slučajeva pogrešne medicinske prakse ima svoj etički, ali pre svega pravni značaj, kakvi su slučajevi procesuiranja krivične, imovinske i staleške odgovornosti. Pripadnici medicinskih profesija u Srbiji često smatraju sudske postupke protiv sebe nepravедnim. Većinom je to posledica upravo nepoznavanja odnosa normi medicinskog prava i etičkih pravila. Razmatranje slučajeva iz prakse ima i svoju edukativnu komponentu koja na taj način unapređuje etičko promišljanje i osnažuje pravno odlučivanje.

Ključne reči bioetički principi, medicinska etika, medicinsko pravo, pravni standardi, implementacija.