



Difficulties in proving medical errors – Where do we stand?

Teškoće u dokazivanju medicinskih grešaka – Gde smo trenutno?

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Key words:

ethics, medical; physician-patient relations; medical errors; jurisprudence; legislation; serbia.

Ključne reči:

etika, medicinska; lekar-bolesnik odnosi; medicinske greške; pravna nauka; zakonodavstvo; srbija.

Introduction

Developements in medicine, better informed patients and more complicated medical procedures have increased public interest in regard to errors in treatment. Heightened public awareness is also reflected in the increased number of judicial proceedings related to medical malpractice in many countries worldwide¹. Approaching European standards dealing with protection of patient's rights further magnifies the significance of this subject. Awareness of contemporary medical achievements and development of pharmaceutical technology often leads patients to form unrealistic expectations of doctor's and medicine's capabilities, and the perception that all ills must be cured. The sensitivity of this subject heightens the importance of health and the perceived impact that actions or omissions on the part of medical practioners may have on the lives of individuals. The constitutions of many countries address this as well².

According to the report of Institute of Medicine, between 44,000 and 98,000 deaths *per* year were caused by errors in treatment in the U.S. health system alone³. One of the report's main conclusions was that the majority of medical errors do not result from the recklessness of one individual. More commonly such errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. Ten years later, with little transparency and no public reporting (except in jurisdictions where hard fought state laws now require public reporting of hos-

pital infections), scarce data does not paint a picture of real progress³.

Medical ethics on infallibility leads to an atmosphere in which errors are seen as an individual problem of the one who treats, for which the doctor punishes him and feels ashamed, instead of seeking the root of the problem and searching for a solution to improve the health system. On the other hand, proving guilt often becomes a long process which can be traumatic for patients, members of their family, and also for the doctor who, even if acquitted, has no impression that they gained something, but only that they have lost less.

Medical error – Error in treatment – Medical malpractice

Error in treatment is not synonymous with neglect, negligence and medical malpractice.

Medical error – error in treatment – medical malpractice – these terms are not identical in their meaning or legal and other consequences. Medical error and error in treatment are terms derived from the medical profession with numerous ethical and deontological implications. Medical malpractice is a term arising from the legal standard prescribed by law as the basis of doctors' liability.

According to The Joint Commission (TJC), a Sentinel Event or "Never Event" is defined as an unforeseen event in a health system resulting in death of a patient or serious physi-

cal or mental health damage, non-related to natural course of patient's illness⁴⁻⁶.

The criminal offense of medical malpractice, as defined in the Criminal Law of Republic of Serbia⁷, occurs when a doctor, in providing medical help, uses an obviously inadequate remedy or obviously inappropriate treatment or does not apply appropriate hygiene measures at all, or obviously acts unconscionably, thereby causing deterioration of a person's health.

In order to determine a crime of medical malpractice, it is necessary to establish a causal relationship between a doctor's unconscionable action and a patient's deteriorating health². That means that the aggrieved person can be both healthy and sick. What is important is that their health deteriorated due to medical malpractice. On the other hand, if a doctor did act unconscionably but there was no health deterioration, a criminal offence does not exist. Serbia and neighboring former Yugoslav republics have been and remain among the few countries whose criminal justice specifically exculpates unconscionable doctors^{2,8}.

Penalties in the case of medical malpractice resulting in a patient's deteriorating health are different in different legislatures – a fine or two years imprisonment (Penal Code of Republic of Croatia) or imprisonment from three months to three years (Penal Codes of Republic of Serbia, Republic of Montenegro, Serb Republic, and Federation of Bosnia and Herzegovina²).

In all previously mentioned legislatures, more lenient punishment is provided if it is proven that a doctor's medical malpractice occurred out of negligence – a fine or imprisonment up to one year may be imposed.

Every legal system mentioned above also provides for more serious cases of this criminal offence, as determined by more serious outcomes (such as severe injuries or death of a patient). Therefore, the more serious case of this criminal offence is a separate article of the Criminal Law in Serbian legal system. Serious offenses against public health provide for punishment from one to eight years of imprisonment (in case of severe injury) or two to twelve years (in case of death of a patient). For the same criminal offence, neighboring countries stipulate similar punishments².

Serbia statistics

The crime of medical malpractice is one of the rarest offenses in Serbian judiciary for years⁹. A disproportionately small number of cases of medical malpractice was observed and described in works dating from the mid-nineties¹⁰.

From 2006 to 2010, in Serbia from 4,052 to 4,895 charges *per* year against adult persons for a crime against public health were documented. This is an average of 4 to 5.5% of total charges for all crimes. Looking at individual offenses in 2010, there are 4,052 charges with crimes against public health. Of these, 47 cases were based on negligence in providing medical care, and 4 cases on not providing medical help. The total number of convictions in 2010 for crimes against public health was 2,564, but of that number only 3 cases were based on negligence in providing medical aid, while not a single person has been convicted of not providing medical help. In all 3 cases there was a guilty verdict in whom they received probation sentences.

In order to illustrate the everyday practice in Serbia, we analyzed twelve years data from the Municipal Court in Kragujevac. According to the current organization of the courts, the Municipal Court in Kragujevac covers the territory of city of Kragujevac, municipalities Arandelovac, Batočina, Rača and Topola. Data on the number of all initiated proceedings filed against doctors and other health workers, and the number and gender of the accused persons for the period from 2000 to 2011 were collected and processed (Table 1).

The total number of prosecutions and other prosecution acts during this twelve years period was 18,732, an average of (mean \pm standard deviation) 1,561 \pm 352.3 *per* year. In the analyzed period there were six charges for the crime of medical malpractice, which makes 1 crime *per* two years.

The situation is similar in Croatia. For the five-year period (2005–2009) there were 10 reports for medical malpractice, but were all rejected, so there were no convictions¹¹.

Difficulties in proving medical errors

Any medical procedure that was performed according to the rules of medical profession, with the consent of an informed patient and performed by a qualified person does not

Table 1
Number of cases of medical malpractice in Kragujevac Court

Year	Total number of charges and other acts of prosecution	Number of cases of medical malpractice
2000	1,147	1
2001	1,170	0
2002	1,227	0
2003	1,382	0
2004	1,147	0
2005	1,674	0
2006	1,612	0
2007	1,478	1
2008	1,890	1
2009	2,064	0
2010	2,031	1
2011	1,910	2
Total	18,732	6

come within the scope of criminal behavior even if a harmful outcome for life and health of a patient does occur. On the other hand, even if just one condition is not fulfilled, a medical procedure may result in criminal responsibility.

In order to even initiate a judicial proceeding, it is necessary that the injured patient file a charge. Next, a preliminary proceeding will be conducted to determine whether there are grounds for suspicion of a criminal offense. Of course, charges may also be filed by any other party, especially by the doctors who are familiar with the questionable medical treatment. The prerequisite is that a patient is informed about his rights and the procedure.

To prove that a medical error does exist is problematic *per se*. It is an imprecise standard that refers to the legal standard "manifestly unconscionable (inappropriate)," creating the main problem of proving that such crimes were committed. The next question is whether there is obvious inappropriateness in a general sense or just in the narrow professional sense. If obvious, what defences may be raised by the accused?

An obvious unconscionable/inappropriate act should be seen as a striking fault, which is beyond the scope of medical tolerance⁹. The specificity of the medical profession allows for a certain amount of tolerance, i.e. from the criminal justice/legal standpoint, all monetary losses that are not clearly related and/or obviously ineligible are considered irrelevant⁷.

Where does that dose of tolerance towards medical profession come from?

The concept of a reasonable dose of tolerance primarily comes from the fact that while medicine is a relatively exact science, causes of illness and death are not nearly as clear as their consequences¹². It cannot be predicted with absolute certainty how a person reacts to a disease. Therefore the selection of a particular means of treatment is always relative. Another reason is that medicine is not a complete and closed knowledge system but, on the contrary, medical knowledge is enriched on a daily basis, so questionable treatment will generally be resolved in the health sector within professional circles.

In every specific situation, a doctor's ignorance manifested during the treatment of a patient is a necessary (requisite), but not a sufficient condition for examination of the doctor's responsibility. Obviously using clearly inappropriate means or methods of treatment constitute a more drastic and serious deviation from the rules of science and the medical profession, i.e. reflecting gross medical ignorance⁷.

The question of knowledge, i.e. minimum standards of knowledge, skill and expertise reasonably expected of a qualified doctor to act in every circumstance, is the measure of that tolerance that recognizes the possibility of acceptable variations in treatment while on the other hand does not create suspicion for alleged medical profession privilege. From that comes the obligation for doctors to engage in continuous vocational training and to adopt new practices resulting from the rapid progress of medical science and technology.

The law also recognizes other risk factors in medicine. Every patient's individual reaction to illness, their specific response to therapy, even when applying known and trusted treatment methods, may be variable. This requires that in doctors' everyday practice they must take into account that a certain procedure or therapy may not be successful, i.e. may have a negative effect on the patient⁷. Factors that cannot be predicted or avoided must be recognized as objective risks of treatment that, with all the knowledge, skill, conscientiousness and technical equipment cannot be avoided. Objective risk in medicine may be considered as the equivalent to force majeure that excludes responsibility of a doctor in case of unfavorable outcome of a treatment.

Subjective risk is one that could and should be avoided if a doctor is more professional, careful, and conscientious. In contrast, objective risk is a potential risk factor beyond the control of the doctor which should be disclosed to each individual patient with consent being obtained and understanding confirmed. Subjective risk (insufficient knowledge and competence of a doctor) directly leads to a doctor's responsibility in terms of medical malpractice if proved that it was crucial to harmful effects to the patient's health. Special and delicate discussion is required if attempting to present subjective risk as inevitable, that is, objective risk during treatment, in order to avoid responsibility for the harm caused the patient.

Advantages and disadvantages of team work

One more aspect of the medical profession is teamwork. This implies that several doctors of different specialities are included in the treatment of a common patient. This approach provides the highest quality treatment for each patient, but in case of serious harm to health of a patient, the question of responsibility is raised. There is no doubt that even in a team, every individual is primarily responsible for their own work, and teamwork is based on mutual trust where team members complement and help each other in knowledge and action. Thus there is the potential of causing a mutual impact in which one's error becomes an error in the work of another team member (accumulation of errors), but also the team concept can create the possibility of averting error of one by corrective action of another team member. In each individual case it is assessed whether and to what extent there is a duty/obligation to remove an error of another team member who had treated the patient. In this case also, these issues are resolved by hiring forensic experts.

Expert selection

According to the rules of a proceeding, expertise is determined in the investigation. Bearing in mind that the actions involved in committing the offense may be debatable or unclear, expertise is crucial in determining whether the doctor committed a crime or not. As judges do not have sufficient expertise in medical issues that would shed light on relevant circumstances of the offence, medical evaluation, implementation or lack of implementation of proper medical procedures are entrusted to experts of medical profession by the judges.

When determining the expertise required, all relevant circumstances pertaining to the particular case should be considered before delegating to an expert, an expert commission, an expert institute or other institution. The main objective is to provide appropriate and non-biased professional expertise. Proper selection of experts requires that judges also have a broad enough education and knowledge in those fields to assess which experts are required in each particular case.

In any particular case of medical malpractice, it must be taken into account that experts of the respective specialty are present, or whether it is necessary that several specialists in different fields be involved. The decision also depends on the institution where the offender works.

After that assessment, the judge or president of the panel decides the composition of the commission or institution to which the expertise will be delegated. Due to the very few specialized institutions available to provide expertise and the narrow scope of their work, the process of selection may be unjustifiably long. This can be affected by the administrative part of a proceeding – correspondence and paying the costs of expertise.

Practice has shown that judges often hire the same experts. This is usually a consequence of a judge's trust and confidence and the need for quick and competent expertise, rather than, as sometimes negatively portrayed, that some experts are privileged.

In the judicial process itself, of great importance is to what extent the clinical environment in which a doctor or other health care provider operated may have impacted the circumstances (i.e. conditions in the institution, equipment, number of patients, level of training of other staff). Also relevant are the problems of collecting valid documentation related to a particular patient. Proving guilt therefore often becomes a long process which can be traumatic for patients, members of their family, and also for the doctor who, even if acquitted, has no impression that they gained something, but only that they have lost less than would otherwise have been the case.

Final remarks

On behalf of patients

The prerequisite is that a patient is informed about his rights and the procedure. Patient safety may be enhanced by better information, which depends primarily on the doctor's competence, the conditions provided by the institution, the time the doctor can devote to patient, and also on the interest

of the doctor to provide services and information to the patient.

On behalf of doctors

Doctor's safety would be influenced by protocols used, good teamwork, trained "support staff", better working conditions, continuous education of doctors, financial satisfaction, and anything else that could improve medical knowledge and provide the basis for the provision of better medical care. Regulating error reporting in medicine is also very important in reducing potentially fatal medical errors. In the future, medical associations should be open to discussion of these issues also.

On behalf of law

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Conclusion

Errors do happen. Like every human being, doctors and other medical workers are not infallible. As the errors in the course of treatment can be rightly expected, the system must be adjusted so that it prevents errors and resolves them.

Acknowledgement

This work was partially supported by the Ministry of Education, Science and Technological Development of the Republic of Serbia (Grant N°175014 and 175007). The authors expressed their gratitude to Frank J. Reichert, Master Business Administration, Chicago, Illinois, for carefully reading draft versions of this article as well as for helpful advices on English language.

R E F E R E N C E S

1. Gundogmus UN, Erdogan MS, Sebiralti M, Kurtas O. A descriptive study of medical malpractice cases in Turkey. *Ann Saudi Med* 2005; 25(5): 404–8.
2. Stepić D. Criminal responsibility of medical practitioners for negligent provision of medical assistance – A comparative analysis of the criminal legislation of the southeast European countries. *Strani pravni život* 2009; 2: 189–214. (Serbian)
3. Consumers Union. To Err is human - to delay is deadly: Ten years later a million lives lost billions of dollars wasted. 2009. [cited 2012 Oct 10]. Available from: safepatientproject.org/.../safepatientproject.org-ToDelayIsDeadly.pdf
4. Savić S. Criminal offences relative to medical practice. *Materia medica* 2010; 26(1): 43–51.
5. Joint Commission. Sentinel Events. Comprehensive Accreditation annual for Hospitals: The Official Handbook. CAMH Re-

- freshed Core. 2011. [cited 2010 Oct 5]. Available from: <http://www.jointcommission.org>
6. DH/Patient Safety and Investigations. The "never events" list 2011 [cited 2012 Sep 10]. Available from: <http://www.dh.gov.uk/publications>
 7. *Ćirić J.* Irresponsible treatment of patients: Problems of determining criminal liability of doctors. *Pravni život* 1995; 44(9): 211–22. (Serbian)
 8. *Radišić JD.* Responsibility for not giving first medical aid. *Pravni život* 1995; 44(9): 197–210. (Serbian)
 9. *Ćirić J.* The criminal act of negligent provision of medical assistance. Beograd: Zbornik instituta za kriminološka i sociološka istraživanja 1991; 1–2: 11–3. (Serbian)
 10. Statistical Office of the Republic of Serbia. Justice Statistics. Adult offenders in the Republic of Serbia. Belgrade. 2010. Report SK12, No 201. (Serbian).
 11. *Novosel D, Rogić-Hadžalić D.* Criminal liability of legal persons for criminal acts: 2005-2009. Zagreb: State Institute of Statistics, Republic of Croatia. 2010. (Croatian).
 12. *Radišić J.* Medical standard and liability of physician. *Pravni život* 2008; 57(9): 287–97. (Serbian)

Received on November 2, 2012.
Revised on December 22, 2012.
Accepted on December 25, 2012.