Policy Issue Paper

Patients' Rights in Southeast Europe (working title)

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I. PATIENTS' RIGHTS IN THE EU

The common health and social policy in the EU, despite the differences of the national health systems, is placing the same rights of patients, consumers, users, family members, weak populations and ordinary people at risk.

As described in the Preamble of the European Charter of Patients' Rights, "financial constraints, however justified, cannot legitimize denying or compromising patients' rights. The Nice Charter of Fundamental Rights will soon be part of the new European constitution. It is the basis of the declaration of the fourteen concrete patients' rights currently at risk: the right to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain and personalized treatment, and the right to complain and to receive compensation".[1]

This Charter aimed at fortifying the introduction of patients' rights policies and reinforcing the level of their implementation in different national contexts, can also be used as a tool for the harmonization of national health systems of both the EU member-states and aspirants for EU accession, as part of the improvement of the freedom of movement within the EU and especially the enlargement process.

Despite the benefits they have brought to the individual and the society, the medical advances in the areas of life-prolonging technology, prenatal diagnoses, organ transplantation and genetics have all had a side effects of increasing the technological and decreasing the human aspects of medical care. These advances brought and enlarged the alienation between patients and physicians. Too often

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[1] European Charter of Patients' Rights, Basis Document, Rome, November 2002

physicians forget or simply do not have time to be compassionate. Besides physicians often perceive themselves as absolute authorities in judging patient needs due to their medical knowledge supremacy and they do not perceive the need to discuss diagnoses and proposed treatment with patients. Only commitment to protecting and promoting the rights of patients can a) maintain a balance in which decision-making is shared and patients have and exercise the right as well as the responsibility to make the ultimate decision regarding personal care and medical treatment and b) prevent the dehumanizing influence of the medical technology. Thus patient's rights need to be treated in an interdisciplinary environment of the legal practice, medicine and public health.

II. PATIENTS' RIGHTS IN TRANSITION

In most of the countries of Southeastern Europe prior to the transition there was no single legislation regulating the rights of patients, but those rights were stipulated in several healthcare and healthcare insurance laws and bylaw documents. One of the activities of the new EU member-states during the process of preparation for accession in the EU was the adjustment of the health care legislation towards the European legislation and standards. Such was the case with Hungary that in 1997 enacted the New Health Care Act, in which most of the patients' rights are regulated, such as: the right to healthcare, right to be treated with dignity, right to information, right to refuse treatment, right to information privacy, right to leave the health care institution, right to complaint, right to die with dignity, right to participation in decision-making in health care, etc.

Yet, this process has not been completely undergone by the countries aspirants for EU membership. Among them, the Republic of Macedonia is undergoing the process of reforming the health care and public health systems, but still struggling with defining the most suitable healthcare and healthcare insurance model. Therefore it is an inevitable necessity to undertake analysis of the existing related legislation in these countries that have been going through the similar processes of economic and political transition, which by all means affect the healthcare system, treatment of patients, patients' rights and citizens' rights in general.

On the other hand, the dramatic changes that have taken place in the past decade in Central and Eastern Europe, have caused the large inequalities in health to grow even bigger, not only *between* but also *within* the countries in the region. This statement can be well backed up with the national health statistics, which "give a stark illustration of the effect of economic crisis and widespread pollution on the health of whole populations are reveal a growing health divide".[2]

Macedonia

In the Republic of Macedonia prior to the transition there was no single legislation regulating the rights of patients, but those rights were stipulated in several healthcare and healthcare insurance laws and bylaw documents.

The previously existing healthcare legislation (Health Law of 1970; Law for Healthcare of 1983) has regulated the patients' rights and duties to certain extent. The currently governing Law for Healthcare (1991) is more extensive in regulating these rights, however not all of the rights described in the European Charter of Patient's rights have been regulated.

The Health Care Act of 1991, regulates the functioning of the basic healthcare system in the country, and consists of the following chapters: (1) the health insurance; (2) rights and responsibilities of the healthcare users; (3) the rights and responsibilities of the healthcare providers; (4) organizational structure of the healthcare system, and (5) financing of the healthcare.[3]

In the Macedonian context, following articles from the EU Charter of Patients' rights are applicable:

- Right to preventive measures
- Right to access

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[2] The Health Divide, by Margaret Whitehead, in "Inequalities in Health", 2ed, Penguin Books, 1992.

[3] Закон за здравствената заштита ("Сл.весник на РМ", број 38/91,46/93 и 55/95)

- Right to consent
- Right to free choice
- Right to privacy and confidentiality
- Right to observance of quality standards
- Right to compensation
- Right to complain

According to the legislation, the institutions responsible for protecting the patients' rights are The Ministry of Health, Health Insurance Fund (together with the three chambers of healthcare professionals responsible for the licensing and proper practice of medical and dentistry doctors and pharmacists), the Ombudsman, Committee for ethics and patients' rights (functioning within the Clinical Center, as the major institution for tertiary care in the country), Ethical Committee for medical research within the Faculty of Medicine. Several other bodies and organizations offer legal advice and support for understanding the mechanisms of the system.

However, the analysis of the existing legislation regarding the exercising of rights and duties of the patients, the following conditions have been identified:

- Lack of appropriate and systematized legislation directly regulating patients' rights
- Insufficient level of implementation of the existing legislation
- Lack of knowledge and ignorance of patients regarding their rights
- Nontransparent attitude of the healthcare authorities regarding information of the citizens for their rights (but also duties) as patients
- Lack of technical support in the healthcare facilities for complete implementation of certain rights of patients, such as the right to privacy and confidentiality of personal and medical data

Bulgaria

In August 2004 the Bulgarian Parliament adopted a new Law for Health. This law, often referred to as the "health constitution of Bulgaria", which was reinforced since 1st of January 2005, represents the basic law providing the framework for regulating all public relations concerning the health of the Bulgarian population, its prevention and promotion. The rights of the patients are regulated in the Third chapter of this Law. Its structure and contents are strictly in line with the European Charter of Patients' Rights, covering most of the fourteen basic rights as given in the Charter. In their "Health constitution", the Bulgarian health authorities recognized 10 of the fourteen basic patients' rights included in the European charter as relevant for the Bulgarian context and these are legislatively 'covered' in different acts.

Yet, in September 2005, two Draft Laws on the Patients' Rights and Obligations were submitted to the Bulgarian National Assembly for adoption. The general novelty proposed in the drafted legislation was the proposal for introduction of institution of the Health Ombudsman as a mechanism of the Bulgarian legal system for protection of the patients' rights. The public debate hosted by Bulgarian NGO[4], and attended by representatives of the relevant institutions, academia, NGOs and human rights advocacy groups, showed that there is much controversy around this issue, as the introduction of this medical/legal mechanism would improve the level of implementation and exercise of patients' rights on one side, but it will cause an extra burden on the budget of the health care facilities, which are already pressed by financial problems.

Croatia

Croatia signed and ratified European Convention on Human Rights and Biomedicine in 2003 and thus the provisions of the Convention became directly applicable in its internal legal system. Some of the rights contained in the Convention are self-enforceable; others to be implemented needed further

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[4] Center for Study of Democracy (CSD)

elaboration through national law. Since ratification of this European document, Croatia enacted several acts: The Act on Protection of Patients' Rights, The Act on Extracting and Transplanting Parts of Human Body for Purpose of Medical Treatment, The Act on Protection of Persons Suffering from Mental Disorder, and also has drafted the Act on Medically Assisted Reproduction.

Some of the rights of patients have not been yet recognized in Croatian legal system as legal rights and they still remain mere aspiration. Traditionally, as in the whole region, the patient welfare is perceived as more important than the patient right to health care and self-determination. Thus there is a tension of the rights of the society and profession versus the rights of the individual and the patient.[5]

The rights of hospitalized child are treated in a separate manner. Based on the Charter for children in hospital[6], adopted by the European Parliament in Strasbourg in 1998, the Croatian Medical Association in 2002 introduced changes in its Codex of Medical Ethics and Deontology in the aspect of pediatric care. According to this document, except in urgent situations, the physician will perform the medical examination and health care to children and minors, with full respect of the child's personality, in accordance with the UN Convention on Children's Rights, as well as with the written consent of the parents or other persons responsible for the child.[7] In 2003, the Workgroup of ethics of the Government of Croatia has adopted the Ethical Codex on Research with Children, which is another document protecting the rights of children in the healthcare system.

Serbia and Montenegro

a) Serbia

The existing Health Care Law regulates patients' rights under the chapter on Principles, Conditions and Action for health care treatment. The most distinguished

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[5] Turkovic, K, The right to informed consent according to Croatian Act on Protection of Patients' Rights, in "Bolesnik: prava i obaveze", Hrvatski lijecnicki zbor, Zagreb 2005.

[6] National Association for Welfare of Children in Hospital. A charter for children in hospital. *Lancet* 1984;2(8415):1350

[7] Hrvatski lijecnicki zbor, Kodeks medicinske etike i deotnologije, 2002.

rights are pointing that medical intervention cannot be undertaken unless consented with a written agreement of patient. Yet, the law considers the cases of unconsciousness and specific psychiatric condition which can endanger people in surrounding as special circumstances, for which treatment can be provided even without patient's signature.

In the new Draft-Health Care Law, launched in December 2004, the patients' rights in Serbia and Montenegro are regulated more precisely than in the previous healthcare acts.

The Draft Health Care Law proposes wider scope of the patients' rights, as well as regulating human rights in healthcare. Most of the rights stated in the European Charter on Patients' Rights are covered, including: right to health care according to the highest possible level of human rights standard and values, right to physical integrity, personal safety, full respect of patients' ethical, cultural, religious and philosophical beliefs, etc.

The Draft-Law regulates the following rights:

- *Right to accessibility* to health care, according to the financial possibilities of health care system
- *Right to all kinds of information*, regardless of patient' health condition, type or way of utilization of health services
- *Right to consent*; the oral information should be given to patient in time, in a way which is understandable to him/her, in terms of his age, education and emotional state. In case that the patient does not understand common language or his/her hearing is seriously impaired, translation must be provided.
- *Right to free choice* of physician and health care service
- *Right to privacy and confidentiality* of personal data, data concerning patient' health status, and potential diagnostic and therapeutic procedures
- *Right to free decision* on everything concerning his/her life and health, and agree freely on proposed medical measures
- *Right to being introduced* with his/her medical documentation, except in case of

serious endangering his/her health by doing so.

- *Right to complaint*, in cases of dissatisfaction with the service received or procedure of health care staff, the patient can submit an objection to the manager responsible for the operation of the healthcare facility
- *Right to reimbursement* for malpractice or harm caused by physician's error during medical intervention

In the Serbian circumstances, the following conditions have been identified:

- Lack of wide-spread knowledge/expertise in medical law (except for small number of specialized lawyers and misinterpretation by medical professionals that medical law is identical with forensic medicine)
- Medical law is just beginning to develop as a new scientific field
- Dissatisfactory level of exercising of human rights concerning health
- Obvious and very dominant paternalistic concept of medicine
- Some laws and regulations need further adjustment with the regional and international standards.

As an attempt to improve the level of implementation of the health care law in the area of protection of patients' rights, the health care services have established a formal mechanism of appointing a so-called advocate in each healthcare facility. An appointed advocate is responsible for receiving and considering patients complaints, as a step forward to higher level of respect of patients and increased physicians' awareness on this issue.

b) Montenegro

Situation in Montenegro is quite similar to the one in Serbia. As most of the countries in the region, Montenegro does not have any specialized institutions for protection of patients' rights, except the Ministry of Health and the Ministry of Justice.

The current law regulates the following patients' rights:

- *Right to the fair and equal accessibility* of medical services
- *Right to high-quality medical care*
- *Right to medical care* covered by the obligatory insurance
- *Right to a human dignity and privacy* in medical service
- *Right to information*
- *Right to medical record information* concerning patient's illness
- *Right to information* regarding identity and professional level of the physician
- *Right to criticism and complaint* in case of unsatisfied patients

The *right to free choice* of physicians exists in the law, but its implementation is in the process of reforming and detailed regulation with bylaw documents.

Several documents related to the protection and promotion of the patients' rights are existing (Law on Health care, Law on Medical Insurance, Law concerning rights of mentally disabled patients, Law on Ombudsman, etc.); yet some, which are seen as important tools and mechanisms for proper implementation of the legislation are not still enacted, such as the Strategy on reproductive health, Strategy for mothers' and children health, including the rights of hospitalized child, etc.

Romania

The Romanian Constitution8 adopted in 1991 under the Title II (Fundamental Rights, Freedoms and Duties) recognizes the rights of privacy, inviolability of domicile, freedom of conscience and expression. The Article 26 states that: "(1) Public authorities shall respect and protect intimacy, family and private life. (2) Any natural person has the right to freely dispose of himself unless by this he causes an infringement upon the rights and freedoms of others, on public order or morals." Article 27 of the Constitution states, "(1) The domicile and the residence are inviolable. No one may enter or remain in the domicile or residence of a person without consent. (2) Derogation from provisions under paragraph (1) is permissible

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[8] Constitution of Romania, 1991. Title II: Fundamental Rights, Freedoms and Duties. available at: http://www.cdep.ro/pls/dic/act_show?ida=1&idl=2&tit=2#t2c2s0a26 (accessed December 2005)

by law, in the following circumstances: for carrying into execution a warrant for arrest or a court sentence; to remove any danger against the life, physical integrity or assets of a person; to defend national security or public order; to prevent the spread of an epidemic. (3) Searches may be ordered only by a magistrate and carried out exclusively under observance of the legal procedure.

In 2003, the Romanian Parliament adopted The Law on Patients' Rights (the so-called Law 46). The law consists of eight chapters and is aimed at consolidating basis human rights in the medical field; ensuring patient's dignity and integrity without discrimination, as well as enhancing the participatory role of citizens in healthcare decisions. Recent developments in the medical care and technologies have determined a special attention to patients' right to information and self-determination, as well as the right to making decisions regarding medical care practices. The law gives special attention to the treatments that cannot be given without the consent of the patient and his rights for reproduction under medical observations. The law outlines the extra-judiciary methods for observing patients' rights, to be undertaken by various institutions as: Ministry of Health and its regional and local branches, medical and sanitary institutions, insurance companies, professional medical organizations and medical insurance organizations.

Law No. 677 enacted in 2001, regulates the processing of personal data, made, totally or partially, through automatic means, as well as the processing through means other than automatic, which are part of or destined to an evidence system. The supervisory authority for Law No. 677/2001 is the Ombudsman (also called "The People's Advocate"). The Ombudsman regulations also enable the creation of a special Private Information Protection Office (PIPO), concerned with the protection of individuals in relation to private data processing.

III. LEGISLATION FACING THE IMPLEMENTATION

The principles of solidarity, humanity and social justice, as well as the constitutional responsibility to protect and promote personal health and the health of others, are unfortunately, rarely respected and complied with.[9] It is an obvious necessity and commonsense that the “rights”, as well as the responsibilities of the patients, related family members, subjects that are involved in the care of the patients, as well as of the healthcare providers have to be regulated, respected and reinforced. The experience shows that the enforcement of patients’ rights legislation and related healthcare acts produces no results unless the appropriate system for their consistent implementation is in place.

Besides the necessity for enforcement of the patients’ rights legislation and implementation mechanisms, the crucial role is often played by the health education of the general population. Both the preventive and other health information can make a significant contribution towards the overall improvement of the health status of the population, but further more, can add a significant meaning to the real and appropriate functioning of the healthcare system, through a proper exercise of the rights that both patients and healthcare providers have.

Despite the benefits they have brought to the individual and the society, the medical advances in the areas of life-prolonging technology, prenatal diagnoses, organ transplantation and genetics have all had a side effects of increasing the technological and decreasing the human aspects of medical care. These advances brought and enlarged the alienation between patients and physicians. Too often physicians forget or simply do not have time to be compassionate. Besides physicians often perceive themselves as absolute authorities in judging patient needs due to their medical knowledge supremacy and they do not perceive the need to discuss diagnoses and proposed treatment with patients that in their opinion are not capable of making reasonable decisions. Thus the most common complaints of patients across the national milieus investigated are that in largest number of cases the physicians don’t listen, don’t take much time and don’t explain or give a partial explanation in a difficult to understand (referring to the professional and specialized terms) language. At the same time if anything happens beyond the expected procedure, the physicians would in the first place “blame it on” the patient for non-

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[9] "Пациенти во Македонија со права по европски стандарди”, MIA-AIDS, 2004

compliance, more often than not being reluctant to take responsibility for malpractice or other mistakes that may harm patients.

The above explains the paternalistic roles very commonly taken in the physician-patient relationship, rather than the paternalistic concept of the health care system. Despite the different but very high levels of regulation of patients' rights in the legislation, the implementation levels have been expectedly similar. The interviews held in all of the countries subject to this analysis, reported a similar situation with the physician-patient relationship, in some occasions even expressed as "father-physician taking care of the child-patient".

The reasons can be searched in the previous system, but can also be found in the ignorance of the patients regarding their rights. The only survey that was undertaken under this research (conducted in Macedonia on 282 individuals)[10] shows that over 80% of the interviewed are not aware of the benefits from or the mere existence of most of the patients' rights. The most commonly heard of (but not often exercised) is the *right to compensation* for treatment received abroad; next to it is the *right to compensation* for the medications on the positive list (heavily subsidized), which have been purchased for a full price in a private pharmacy. The main reason why the 85.8% of the interviewees are not exercising these rights are the complicated and lengthy procedures administered by the Health Insurance Fund, as well as the unclear method of reimbursement.

Apart from these two, the other rights are mostly looked at as obligations. For example, *the right to free choice* of physician in the primary healthcare (the so-called "maticen lekar", with similar functions as the family physician) is considered an obligation imposed by the law; on the other hand, the more general explanation of *the right to free choice* of physician is almost prejudicially linked to the visit of a private physician's office (most of which have no contract with the Health Insurance Fund, charging the full price for the health services provided), which can be done without any referral and upon free judgment of the individual. Closely resembling to

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[10] details of the survey are given as annex to this paper

this is the attitude for signing the informed consent, which for over half of the interviewed patients is just another “administrative procedure”.

The survey has confirmed the general notion and the acceptance by the patients of the paternalistic approach in the physician-patient relationship. Among the interviewees, 90.8% are satisfied (56% very and 34.8% averagely) from the services received; over 60% have never intentionally been to another physician or asked for a second opinion. Furthermore, 86.5% are convinced that the physician is prescribing them the best possible medications/therapy that they need, and 93.6% comply, as much as they can afford, with the recommendations and advices given by the doctor.

Even though *the right to complain* is regulated and guaranteed in the legislation, an astonishing 84-86% have never had any questions or complaints regarding the medical services received or healthcare facility procedures undergone. The background to this is more likely the decreased confidence in the institutions of the system, or ignorance regarding the mechanisms and institutions in which the legal advice or cure can be sought.

The reasons for such high level of satisfaction may be partly related to the structure of the interviewed group; namely, 60.9% have no official job or no job at all, of which 92.2% are covered with basic health insurance through the unemployed benefits system - the basic health insurance which is in no way different than what a regularly employed person receives by regular payment of taxes and social contributions to the state budget. (note: the Macedonian system of health insurance still being in a very primitive stage of healthcare reforms, does not have different health insurance policies which employees or employers can choose from for better health care).

IV. PROPOSED ALTERNATIVES

The comparative analysis of the legislation and regulative instruments in the countries of Southeast Europe and the survey of the level of implementation of the legislation in the Republic of Macedonia, two approaches for improvement of protection and promotion of the patients' rights impose, both involving changes in the legal environment (in terms of improved implementation of the current legislation or introduction of new instruments and mechanisms for exercising patients' rights), combined with other advocacy and public awareness raising activities involving the civil sector.

Alternative 1: Improved implementation of the current legislation

This alternative includes changes in the implementation mechanisms of the legislation, but also assuming undertaking public awareness raising activities. One of the main components to protection of patients' rights is the understanding of their violation by both the patient and the physician or the institution.

Moreover, as the patients are usually treated by a team of physicians, nurses, and technicians in a complex, unfamiliar, and sometimes frightening setting, they are often being treated as non-person and thus raising feelings of anonymity and isolation. Because of this the institution-patient relationship is almost equally important as the doctor-patient relationship.

Significant aspect in the improvement of the implementation of the legislation is the enhanced knowledge and perception of the general public but of the health professionals as well, in which the civil sector is expected to play major role - through awareness raising campaigns, offering legal advices and assistance in understanding and utilizing the mechanisms of the system.

The main portion of the costs for implementing this alternative will be related to the public awareness raising campaigns. Yet, a significant portion shall be considered for providing technical support (computers, database servers, software development) for enabling the implementation of certain rights, such as *the right to confidentiality*, but also the *right to information* about the medical condition of the patient.

Alternative 2: Improvement of the legislation

A far more complex alternative is the one requiring changes in the current legislation. This means restructuring of the existing healthcare acts for better presentation of the patients' rights in one place (commonly in one chapter of a single law, as seen from the experiences of the countries in the region), but possibly introduction of new mechanisms for implementation and monitoring of the level of exercising of patients' rights.

One such idea, vastly debated in the health and legal professional communities is the introduction of a separate system of Healthcare Ombudsman, under which patients can sought legal advice and assistance through recommendations for the institutions of the judiciary system. In some countries, like Hungary, and since recently Serbia and Montenegro, each health care setting has an appointed "advocates" responsible for receiving and advising upon patients' claims or complaints. This approach provides first-hand legal aid on the existing mechanisms, but can also serve as a filter for the unjustified claims, thus contributing towards the more efficient implementation of the legislation regarding this very neglected but important legal sphere.

The costs incurring from implementing this alternative are mostly in the setting up and maintaining the newly proposed institutional settings and mechanisms; however, in this alternative as well, some public health education campaigns will be required, mostly in the direction of increasing the knowledge and awareness of the general public both of the existing rights but of the novelty in the system as well. With the current level of reforms in the healthcare system, but in the judiciary as well, it is hard to expect that additional funds can be provided for the implementation of this alternative. Rather, the existing Ombudsman office and its infrastructure can be used for engagement of a specialized health law professional. Also, another low-cost intervention is the public reporting of the Ombudsman about the number and types of claims, which will encourage the patients to more awarely accept and exercise their rights, but duties as patients as well.

V. CONCLUSIONS AND RECOMMENDATIONS

Vast research and litigation in Macedonian legal system are required to define and enforce patients' rights that have to be introduced in the legal environment. To have a meaningful impact these rights have to have clear content understandable to each patient and patients have to be aware of these rights. Patients should not fear to enforce them. We have to develop efficient mechanisms for handling complains and assigning and enforcing responsibility. Enforcement of patients' rights should be measured and monitored. But all these are not sufficient to fundamentally change the doctor-patient i.e. the institution-patient relationship. The health system mirrors the larger social, political and economic system. Physicians' relationship with patients and physicians behavior is strongly influenced by structure of medical plans, physician relationship with other health providers, numerous governmental agencies and so on. Consequently fundamental change in the doctor-patient relationship is possible only after basic changes happen in our social structure. In this transitional period of transforming rights of patients from myth to reality we should constantly remind ourselves that patients' rights are not only abstractly important but they can in fact save a patient's life - patients' rights and health are fundamentally connected.