



## Patients' Rights in Southeast Europe by Neda Milevska-Kostova<sup>1</sup>

The argument of this paper is that the EU's common health and social policy is placing the rights of patients, consumers, users, family members, weak populations and ordinary people at risk. The Preamble of the European Charter of Patients' Rights provides that "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".<sup>2</sup> This Charter aimed to foster the introduction of patients' rights policies and reinforcing their implementation in different countries. Undoubtedly, they can also be used to harmonize national health systems of both EU member-states and EU aspirants, in particular, as part of improved freedom of movement within the EU.

However, despite the benefits they have brought, medical advances in the areas of life-prolonging technology, prenatal diagnoses, organ transplantation and genetics all increased the technological and decreased the human aspects of medical care. These advances have enlarged the alienation between patients and physicians. Too often physicians forget or simply do not have time to be compassionate. Due to their superior medical knowledge, physicians often perceive themselves as absolute authorities in judging patient needs and they do not perceive the need to discuss diagnoses or proposed treatment with patients. Only a strong commitment to protecting and promoting the rights of patients can a) maintain a balance whereby decision-making is shared and patients can make ultimate decisions 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.

### 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. Instead, rights were stipulated in certain healthcare insurance laws and bylaw documents. One activity of the new EU member-states during EU accession was adjusting health care legislation towards European standards. In 1997 for example, Hungary enacted the New Health Care Act to regulate the majority of patients' rights such as: the right to healthcare, the right to be treated with dignity, the right to information, the right to refuse treatment, the right to information privacy, the right to leave the health care institution, the right to complain, the right to die with dignity, and the right to participate in decision-making in health care.

Not every country aspiring for EU membership has followed this process. The Republic of Macedonia is reforming its health care and public health systems, but is still struggling defining the most suitable healthcare and healthcare insurance model. In this regard, it can be instructive to analyse existing legislation in countries which have gone through similar processes of economic and political transition.

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<sup>2</sup> European Charter of Patients' Rights, Basis Document, Rome, November 2002

Whilst there have been great changes in patients' formal rights, the dramatic changes that have taken place in the past decade in Central and Eastern Europe have also created large inequalities in health, not only between but also within the countries in the region. This can be well supported with 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".<sup>3</sup>

### **Macedonia**

In the Republic of Macedonia prior to the transition there was no single law regulating the rights of patients, but patients' rights could be found in several healthcare and healthcare insurance laws and bylaw documents. The previous legislation (Health Law of 1970; Law for Healthcare of 1983) 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 1991 Act regulates the functioning of the basic healthcare system in the country, and consists of the following chapters: (1) health insurance; (2) rights and responsibilities of healthcare users; (3) rights and responsibilities of healthcare providers; (4) organizational structure of the healthcare system, and (5) financing of the healthcare.<sup>4</sup> In the Macedonian context, the following articles from the EU Charter of Patients' rights are applicable: the right to preventive measures: the right to access: the right to consent: the right to free choice: the right to privacy and confidentiality: the right to observance of quality standards: the right to compensation: and the right to complain.

The institutions responsible for protecting these rights are the Ministry of Health, the 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, the Committee for ethics and patients' rights (functioning within the Clinical Center, as the major institution for tertiary care in the country), and the 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, in carrying out research into existing legislation regarding patients rights, the following conditions have been identified. There is a lack of appropriate and systematized legislation directly regulating patients' rights. Within the existing legislation, there is uneven and insufficient level of implementation, and amongst patients there is widespread ignorance regarding their rights. Within the healthcare authorities it is common to find non-transparent attitudes regarding information for citizens concerning their rights and duties as patients. Finally, there is a 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. Often referred to as the "health constitution of Bulgaria," this law represents the basic framework for regulating all public relations concerning the health promotion. The third chapter of this Law regulates the rights of the patients. 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 "constitution", the Bulgarian health authorities recognized ten of the fourteen basic patients' rights included in the European charter. Despite this, in September 2005, two Draft Laws on the Patients' Rights and Obligations were submitted to the Bulgarian National Assembly for adoption. The general novelty of the drafted legislation was the proposal to introduce the institution of the Health Ombudsman into the Bulgarian legal system. The public debate hosted by an Bulgarian NGO<sup>5</sup>, and attended by representatives of the relevant institutions, academia, NGOs and human rights advocacy groups, showed that there is much controversy around this issue. Whereas, the introduction of this medical/legal mechanism would undoubtedly improve the level of implementation and exercise of patients' rights on one side, it will cause an extra burden on the budget of the health care facilities, which are already pressed by financial problems.

<sup>3</sup> The Health Divide, by Margaret Whitehead, in "Inequalities in Health", 2ed, Penguin Books, 1992.

<sup>4</sup> Zakon za zdravstvenata zaštita ("Sl.vesnik na RM", broj 38/91,46/93 i 55/95)

<sup>5</sup> Center for Study of Democracy (CSD)

## **Croatia**

Croatia signed and ratified the 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 whilst others need to be further elaborated through national law. Since ratification, Croatia enacted several pieces of legislation: 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. Traditionally, as in the whole region, 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.<sup>6</sup>

The rights of hospitalized children are treated in a separate manner. Based on the Charter for children in hospital<sup>7</sup>, 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.<sup>8</sup> 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 rights provide that medical intervention cannot be undertaken unless consented with a written agreement of patient. Yet, the law considers cases of unconsciousness and specific psychiatric as special circumstances, for which treatment can be provided 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 a wider scope for patients' rights, as well as regulating human rights in healthcare. Most of the rights from the European Charter on Patients' Rights are covered, including the 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 proposes to regulate the following rights, the right to accessibility to health care, according to the financial possibilities of health care system; the right to all kinds of information, regardless of patient's health condition, type or way of utilization of health services; the right to consent; that 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. There is a right to free choice of physician and health care service, right to privacy and confidentiality of personal data, data concerning patient's health status, and potential diagnostic and therapeutic procedures, a right to free decision on everything concerning his/her life and health, and agree freely on proposed medical measures, and a right to being introduced with his/her medical documentation, except in case of serious endangering his/her health by doing so. There is a 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 and finally, a right to reimbursement for malpractice or harm caused by physician's error during medical intervention.

<sup>6</sup> Turkovic, K, The right to informed consent according to Croatian Act on Protection of Patients' Rights, in "Bolesnik: prava i obaveze", Hrvatski liječnički zbor, Zagreb 2005.

<sup>7</sup> National Association for Welfare of Children in Hospital. A charter for children in hospital. Lancet 1984;2(8415):1350<sup>9</sup> Edward Said, Orientalism, London: Routledge and Kegan Paul, 1978, p. 265.

<sup>8</sup> Hrvatski liječnički zbor, Kodeks medicinske etike i deontologije, 2002.

In the Serbian circumstances, the following conditions have been identified in practice. There is little widespread knowledge/expertise in medical law. There are a small number of specialized lawyers, but on the whole, medical professionals tend to associate medical law is identical with forensic medicine. As a scientific field as well as a professional domain, medical law is just beginning to develop as a new scientific field. There is an inadequate level of exercising human rights concerning health, within existing practices, there is a very dominant paternalistic concept of medicine. Finally, several 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

The situation in Montenegro is quite similar to Serbia. As in most countries in the region, Montenegro does not have any specialized institutions for protecting patients' rights, except the Ministry of Health and the Ministry of Justice. The current law provides for the following patients' rights: the right to the fair and equal accessibility of medical services; the right to high-quality medical care; the right to medical care covered by the obligatory insurance; the right to a human dignity and privacy in medical service; the right to information; the right to medical record information concerning patient's illness; the right to information regarding identity and professional level of the physician and the right to criticism and complaint in case of unsatisfied patients

The right to a free choice regarding physicians does exist in the law, but its implementation is subject to ongoing reforms detailed regulation with bylaw documents. Several documents protect and promote patients' rights such as the Law on Health care, the Law on Medical Insurance, the Law concerning rights of mentally disabled patients, and the Law on Ombudsman, etc. Notwithstanding, there are some important omissions such as the Strategy on reproductive health, Strategy for mothers' and children health, including the rights of hospitalized child, etc.

#### **Romania**

The Romanian Constitution 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. 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 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 (Law 46). The law consists of eight chapters and is aimed at consolidating basic 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 medical care and technology 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. 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.

### ***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.<sup>9</sup> It is an obvious necessity and commonsense that "rights", as well as the responsibilities of the patients, related family members, those involved in the care of the patients, as well as of the healthcare providers have to be regulated, respected and reinforced. 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. Health education plays a crucial supportive role towards the general population. Both preventive and other health information can make a significant contribution towards improving health status. Furthermore, it can add a significant meaning to the real and appropriate functioning of the healthcare system, through a proper exercise of the rights of both patients and healthcare providers.

Despite the benefits they have brought, the medical advances in the areas of life-prolonging technology, pre-natal diagnoses, organ transplantation and genetics can undermine some of the traditional aspects of medical care. Technological advances have added to the alienation between patients and physicians. Thus the most common complaints of patients across the national milieus investigated are that, in many cases, physicians don't listen, don't take much time and don't explain in accessible language. If anything happens beyond the expected procedure, physicians would first "blame it on" the patient for non-compliance. This helps explain the paternalistic roles in the physician-patient relationship rather than the paternalism of the health care system. Despite the different patients' rights in the legislation, the implementation levels have been similar. The interviews for this research found a similar situation with the physician-patient relationship, in some occasions even expressed as "father-physician taking care of the child-patient".

The reasons for this approach can be looked for in the previous system, but can also be found in the present ignorance of patients regarding their rights. The only survey that was undertaken under this research (conducted in Macedonia on 282 individuals) 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 cases, other rights are mostly looked at as obligations. For example, the right to free choice of physician in the primary healthcare 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 this is the attitude for signing the informed consent, which for over half of the interviewed patients is just another "administrative procedure".

The survey confirms a widespread acceptance by patients of a paternalistic approach to the physician-patient relationship. Among interviewees, 90.8% are satisfied (56% very and 34.8% on average) for 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 given by the doctor. Even though the right to complain is regulated and guaranteed in the legislation, an astonishing 84-86% have

<sup>9</sup> "Pacienti vo Makedonija so prava po evropski standardi", MIA-AIDS, 2004

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).

## **Proposed alternatives**

This comparative analysis of legislation in Southeast Europe and the survey of implementation in the Republic of Macedonia, leads to two alternative approaches for improving protection and promotion of the patients' rights. Both suggestions involve changes in the legal environment (in terms of improved implementation of 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 includes changes in implementation mechanisms, but also assuming undertaking public awareness raising activities. One main component is understanding how rights are violated by the patient, the physician or the institution. Moreover, as 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.

One significant ingredient in the improvement of implementation is enhanced knowledge and perception of the general public and health professionals as well. Here, the civil sector can play a major role through awareness raising campaigns, offering legal advice and assistance in understanding and utilizing the mechanisms of the system. The main costs for implementing this alternative will be the public awareness raising campaigns. Yet, a significant portion could be considered for technical support (computers, database servers, software development) for enabling 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 requires changing current legislation. This means restructuring existing health-care acts for better presentation of 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 an independent Healthcare Ombudsman, under which patients can seek legal advice and assistance through recommendations to the institutions of the judiciary system. Some countries, like Hungary and, recently, Serbia and Montenegro have appointed "advocates" who are 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 establishment of new institutional settings. However, some public health education campaigns will be required, mostly in the direction of increasing the knowledge and awareness towards existing rights but also the new recommendations. With the current level of reforms, it is hard to expect that additional funds can be provided for this alternative. Rather, the existing Ombudsman office and its infrastructure could be used for engaging 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 exercise their rights.

## **Conclusions and recommendations**

Much research and litigation within Macedonian legal system is required in order to define and enforce patients' rights. To have a meaningful impact these rights need to be clearly understandable for each patient and patients should not fear to enforce them. There needs to be efficient mechanisms for handling complaints and assigning and enforcing responsibility. The enforcement of patients' rights should be measured and monitored. But all these are insufficient to fundamentally change the doctor-patient i.e. the institution-patient relationship. The health system mirrors the larger social, political and economic system and physicians' relationship with patients is strongly influenced by the structure of medical plans, the relationship with other health providers, numerous governmental agencies and so on. Consequently fundamental change in the doctor-patient relationship is only possible after basic changes to our social structure. In this transitional period, we should constantly remind ourselves that patients' rights are not only abstractly important but they can in fact save a patient's life, in other words, patients' rights and health are fundamentally connected.