

# *Informed Consent in Croatia*

## *A Work in Progress*

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**Abstract:** As Croatia makes the transition from one political system and type of economy to another, there are inevitable social and political changes that have a profound affect on the healthcare system. This article charts some of the progress of change with respect to patients' rights and informed consent.

**Keywords:** Croatia; patients' rights; informed consent; healthcare system

### Introduction

When, on July 1, 2013, Croatia became a fully fledged member of the European Union, the newest of the 28 member states, it might have seemed that a certain period of its development had passed. However, the Croatian citizens, the government, and the European Union are aware that there is still work to be done. Despite its status as part of the European Union, Croatia is still a country in transition. It will still be wrestling with some of the same problems as other transitional countries, some of which have been in the European Union for a longer period, like Slovakia, Poland, the Czech Republic, Romania, Bulgaria, Estonia, Lithuania, or Latvia. A change from one political system (communist, totalitarian) and type of economy (a socialist command economy) to another (a market-oriented economy) does not happen overnight; it is difficult to root out old habits and patterns of behavior. However, changes—both social and political—have occurred, and they have had an effect on the healthcare system.<sup>1</sup> Nowhere can these changes be better observed than in the issues related to patients' rights, especially in the area of informed consent.

### Patients' Rights Legislation

Prior to the social and political changes of the 1990s, in most of the countries of southeastern Europe, including Croatia, there was no legislation directed specifically to patient rights.<sup>2</sup> Transitions that included reforms in the healthcare system in Croatia began in 1993 with the introduction of the Health Care Act,<sup>3,4,5</sup> making Croatia the first among the former Yugoslavian countries to regulate patients' rights by law.<sup>6</sup> Initially Croatia did not have a special law for patients' rights. However, in 2003, Croatia signed and ratified the European Convention on Human Rights and Biomedicine, the Oviedo Convention. Thus the internal legal system of Croatia became responsible for the provisions of that convention.<sup>7,8</sup> As a step toward this alignment, in 2004 Croatia adopted the Act on the Protection of Patients' Rights.<sup>9</sup>

The act guarantees patients the following rights: the right to joint physician-patient decisionmaking, the right to be informed, the right to accept or refuse

individual diagnostic or therapeutic procedures, the right to protection when participating in clinical trials, the right of access to medical records, the right of confidentiality, the right to maintain personal contacts during hospitalization by having visitors, the right to leave health establishments voluntarily, the right to privacy during medical treatment, and the right to compensation for injuries. The act also makes provision for patients' complaint procedures, through a system of regional and national patients' rights protection commissions. It also sets out a number of penalties and punitive repercussions for those institutions or individuals responsible for not enforcing patients' rights. However, numerous studies by legal experts have noticed various discrepancies between the rights implicit in the legislation and the actual situation of patients within the Croatian healthcare system.<sup>10</sup> This is especially true for certain issues.

The several analyses have shown, for instance, that although there is a law regulating access to health records, this access cannot be described as full access, because the patient is responsible for the cost of copying the records. Furthermore, it is often difficult to get a second opinion, and the list of registered legitimate doctors is also difficult to access. Moreover, the existing process for resolving complaints functions very poorly. In many countries, various types of ombudsmen have been appointed for patients' rights,<sup>11</sup> some of them local (that is, available in the healthcare institutions themselves), and some of them national. In its best form, the ombudsman system enables patients to have as direct access as possible to the healthcare institution or to the team responsible for protection of patients' rights. Croatia has not chosen this ombudsman approach in its legislation but instead has entrusted the protection of patients' rights to regional and national commissions. The complexity of the procedure for filing complaints further slows down and complicates the process. Thus inquiries may be conducted badly or not conducted at all for various reasons, and there may be a lack of transparency in the process. However interested the institutions themselves might be in resolving their existing organizational and systemic problems internally, it is difficult for them to admit to them publicly. Furthermore, this approach to resolving complaints itself very often depends on the availability of one person or a group of people with both the authority and the means to resolve the problem as effectively and well as possible; but that is very often not the case. So it is no wonder that a series of failures and problems have been noticed. The Constitutional Court of the Republic of Croatia has ruled to strike out Article 35 of the Act on the Protection of Patients' Rights in order to simplify patients' complaint procedures.<sup>12</sup> As a result of the removal of this article, patients will be allowed to complain directly to the commissions when they feel that their rights are violated, whereas, before, the head of the health institution concerned was the first court of appeal, and the commission was only second.

### **Informed Consent**

The concept of informed consent was present in all Croatian laws that regulated patients' rights even before the adoption in 2004 of the Act on the Protection of Patients' Rights: both the 1993 Health Care Act and the Act on Protection of Persons Suffering from Mental Disorder<sup>13,14,15</sup> contained some provisions to that effect. In the Act on the Protection of Patients' Rights, informed consent stems from the right to physician-patient joint decisionmaking, which includes the right

to be informed and the right to accept or refuse medical procedures.<sup>16</sup> However, the actual implementation of this informed consent process in Croatian hospitals is experiencing many problems.

The practice in Croatia is that, on hospital admission, patients sign a general consent form that includes consent for any and all diagnostic and therapeutic procedures that will be performed during hospitalization. However, legal experts have been saying that consent in this form is not valid, and the physician should seek individual consent for every separate medical procedure.<sup>17</sup> The Ministry of Health and Social Welfare in 2008 adopted an ordinance regulating the content of the consent forms for recommended diagnostic or therapeutic procedures.<sup>18</sup> Along with the consent form the patients should also receive a written description of each diagnostic or therapeutic procedure recommended, the content of which is determined by the healthcare provider.<sup>19</sup> But this practice is not always followed in Croatian hospitals, because, according to the ordinance, it is up to each hospital and each department to implement it; and this allows for considerable individual variation. The majority of hospitals have enforced the ordinance provisions in general, but each in its own way. With each hospital having its own informed consent forms, it is difficult to monitor quality and content. There is a need for a single, consistent informed consent form for special medical procedures that would be valid in all Croatian hospitals.

The other issue in informed consent practice in Croatia is the process of obtaining informed consent itself. More needs to be done to ensure that informed consent goes beyond good intentions and becomes a widespread reality. In a study done before the implementation of the Act on the Protection of Patients' Rights, Frković et al. found that, for the majority of patients, the informed consent process is just a formality.<sup>20</sup> Even after the implementation of the Act on the Protection of Patients' Rights, Banić et al. found that 35 percent of patients going for gastroenterology endoscopy gave only verbal consent, and 12 percent of patients did not give either written or verbal consent.<sup>21</sup> In 17 percent of cases, the information was given to patients by nurses (who typically have only a middle-school or higher education level), not by physicians, as is required by the Croatian Act on the Protection of Patients' Rights. According to the law, only persons with a college degree working in the healthcare system can obtain valid informed consents.<sup>22,23</sup> In another study done two years after implementation of the law, little had changed. Jukić et al. found that only two-thirds of physicians knew that the Act on the Protection of Patients' Rights had been adopted, and only slightly more than half of the physicians knew that what constituted valid informed consent was regulated by law.<sup>24</sup>

Even several years after the implementation of the Act on the Protection of Patients' Rights, two studies done in 2011 by Vučemilo et al. indicate problems in the process of informed consent in Croatia.<sup>25,26</sup> The first study, a field survey with a short questionnaire administered to a national representative sample, was conducted in October 2011 in Croatia.<sup>27</sup> The study addressed the experience and knowledge of the general population about patients' rights and informed consent in Croatia. Nearly a third of respondents did not know their rights as a patient and were not familiar with the concept of informed consent. Only 1 in 10 respondents knew their rights fully. One worrying thing also noticed in the study was that every seventh subject who had been hospitalized did not know or did not remember whether he or she had had to sign a consent form. Only one-third of them reported signing a consent form, despite the fact that it is a prerequisite for

entering a hospital service in Croatia, and such a form is supposed to be included in each patient's chart. Furthermore, one-quarter of the hospitalized subjects reported receiving a low level of information from healthcare workers. The results also showed that in one-third of cases, the decision about the patient's treatment was made by the doctor alone. The majority of the subjects who were not acquainted with informed consent procedures were found among those with a lower level of education, especially those with only an elementary school education, and among older subjects.<sup>28</sup>

More promising results were found in another study, also conducted by Vučemilo et al., on physician-patient communication practices during the process of obtaining informed consent in a hospital setting in Croatia in 2011.<sup>29</sup> In the period from April to December 2011, 250 patients (with a response rate of 78%) from five tertiary-level hospitals in Zagreb anonymously filled in the questionnaire by Nemcekova et al. on informed consent and communication practices.<sup>30,31</sup> Eighty-five percent of patients reported that they had received complete and understandable information, presented in a considerate manner. Patients in surgical departments received a higher level of information than those in internal medicine departments. Patients were informed about the health risks of the proposed treatments (in 74% of cases) and procedures (76%), the health consequences of refusing a medical intervention (69%), and alternative methods of treatment (46%). However, patients pointed out a number of problems in physician-patient communication, which can be observed in the qualitative part of the questionnaire, in which patients could leave their comments. Nevertheless, the results from the study show that physician-patient communication practices are slowly changing when it comes to informed consent processes. The communication practices during informed-consent-obtaining processes observed in hospitals in Zagreb were based on a model of shared decisionmaking, although there are still vestiges of a paternalistic physician-patient relationship. On the whole, the results indicate that Croatia is undergoing a transition in physician-patient relationships and communication.<sup>32</sup>

### **Concluding Remarks**

Croatia has come a long way in its process of transition from one political system and type of economy to another. With those changes also came changes in other areas of life, and healthcare is one of those areas. This article charts part of the progress of change in Croatia with respect to patients' rights and informed consent. We can say that the Croatian situation can fairly be described as a work in progress; a lot has been done, but more needs to be done in the future. This is true when it comes to improving informed consent processes and requiring uniform informed consent forms, but it is especially true when it comes to educating both physicians and patients about patients' rights and informed consent.

### **Notes**

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