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Borovečki, A., ten Have, H., Orešković, S. (2006) *Ethics committees in Croatian healthcare institutions: the first study about their structure, functions and some reflections on the major issues and problems.* HEC Forum, 18 (1). pp. 49-60.

http://www.springerlink.com/content/420386rh2k24p7t6/
The original publication is available at www.springelink.com

Ethics committees in Croatian healthcare institutions: the first study about their structure, functions and some reflections on the major issues and problems

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HEC Forum 2006; 1:48-59.

ABSTRACT

Objectives: In Croatia, ethics committees are legally required in all healthcare institutions by the Law on the Health Protection. This paper explores for the first time the structure and function of ethics committees in the healthcare institutions in Croatia.

Design: Cross-sectional survey of the healthcare institutions (excluding pharmacies and homecare institutions) to identify all ethics committees.

Setting: Croatia six years after the implementation of the Law on the Health Protection.

Main measurements: Structure and function of ethic committees in the healthcare institutions.

Results: 46% of the healthcare institutions in Croatia (excluding pharmacies and homecare institutions) have an ethics committee; 89% of ethics committees have 5 members 3 of whom are from medical professions and 2 come from other fields; 49% of those committees stated that their main function is the analysis of research protocols. Only a small fraction of those ethics committees sent in standing orders, working guidelines or other documents that are connected with their work.

Conclusions: Although there are legal provisions for ethics committees in the healthcare institutions in Croatia, there is an evidence of discrepancies between the practice and the "Law on the Health Protection," suggesting the need for revision of the law. There is a need for creating separate networks of HECs and IRBs in Croatia. In comparison with other countries, the development of ethics committees in Croatia has some similarities with other transitional societies in Europe. Additional research should be undertaken in the work of ethics committees in Croatia in order to understand committees' group dynamics, attitudes, and knowledge.

Introduction

The first steps towards the bioethics institutionalization through ethics committees in Croatia were done in 1970s. It was then that the first IRBs (institutional review boards) were created. Those committees were called "the hospital drug commissions, and were formed in the biggest clinical hospitals in Croatia. They were involved in methodological and ethical analysis of the clinical drug trails. Additional impetus for further establishment of the ethics committees in Croatia followed in 1990, when the Croatian Medical Association formed the Commission for Medical Ethics and Human Rights. After the reestablishment of the Croatian Medical Chamber in 1995, this commission became the official ethical review board for both the Croatian Medical Association and the Croatian Medical Chamber. The main task of the Commission for Medical Ethics and Human Rights of the Croatian Medical Association and the Croatian Medical Chamber was to review all possible and reported breaches of the medical code and conduct (1). However, in the late 1990s the Croatian Medical Association and the Croatian Medical Chamber went their separate ways, so today there are two ethical boards present in each of these two institutions, who have two separate, but basically the same ethical codes.

In 1997 the legal requirements for the establishment of ethics committees came about. In the "Law on the Health Protection" from 1997, articles 51 and 52 are dedicated to the framework-setting for the work of ethic committees. According to the law, each healthcare institution in Croatia should have an ethics committee constituted of five members, two of whom should not be from the medical field. The ethics committees have the following functions:

-They follow the implementation of ethical principles of medical profession;

-They approve the research activities (protocols) within the healthcare institution;

-They oversee the drug and medical device trails;

-They oversee the organ procurement from the dead persons;

-They solve other ethical issues in the health institution (2).

According to these legal provisions, the ethics committees in healthcare institutions in Croatia are required in their everyday work to combine the functions of an Institutional Review Board (IRB) and a Healthcare Ethics Committee (HEC).

In 2001 the National Bioethics Committee for Medicine of the Government of the Republic of Croatia was founded. This is an independent advisory and multidisciplinary body involved in systematic analysis of ethical and legal implications in the development and implementation of the biomedical sciences. It issues recommendations, guidelines and reports on various ethical issues. It has twenty members, seven of whom are women. The National Bioethics Committee for Medicine of the Government of the Republic of Croatia promotes the values implemented in international declarations and documents in its work (3).

Except for the National Bioethics Committee for Medicine of the Government of the Republic of Croatia and ethics committees in healthcare institutions and professional chambers and associations, there are also committees in scientific institutions (scientific institutes, faculties of medicine, dentistry, pharmacy and veterinary medicine). There is a little data available about the work of these ethics committees, except that one can presume that their function is primarily one of a research ethics committee.

Until now, not a single survey was done on the ethics committees in Croatia, especially those in healthcare institutions, which are mandated by the Law on Health Protection. Recently, in 2002 and 2003, the National Bioethics Committee for Medicine of the Government of the Republic of Croatia has conducted a study of ethics committees in Croatia (number of members, structure of membership, issues that were discussed during the meetings, number of meetings so far, standing orders, working guidelines, and documents related to their work). The results of this survey are presented in this paper.

Methods

A cross-sectional study was performed in 2002 and 2003. A circular letter was sent to all the healthcare institutions by the National Bioethics Committee. Under the title of healthcare institution in the "Law on the Health Protection" from 1997 section IX, the following institutions are mentioned: homecare institutions, primary care clinics, emergency medicine clinics, pharmacies, polyclinics, hospitals (clinical hospital centres, clinical hospitals, special hospitals, clinics, regional hospitals, general hospitals), spas, state health institutes (Croatian Institute for Public Health, Croatian Institute for Transfusion Medicine, Croatian Institute for Toxicology, Croatian Institute for Occupational Medicine, Croatian Institute for the Protection from Radiation, Croatian Institute for the Control of Immunobiological Substances, Croatian Institute for the Control of Drugs and finally the referral centres of the ministry of

health (2). All of these institutions (except for the pharmacies and home care institutions) were involved in this research (241 in total). The ethics committees in healthcare institutions were asked to provide out the following information:

Does an ethics committee exist in the institution?

If there is an ethics committee in the institution:

a) What is the number of its members, their names, professions and functions within the ethics committee (president, vice-president, secretary)?
b) What type of work has the committee done so far? (How many times has the committee met so far? What were the main topics that were discussed during the meetings? What kinds of decisions were made?)
c) Are there any official documents (standing orders, working guidelines) of the committee?
d) Are there any other committees (for example: a committee for transplantation) in addition to the ethics committee working in their institution?

Ethics committees that exist in institutions other than health care institutions (such as chambers of physicians, dentists, biochemists, pharmacists, medical faculties, faculties of pharmacy, faculties of veterinary medicine, research institutes) were also involved in this research but the data obtained from those committees will not be presented in this paper.

Results

The response rate to the circular letter sent by the National Bioethics Committee was between 100-75% depending on the type of the healthcare institution (100% response rate for clinical hospitals and clinical medical centres, 91% for regional and local general hospitals, 80% for clinics and policlinics, and approximately 77% for all the other healthcare institutions [state health institutes, primary care clinics, emergency medicine clinics]) (Table 1).

Table 1 Response rates of different institutions involved in the survey

	Clinical hospital centres and clinical hospitals 7	*Regional and local hospitals* 23	*Clinics and polyclinics* 15	*Other healthcare institutions* 196	*All Healthcare institutions without pharmacies and home care institutions* (state health institutes, primary care clinics, emergency medicine clinics) 241
TOTAL	7	23	15	196	**241**
Did not respond	0	2	3	43	**48**
Non response rate	0%	9%	20%	21 %	**18%**
Responded	7	21	12	153	**198**
Response rate	100 %	91%	80%	77 %	**82%**
Do not have an ethics committee	0	0	0	82	**82**
Have an ethics committees	7	21	12	71	**111**

Of 241 healthcare institutions involved in this research, 111 have an ethics committee. Of ethics committees in the healthcare institutions in Croatia, 89% have five members as required by the "Law on the Health Protection" from 1997. Two ethics committees have not stated the number of their members, four of them have only three members, two have four members, two have six members, and one has eight members. All of the committees have physicians for members. Thirty-four committees have a nurse as a member. Only one committee has a philosopher as a member. Other professions that are mentioned as members of the committees are: 1 biologist, 6 pharmacists, 1 musician, 3 biochemists, 5 psychologists, 1 biotechnologist, 3 social workers, 4 teachers, 1 economist, 2 sociologists, 1 archaeologist, 1 historian, 12 dentists, 1 university professor, 1 scientist, 1 member of the administrative staff of the institution, 1 civil engineer, 1 expert in educational rehabilitation, 3 civil servant. Some 46% of the healthcare institutions who had an ethics committee did not state the occupation of the president of the committee. In 9 institutions of those healthcare institutions that stated the president's profession, the president is not a physician (1 psychologist, 1 dentist, 2 theologians, 1 sociologist, 4 lawyers). Only two healthcare institutions mention that they also have a secretary and a vice president of the committee (in the first case the vice-president of

the committee is a theologian and a lawyer is the secretary, in the second case the vice-president is a theologian and the secretary is a physician). The sex distribution among the members could not be analyzed from the obtained data.

Only 49% of the ethics committees in the healthcare institutions described what type of work they had done so far. Review of research protocols was presented as the most often performed task among the ethics committees in the healthcare institutions in Croatia.Some of the committees also deal with other issues (new informed consent forms (1), patient complaints and malpractice issues (4), involuntary hospitalization (1), education (2), deontological issues (3), transplantation issues (2), termination of pregnancy issues (1), formation of ethical guidelines (1), problems with Jehovah witnesses (1), issues connected with the treatment of the dead(1)). Some of the committees in the healthcare institutions, when asked what tasks they performed in their everyday work, answered "those according to the law", meaning all those that are explained as tasks of ethics committees in the Law on Health Protection from 1997. The data on how often the ethics committees meet was insufficient and could not be analyzed.

Only 18 standing orders and working guidelines were sent in from all of the ethics committees. Only in three cases of the standing orders specific international documents and declarations were cited (Helsinki declaration, Tokyo Declaration, Guideline for Good Clinical Practice). Other documents that were cited were: the Ethical Codex of the Croatian Medical Association (1), the Law on Protection of the Mentally Ill (1), the Law on Healthcare Protection (3), and the Law on Health Insurance (1).
When asked about other types of committees present in their healthcare institutions, 19 institutions reported having "commissions for drugs" that also do reviews of clinical protocols. Other types of committees were not mentioned.

Discussion

Development and history of ethics committees is closely linked with the emergence of biomedical ethics as a new discipline in 1960s and 1970s. At this time, basically two types of ethics committees emerged: IRB (institutional review board, or research ethics committee) and HEC (healthcare ethics committee or hospital ethics committee or clinical ethic committee) (4).

The existence of the research ethics committees came about through a number of issues and documents, which were connected with human experimentation. The most influential of these documents was the Nuremberg Code from 1947, which introduced for the first time the concept of "informed consent" and set standards for human experimentation. The rationale for the creation of the research ethics committees was to have independent bodies that could have authority and knowledge for approving or disapproving proposals of research involving human subjects. Their existence was soon codified in numerous international documents and legal provisions which dealt with the issue of the human experimentation (Helsinki Declaration, CIOMS Guidelines, and Good Clinical Practice Guidelines). The research ethics committees have at least five members at least one of whom is not a member of the institution that is conducting the research. The structure of membership is multidisciplinary (5). There is an ongoing discussion present in the literature about the organizational structure of the network of research ethics committees. Some say that the network should be organized on a regional level (one research ethics committee per region) in order to avoid conflicts of interests if an evaluation is done by a research ethics committee within the institution that is performing the research (6).

The healthcare ethics committees were born out of a grass-root process in American hospitals (7). In their everyday work healthcare ethics committees try to cover three domains or functions. The first function is education of the HEC members and also education of hospital staff and patients about ethical issues. As the second task the HEC may involve itself in the creation and revision of different hospital policies and guidelines which can facilitate work of the hospital staff. The third function of a HEC is the task of ethical case analysis. Here the committee is involved in solving difficult ethical dilemmas that appear in everyday clinical practice. Usually, HECs have no more than 10 members whose background is multi-disciplinary (8).

Ethics committees in the healthcare institutions in Croatia are of "mixed" type, meaning that each committee in a healthcare institution combines the function of an IRB and of a HEC. This type of an ethics committee is not uncommon among the countries in Europe (Belgium, Italy and Slovakia) (Table 2).

Table 2- Ethics committees in Europe according to data from available literature

Country	**National Bioethics Committee**	**IRB**	**HEC**	**Ethics committees which perform HEC and IRB functions**
Albania	Yes	Yes	no	No
Belgium	Yes	No	no	Yes
Byelorussia	No	under development	no	no
Croatia	Yes	No	no	Yes
Czech Republic	yes	Yes	no	No
Denmark	yes	Yes	no	No
Estonia	yes	Yes	under development	No
France	yes	Yes	under development	No
Georgia	yes	Yes	under development	No
Germany	yes	Yes	under development	No
Great Britain	no	yes	under development	No
Greece	yes	yes	no	No
Hungary	yes	yes	no	No
Italy	yes	no	no	Yes
Latvia	yes	yes	no	No
Lithuania	yes	yes	yes	No
Netherlands	yes	yes	yes	No
Norway	yes	yes	under development	No
Poland	no	yes	no	No
Rumania	yes	yes	no	No
Russia	yes	yes	no	No
Slovakia	yes	no	no	Yes
Slovenia	yes	yes	no	No
Spain	yes	yes	yes	No
Sweden	yes	yes	under development	No

However, as it can be seen from the Croatian example this type of committee can have many drawbacks. “Mixed” type ethics committees in healthcare institutions tend to devote the majority of their working time to analysis of research protocols, which is time consuming. Thus, the committee actually transforms itself into an IRB neglecting its other functions, such as education, policy-making and clinical case analysis (i.e., the functions of a HEC) (9). Education, policy-making, clinical case analysis and promoting a good ethical climate in the clinical settings are essential for the quality of healthcare and are associated with good clinical governance (10). However, all of those three functions are virtually non existent among Croatian ethics committees operating in the healthcare institutions. Among these three functions clinical case analysis or clinical case consultation, as some authors call it, presents a special challenge. Case consultation provides an important service for a healthcare institution. It is an essential tool for teaching communicational skills and conflict mediation in clinical settings, both for patients and clinicians (11). In the U.S., clinical case consultation is common practice, while in Europe clinical case consultation is at its beginnings. However, European experiences in this direction show us that the development of clinical case consultation can be an important tool in the clinical environment (12, 13). In addition to having no ethics committees that deal with ethical issues that arise in everyday clinical practice, the Croatian situation of having local IRBs, which evaluate research protocols in hospitals where this research will be carried out, cannot operate without pressure and without possible conflicts of interest. As previously stated, regional, not local IRBs should evaluate research protocols in order to avoid problems and unwanted pressure (5).

Having all this in mind, one can state that there is a need for splitting ethics committees in Croatia into two types, IRBs and HECs, and to create the new legal provisions that will regulate the practice of ethics committees. That is why the National Bioethics Committee for Medicine of the Government of the Republic of Croatia has recently proposed changes to the existing legal provisions for ethics committees.

According to this proposal there would be separate structures for IRBs and HECs. The IRBs would be organized on the regional level, according to European guidelines. They would have legal responsibility for their decisions and would have the task of reviewing research protocols. Clinical ethics committees would be organized locally or regionally, depending on the type and needs of individual healthcare institutions and would address three tasks: education, policy-making and clinical case consultation. This proposal would try to solve the previously discussed problems that ethics committees face in their everyday work in

Croatia. The proposal has also addressed two other issues important for the ethics committees in Croatia.

The first issue is the issue of a confusion that was created by the definition of healthcare institutions in the 1997 "Law on the Health Protection." According to this definition, pharmacies and homecare institutions are also classified as healthcare institutions and were required to have an ethics committee. However, it has become apparent that such a definition in practice creates many problems. Small pharmacies, homecare institutions, primary care clinics, and emergency medicine clinics usually do not have enough personnel for creating an ethics committee. Thus, one wonders what issues would ethics committees in such small environments discuss and what would their purpose be. Furthermore, this is the reason why pharmacies and homecare institutions were excluded from the survey of the National Bioethics Committee in Croatia. Moreover, this is also the reason why according to data from this survey, many primary care facilities do not have an ethics committee. Finally, that is why the National Bioethics Committee, in their proposal of the new legal provisions for ethics committees, tried to avoid these problems by creating HECs either on the local or regional level, depending on the size and number of employees of a healthcare institution.

The second issue that the National Bioethics Committee in Croatia has tried to solve with the changes of legal provisions for the ethics committees is the issue of dualism between hospital drug commission and ethics committees, which both still exist in small but significant portions of the healthcare institutions in Croatia. The hospital drug commissions are the relic of the first ethics committees that were created in Croatia in the 1970s; i.e., they function basically as IRBs. They also review research protocols, and thus sometimes duplicating the work of ethics committees, creating confusion. In the new legal provisions for ethics committees proposed by the National Ethics Committee in Croatia, whereby IRBs would be organised regionally not locally, such parallelism and confusion would be prevented.

The discussed proposal of the new legal provisions for regulation of the work of ethics committees in Croatia drafted by the National Bioethics Committee was sent out by the Committee to all the important institutions in the governmental structures in Croatia. Unfortunately, this proposal was not accepted, thus leaving the confusion and status quo regarding ethics committees in Croatia.

Nevertheless, the question that arises is whether the Croatian situation regarding ethics committees is something unique or if it could be compared to other countries. The development of research ethics committees has gone the furthest in Europe. Now, in almost all European countries there are legal provisions and research ethics committees are mandated

by law (14). However, the type, level and the mode of establishment of clinical ethics committees varies from country to county (15, 16). Croatia is, as one can see from the data of the survey, clearly the part of this development. However, Croatia is a transitional society and the Croatian situation regarding development, structure and functions of ethics committees can be best compared to other transitional societies. The process of institutionalization of bioethics is regarded by some authors as especially important to European transition societies. The development, especially, of the clinical ethics committees or health care ethics committees could encourage the development of the professional bioethics and the creation of important networks within a specific country (17). However, such an institutionalization if not carefully thought of within a specific context, can produce scepticism and bureaucratic behavior (18). Croatian experience clearly testifies to this consequence. While, on one hand, it seems that ethics committees are flourishing in Croatia, when one looks at the daily functions of these committees one can see that some of them are merely present just to satisfy the legal requirement of healthcare institutions.

When comparing the Croatian situation to that of the U.S. one can easily conclude that it is less than desirable. Both types of ethics committees are well developed and present in the U.S., although lately there is a great debate on the problems and drawbacks facing development of the HEC (19, 20).

The Croatian situation is very different from that which exists in the U.S. However, one must observe that between Croatia and the U.S., and between Croatia and other countries in Europe especially those in Western Europe, there are differences in historical development and cultural issues and most importantly there are differences in the structure and organization of a healthcare system and its development.

Although this study provides an invaluable insight into the functions of ethics committees in healthcare institutions in Croatia, certain limitations clearly exist. The number of committees included in this survey and the response rate are sufficient to draw conclusions about major issues related to structure, functions and work of ethics committees in Croatia. However, the data about committees' sex distribution, education, attitudes, and knowledge of members, as well as more detailed information on their meetings and group dynamics is lacking and further research should be undertaken to enlighten those issues.

In conclusion, if Croatia wants to manage the situation regarding ethics committees in the healthcare institutions in a proper way it has to take the best from U.S. and European experiences, trying to adapt their ideas and development to the specific Croatian situation,

baring in mind that certain main principles of ethics committees structure, organization and functions are not to be change because their existence is closely linked with the certain level of quality in the healthcare and the basic principles of good clinical governance.

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