Ethics Committees in Croatia

Ethiek Commissies in Kroatie

(Studies in Bioethiek)

Een wetenschappelijke proeve op het gebied van de Medische Wetenschappen

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Studies in Bioethics

A scientific essay in Medical Sciences

DOCTORAL THESIS

to obtain the degree of doctor
from Radboud University Nijmegen
on the authority of the Rector, prof. dr. S.C.J.J. Kortmann,
according to the decision of the Council of Deans
to be defended in public

on Tuesday 4 September 2007
at 1:30 pm precisely

by

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Introduction

INTRODUCTION

The changes experienced in the traditional Hippocratic approach to medical ethics around the middle of the 20th century resulted in the emergence of new theories and tendencies in medical ethics. Over the last 30 years analysis and criticism of the traditional methods and concepts related to ethical problems in medicine and healthcare have resulted in a new discipline: bioethics. The emergence of bioethics was also a result of the enormous advances in life-sciences and the changes in the socio-cultural context of medical practice. The plurality of values, the emphasis on the personal autonomy of patients in the healthcare decision-making process, the creation of new expertise in bioethics, an increasing public interest in the new field and institutional changes like the development of new bioethics laws, regulations and ethics committees have all contributed to the development of the new interdisciplinary field of bioethics. One of the most powerful institutional changes leading to the emergence of bioethics has been the establishment of ethics committees. Committees have been formed as institutional platforms for moral debate, involving other professions besides the medical one and sometimes also lay persons. Such committees have been able to transform the private character of moral deliberation in the context of the physician- patient relationship into an inter-professional and inter-personal debate over moral issues (1).

Nowadays, ethics committees are an essential part of healthcare systems in many countries. They were initially established to make difficult ethical choices faced by social institutions in the healthcare and legal systems (2). According to David Rothman (3), the first committees appeared in the 1970s and 1980s. At that time they presented themselves as "strangers", a third party that was there to protect the patient, ensuring that physicians had the patient's best interest in mind either when making treatment decisions or undertaking research that involved patient participation. Two basic types of ethics committees emerged: research ethics committees and clinical ethics committees (4).

Research Ethics Committees

Research ethics committees (REC) or institutional review boards (IRB) emerged as a consequence of many cases of widely publicized revelations of physician researchers who were using patients as their subjects without the patients' knowledge or their understanding of the risk involved. In 1960 these revelations led to government commissions in the United States and the establishment by law of institutional review boards which were involved in reviewing federally funded research projects ensuring adequate subject protection. The first

federal document requiring a committee review was issued in 1953 under the title: ”Group Considerations for Clinical Research Procedures Deviating from Accepted Medical Practice or Involving Unusual Hazard” (5). These recommendations applied only to research conducted within the facilities of the National Institute of Health in the U.S.A. In 1966 the surgeon general of the U.S. Public Health Service issued the first federal policy statement requiring research institutions to establish committees that subsequently came to be known as research ethics committees. The first explicit reference to a committee review of a research protocol in an international document was in the 1975 Tokyo revision of the Helsinki Declaration.

The function and the purpose of the research ethics committee is to ensure that the research is designed in conformity to relevant ethical standards. However, it also has the task of assessing the adequacy of the design of the study reviewed. As a result of those requirements the IRB is both an ethics committee and a professional review board. This is also reflected in its membership structure. The number of members may vary from 5 to 20. The membership structure is interdisciplinary. However, membership selection in an IRB is also focused on the competencies of the members to assess the acceptability of research in terms of legal standards, professional practice and community acceptance (5). Today, research ethics committees are present all over the world and their formation and functioning are usually regulated by different types of legal provisions and implemented in a number of international documents (CIOMS guidelines, Helsinki Declaration, Good Clinical Practice, directives of the European parliament and the Council of Europe) (6).

Healthcare Ethics Committees

Another type of ethics committee was also emerging in the Unites States during the1970s: the healthcare ethics committee (HEC) or clinical ethics committee or hospital ethics committee. This type of committee deals with making treatment decisions. The predecessors of HECs can be found in four types of committees that emerged in the U.S.A. in the 1960s. Around that time long-term dialysis became possible; however, there was not a sufficient quantity of artificial kidneys to treat all patients with end-stage renal disease. Ethics committees were established to select those among the medically eligible patients who were to be given a chance to have dialysis. The physicians were then informed which patients had been selected. In 1976, another impetus for HEC development came with the requirements of the New Jersey Supreme Court in the Quinlan case for the establishment of so-called prognosis committees in hospitals. In the Karen Ann Quinlan case the court required the hospital to convene an “ethics committee” to determine whether the patient’s reported prognosis was correct. The committee was required

to decide whether Ms. Quinlan, who was in a persistent vegetative state, had a reasonable chance of returning to a cognitive and sapient state. If the committee concluded that there was no chance, the patient's surrogate would be able to request her treatment to be stopped. The abortion selection committees, which existed in many states in the United States before the 1973 legalization of abortion in Roe vs. Wade, were another impetus for the establishment of HECs. Those committees had to decide whether a pregnant woman requesting abortion was likely to risk her life or health if the pregnancy was not terminated. The medico-moral committees in Catholic hospitals that assessed the treatment decisions in the light of Catholic teaching were another ancestor of the HEC. The formation of HECs in the United States was a "grass root" process. This grass-root process was additionally promoted in 1983 by a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research to establish ethics committees in each American hospital (4). HECs, unlike IRBs, were not required by the law in the Unites States, but their development was rather a result of the democratic notion that a variety of individuals from different backgrounds with different professional perspectives and experiences can come together and openly discuss problematic issues involving conflicting values. The emphasis in the HEC development was on discussing and exchanging ideas with morally justified decision making emerging from this process of deliberation. However, the point of the committee's discussion was and is process not product, forum not decision (7).

HECs, like IRBs, have a multidisciplinary membership structure aimed at thorough discussion and debate among representatives of different perspectives. The number of members may vary from 5 to 20. In setting up an HEC one should try to balance its membership (4). Physicians are essential for an HEC in healthcare institutions. However, ethical decision-making is based on a multi-facetted dialogue, thus physicians represent only one facet (8). Nurses should not be omitted from membership in HECs. As opposed to physician's perspective, which is more concentrated on the patient and his or her disease, nurses bring the patient's perception of the healing process to the committee's work. Nurses often tend to reexamine the physicians' views and be advocates of the patients' will (9). Theologians bring spiritual perspectives to the committee, and together with ethicists and philosophers they stress the humanistic side of the physician-patient relationship (10). Ethicists, besides fostering the humanistic approach to the everyday reality of medical encounters, can also bring expert knowledge from the field of medical ethics to the committee work (11). Lay members are not often involved or their participation is often underestimated by the other members of the HEC because of their supposed lack of medical knowledge. However, the importance of lay members

for the work of an HEC is precisely their ability to articulate the perspectives of the everyday life and experience of the patient (12).

In general, healthcare ethics committees have three functions: education, case review and recommendation or formation of policies and guidelines. Providing ethics education at every level of healthcare for the committee members themselves as well as for the community is arguably the most important function of a HEC. Without the proper establishment of educational practices the other two functions of case review and policy formation cannot be successful and efficient. The educational efforts of HECs can be organized first as the education of committee members in targeted workshops after the HEC has been established, whereas larger educational efforts for hospital staff and patients could be undertaken gradually (13, 14).

Guideline and policy formation serves as a tool for solving a hospital's problems by creating a legal framework and providing directions for decision making in certain categories of patients (4, 14,15). The ethical case review function is probably the most complex and demanding function of an HEC. Here the HEC is instrumental in enabling a discussion and decision-making process between patients and physicians in difficult treatment decision cases. Here the role of an HEC is more of a catalyst than of a decision-making body (4, 14, 16).

The everyday work of the committee, the number of meetings, self- evaluation practices, educational efforts, the committee's influence on hospital work and policy formation are essential components in the evaluation of its performance. Analysing these aspects, one can assess whether an HEC is failing or succeeding in its mission.

Positive group dynamics and support of the hospital administration are also essential for ensuring an HEC's success. However, the hospital administration should avoid interfering in the committee's work or its membership selection but rather accept the committee as an important tool of quality improvement of the work in a hospital.

National Bioethics Committees

Another type of ethics committee has also existed from the beginning – the national bioethics committee. Its predecessors in the 1970s were different presidential commissions in the United States focusing on regulatory frameworks and policies on the national level regarding, for example, research on human beings and brain-death criteria. National bioethics committees are governmental bodies usually formed by the governments according to specific legal requirements. Their main function is to issue recommendations and opinions on specific ethical issues, to participate in the drafting of legal provisions and to encourage and participate in public debate on current bioethical issues. Their recommendations are usually not binding,

but rather of a consultatory nature. National bioethics committees are especially well-developed in Europe, where the Standing Committee on Bioethics of the Council of Europe (CDBI) is constituted of the representatives of the national ethics committees from all member countries. The CDBI has been responsible for drafting a number of important documents, of which the European Convention on Human Rights and Biomedicine represents a legal cornerstone (17).

The ethics committee experience

All types of ethics committees can be found all around the world. Their types and functions can be either regulated by legal provisions (18) or they can come into existence by a "grass-root" process (19). Sometimes they can combine the functions of a research ethics committee and a healthcare ethics committee (20). In some countries ethics committees can be involved in patients' rights advocacy (21), be in charge of technology assessment or be involved in euthanasia cases evaluation (in the Netherlands) (22).

Whatever the function and structure of the committees, there are a number of misconceptions that ethics committees encounter in their everyday work, either on the societal or the institutional level.

On the societal level, obstacles and misconceptions are related to the way in which the medical profession perceives the committees. Physicians are sometimes reluctant to accept the existence of committees; especially in the case of HECs they might have objections. They tend to think that they do not need ethics committees because they are already used to handling decisions and taking responsibility themselves. The lack of time due to the burden of their work, as well as anxiety over their competence, are also some of the reasons why ethics committees sometimes have difficulties in engaging members of the medical profession (23). The development of ethics committees can also be hampered by poor legal provisions and a lack of democratic mentality which is necessary for the "grass roots" process in the establishment of ethics committees. The bureaucratic approach to the formation of ethics committees is a constant threat, especially in transitional societies (24).

On the institutional level, committees can experience many obstacles. Healthcare institutions are often afraid of yet another committee, with institutional and moral authority that is not obvious, whose existence, in the opinion of some professionals, separates ethics from everyday practice, with functions that are sometimes not clear and with the risk that decision-making processes are hampered by committee dynamics and bureaucratic procedures (25, 26).

The work of different types of ethics committees has been investigated quite thoroughly in the United States and to some extent in Western European countries as well. However, there is a lack of in-depth and systematic research in this area in countries in transition like Croatia. The work of ethics committees in Croatia, which have been in existence since 1997, has never been investigated in detail. This study has been undertaken to remedy this situation.

Aim of the thesis

The aim of the thesis is to investigate the work of ethics committees in Croatia for the first time. The investigation is focused on the types of committees and the functions they perform in their everyday work. Special emphasis has been placed on the analysis of the ethics committees in healthcare institutions, especially hospitals, in Croatia and their work and membership structure. In 1997, the Law on Health Protection established legal standards for the introduction of the "mixed" type of ethics committees in healthcare institutions. Our survey wants to investigate whether this top-down approach to the introduction of ethics committees was the right approach for Croatia and what the consequences of this approach were for the work and formation of the Croatian ethics committees. From the Croatian experience possible lessons can be learned for similar situations in other countries in transition. Data was collected using questionnaires.

Outline of the thesis

Chapter 2 gives an overview of the situation and development regarding ethical issues in medicine in the European countries in transition.

Chapter 3 gives an overview of the situation and development regarding ethical issues in medicine in Croatia (bioethics, legal provisions, education, ethics committees, patients' rights).

Chapter 4 presents the first of the three surveys into the work of Croatian ethics committees described in this thesis. This first survey studies the structure, functions and legal provisions and different types of ethics committees in Croatian healthcare institutions. It also outlines some reflections on major issues and problems discovered.

Chapter 5 deals with the education of ethics committee members in Croatia. It presents the first educational workshop ever held for members of ethics committees in healthcare institutions in Croatia, together with the survey that was performed during this workshop, and which dealt with the everyday work, functions and structure of ethics committees in hospitals (since almost all participants of this workshop came from hospital ethics committees).

An effort was made to analyze the bioethical knowledge and attitudes of the participants of the workshop. This survey was a pilot-study project with the purpose to test a specially designed questionnaire and to highlight problems and issues concerning hospital committee work.

Chapter 6 presents an in-depth analysis of the work of hospital ethics committees in Croatia. A specially designed questionnaire was used for this purpose. This was the third and final survey of the work of ethics committees in Croatia.

Chapter 7 comprises the evaluation of the previously obtained results of the three surveys in this thesis in the light of ethics. The objective was to analyse structural ethics issues observed in the work of ethics committees in Croatia.

Chapter 8 gives an overview of worldwide experiences in hospital ethics committees' education with the description of current problems and approaches. The Croatian situation of ethics committees' education is also discussed. Possible solutions and approaches in ethics committees' education for transitional societies with special emphasis on Croatian healthcare system are discussed.

Chapter 9 concludes the thesis with a discussion on the findings obtained from the previously described studies.

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Chapter 2

Ethics and the European Countries in Transition - past and the future

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ABSTRACT

The paper surveys the situation regarding bioethical issues in European transitional societies. It aims at exploring past, present and future characteristics of bioethics in the European countries in transition, analysing similarities, differences and common themes together with the historical development. By carefully studying articles published since the early1990s, one can perceive a number of bioethical issues, varying from specificities for certain countries and similar problems for all transitional European societies. It seems that more than 15 years after the fall of Berlin wall, Central and Eastern European societies were able to achieve significant improvements in the development of bioethics. However, looking at the bioethical issues important for European transitional societies, it seems that the invisible wall between European East and West societies is still there and that it will take years to remove it.

INTRODUCTION

In her article on cross-cultural issues in European bioethics, Donna Dickenson states that there is a difference between American and European approaches to bioethics. She identifies both as "Western" approaches to bioethics. Within the framework of European approaches she cites three different "voices". She describes the first approach as deontological approach of Southern Europe and Ireland where the emphasis is placed on deontological professional codes and patients' dignity (rather than rights). The second one is the liberal rights-based model of Western Europe present in the Netherlands and the UK. This approach is probably most similar to the American autonomy-based approach. She describes the third approach as social welfarist model of the Nordic countries in which the social context, resources and social structures are there to empower and bring balance to all the participants in the process of providing healthcare services. However, Dickinson does not really elaborate bioethics in the European Countries in transition. She briefly mentions the fourth model - the imperial concept of justice as a gift of the emperor which she sees as dominant in some Eastern European former communist countries (1). Nevertheless, Dickenson does not go into detail about the approaches in bioethics and its particularities in European transitional societies. This paper aims at exploring the past, present and future of bioethics in European countries in transition. Possible similarities, differences and common themes together with the historical development of the field in European countries in transition will be explored.

How did bioethics come into existence in European transitional societies?

In 1989-1990 the fall of totalitarian regimes in the countries in Central and Eastern Europe started the tide of change and political, social, economic and cultural transition. Just about that time a number of efforts towards development of bioethics began. However, before these developments, in the 1980s at the Inter University Centre in Dubrovnik in Croatia, a course on human rights and medicine provided the meeting place for the East and West before the fall of communism (2). However, this course was more of an exception than a rule in Central and Eastern European countries at that time.

What was the situation regarding bioethics in those countries? In the majority of the countries there was no teaching of subjects connected to biomedical ethics (3). Moreover, there were almost no experts educated in the field of biomedical ethics (4). In some countries medical deontology was taught (5). There were legal provisions in place regarding research ethics (6), mainly in those countries that were able to cooperate in international research

projects while in other countries ethical research procedures, although in place, were seldom used (5). The field of psychiatry was in turmoil because, during the time of communist regimes, many psychiatrists in a number of post-communist countries were involved in 'diagnosing' and 'treating' political opponents, removing them involuntarily from public life (7,8,9). With the help of the Hastings Centre in the U.S.A., a project called "East-east program in bioethics" was developed, which enabled the researchers interested in the study of the field of bioethics to come and participate in training programs and courses or doing research with individual grants. A number of bioethics publications were donated to various universities in Eastern and Central Europe. The significant number of articles about this development is a proof of these activities (10). Journals like *The Hasting Centre Report* or *Bulletin of Medical Ethics* brought the authors from European countries in transition to the readers interested in the field of bioethics all over the world (11). At the beginning the main efforts were directed at developing bioethics education and teaching programs (12). At the same time different legal provisions enabling the establishment of bioethics committees took place as well (13, 14). However, these developments were not free of problems. Suddenly, in some countries a new phenomenon emerged that is still present: the transformation of former teachers of Marxist-Leninist sciences into teachers of bioethics (as well as business ethics). In medical curricula in a number of universities mandatory courses in Marxism have been substituted with courses in bioethics. These transformations created confusion among students but also among teachers. Nowadays, one can, for example, still observe that in some universities technical engineering students are taught subjects of bioethics when it would probably be much more relevant to teach them ethics of science and engineering. The teachers of such courses are rarely well trained philosophers but rather persons who have finished studies of Marxist sciences. It is questionable what the level of their knowledge is and how well they are versed in the subject of ethics. At the same time, the implementation of new laws regulating the area of research has led to the establishment of research ethics committees and at the same time in some countries to the foundation of clinical ethics committees as well (15). This development has improved the quantity of different types of ethics committees all over Central and Eastern Europe. It is not however focused so much on enhancing the quality of work of these committees since it is often the case that the majority of the members have no experience in the field of bioethics or their experience is limited (16). However, the situation regarding ethics committees was assisted and improved through the efforts of the Council of Europe. Its ethical advisory committee, the Steering Committee on Bioethics (CDBI) made the organisation of different training events and educational workshops for members of ethics committees into one of its

priorities. The Committee also supported the creation of national ethics committees in various Central and Eastern European countries which then undertook the enormous task of bioethics education of the public, medical professionals and ethics committees' members through their programme of work (17). These efforts have not been equally successful in all countries but it is at least brought to the attention of the public that bioethical issues are also relevant and important in European transitional societies. All in all slowly but constantly, bioethics has become a permanent fixture of public life in European transitional societies.

Differences and commonalities in ethical issues in European countries in transition

Examining bioethics publications since the early 1990s until now, one can perceive a number of bioethical issues discussed. Certain issues have remained a constant and recurrent problem, other are more specific for certain countries, while other issues have changed over time.

In the Russian Federation, significant issues of ethical debate are corruption, double standards in the healthcare system, the independence of researchers and patient rights. These have remained significant problems for most European transitional societies (18, 19). However, the issue of abuse of psychiatry for political purposes is one of the particularities of the Russian debates on bioethics (7). Similar abuses were discussed in Ukraine (9) and Romania (8) but from the literature available one may conclude that Russian authors feel that these practices were extremely present in their country. They have for example undertaken special efforts to write codes of ethics for Russian psychiatrists (7). The issue of the moral status of the human embryo is also peculiar for the Russian Federation if we compare the bioethical debate with that in other European transitional societies. Due to the extremely liberal laws on abortion dating from Communist times, all sorts of embryonic and foetal research have been reported. However, recently, the Orthodox Church together with some physicians and philosophers presented a "Bill on Bioethics Protection" which is trying to promote more conservative views in the areas of abortion, embryo manipulation and reproductive technologies (20, 21). Another characteristic of the Russian debate is a certain technological enthusiasm. Some researchers are reporting a certain openness and permissiveness to all sorts of genetic procedures and enhancements among the Russian population, although the development of genetics in Russia and other Soviet satellites during the communist era was hampered by the 1949 elimination of Soviet genetics by Lysenko (22). Patients' rights are still an important issue as well as medical research but what is interesting is that, according to some researchers, Russia already had a number of regulations regarding medical research and informed consent during the period of czarism and afterwards during the period of communism (21, 23).The

bioethical issues in Poland are similarly concentrated on the issues of patients' rights, research and quality of healthcare (24, 25). However, the influence of the Catholic Church in the area of legislation and research in the field of bioethics is probably much more important than in other European transitional societies. This influence has prompted the introduction of conservative views on abortion, and emphasised the culture of life in Polish society and the introduction of a conservative code of ethics for Polish physicians, although it has undergone some changes especially in the case of the question of the beginning of life (26, 27). Nursing ethics issues are, also, important for Polish researches in bioethics (28). The emphasis on nursing ethics can also be observed among bioethics researchers in Hungary, Romania, Bulgaria and Croatia (29, 30, 31, 32). On the other hand, issues regarding the activities of ethics committees and their institutionalisation are rarely dealt with both in Russia and Poland (25, 33). Hungarian researchers in bioethics are also putting special emphasis on the topic of the end of life as well as patients' rights, beginning of life, and the work of ethics committees (34, 35). Czech and Slovak authors are mostly concerned with the issues of patient's rights, work of ethics committees and research, genetic issues and the allocation of medical resources (36, 37, 38). Romanian researchers have a special interest in reporting on corruption and patient rights. The abuse of psychiatry and the nursing ethics issues are also present in this country (8, 30, 39). Bulgarian researchers are dealing mainly with similar issues as their Romanian colleagues. Only abuse of psychiatry does not seem to be a significant problem in Bulgaria (31).

In the former Yugoslav countries the major ethical issue discussed is medical research. This topic is furthermore mostly discussed in Croatia and in Slovenia. These countries have significant regulatory frameworks and they are perhaps mostly involved in (international) medical research. The issues discussed are patients' rights, ethics committees, nursing ethics, and those connected with ethics of research such as the use of placebos, conflict of interests, research integrity and academic misconduct (40, 41, 42, 43). Most problems of ethical nature can probably be found in Albania with corruption and organ trafficking, research issues being the major issues discussed during the past 15 years (44).

What does the future hold for bioethics in European transitional societies?

"Political revolution that is not grounded in social evolution at the basic level of satisfaction of 'simple' human economic, physical and psychological needs could only reproduce the same totalitarian pattern under a new ideological label". These are the words of the Russian philosopher L. S. Frank, cited by Pavel Tichtchenko and Boris Yudin in their article on Russian situations in bioethics (20). Even after 15 years of development in the field of bioethics, after

fundamental political changes, and after the incorporation of many European transitional societies into the European Union, this quotation is still relevant in articulating the main concern in all those societies. Though the general situation has improved for many countries, especially for those countries that are now members of the European Union, one can conclude after analyzing the published literature during recent years on the bioethical issues in the European societies that the issues of patients' rights, allocation of the healthcare resources, research, ethics committees and corruption have continued to remain basic issues (19, 45). On the other hand, researchers in bioethics in Western countries are apparently mainly concerned with genetic issues, allocation of scarce medical resources, and end-of-life issues like euthanasia. Nevertheless, some of these issues, for example genetic issues, have become present in the recent years in Central and Eastern European bioethics debates too (46). The same holds true for debates on end-of-life issues and research ethics. At the same time, the quality of bioethical research has improved significantly, with more and younger researchers formally educated in the field of bioethics either in the USA or the EU. It seems that more than 15 years after the fall of Berlin wall, Central and Eastern European societies were able to achieve significant improvements in the development of the field of bioethics (47). However, if we look at bioethical issues important for European transitional societies it seems that the invisible wall between European East and West societies is still there and it will take years to remove it.

The lack of young and educated researchers in the field of bioethics is at the basis of this invisible wall. Only if we can change the situation by developing quality bioethics education programs on undergraduate and postgraduate levels with changes in the continuous education of practitioners and nurses, will we be able to produce some cracks in the foundation of this invisible wall. The results of this change would also represent a transformation in the bureaucratic mentality in transitional societies, so present when we speak about many issues. It is often the case that standards including important legal frameworks for the institutionalisation of bioethics like ethics committees statutes and patients' rights standards are only formally proclaimed within different legal provisions while their actual implementation in everyday practices is non-existent or deficient. Although de jure European transitional societies have in the majority of cases implemented almost all relevant bioethical legal standards, de facto the situation is less than satisfactory. The important lesson is that one cannot just bring about changes in the system without first changing the climate that pervades the system. One can only achieve this by education and gradual and well-structured changes of practices, which could take years. There is no wonder that the bioethical issues in the European countries

in transition have basically remained the same: patients' rights, corruption, ethics committees' establishment, and inequalities in healthcare provision.

However, within this invisible wall between the East and West of Europe in bioethics there is one layer that can be important for the whole of European bioethics.

This layer is constructed from communitarian values and ideas that are more present in European transitional societies, although with the rampant globalization and laissez-faire economical approaches they have been put under strain. This ethical orientation in European transitional societies can be compared to those of Southern Europe and Nordic countries. Values like solidarity, liberty, personal dignity and communitarian approaches to social inequalities are being reinforced in the debates in transitional societies with less emphasis on liberal approaches to the issues of personal autonomy and individualism.

CONCLUSION

The future of bioethics in European transitional societies lies in overcoming the burden of totalitarianism and bureaucratic mentality. One way is to foster democratic procedures, transparency and accountability through education at all levels. An additional way is to promote patients' individual choices, at the same time staying true to the countries' orientation towards solidarity, liberty, personal dignity and communitarian values in bioethics. This process will take a lot of time. However, it is a process that has already started and one that will, after its completion, bring down the invisible wall in bioethics between European East and West.

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Chapter 3

Developments regarding ethical issues in medicine in the Republic of Croatia

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ABSTRACT

In Croatia, the subject of medical ethics, or bioethics, was introduced into the curriculum in the early 1990s at the medical schools of the University of Rijeka and the University of Zagreb. Today, bioethics education has become a basic part of undergraduate medical education not only in Rijeka and Zagreb but also in Osijek. Different types of ethics committees have been established as well.A number of new healthcare laws have been established or are being drafted in the Republic of Croatia. However, some remaining issues have been a continuing source of legal and ethical problems. In conclusion, one could say that developments regarding ethics issues in medicine have gone far in Croatia, but a lot of work remains to be done, especially on the educational and legal levels.

INTODUCTION

In Croatia, the subject of medical ethics, or bioethics, was introduced into the curriculum in the early 1990s at the medical schools of the University of Rijeka and the University of Zagreb (1). Today, bioethics education has become a basic part of undergraduate medical education not only in Rijeka and Zagreb but also in Osijek.

Even before the 1990s, however, efforts had been made to forward the field of medical ethics in Croatia. Early examples were the creation of a Center for Medical Ethics at the Andrija Štampar School of Public Health at the University of Zagreb Medical School in the 1980s and the establishment of the annual workshop on human rights and medicine at the Interuniversity Centre in Dubrovnik. To date, though, there has been no development toward introducing postgraduate courses, and there is still a lack of skilled professionals in this field, although the number of scholars is growing.

Throughout central and southeast Europe, the situation varies, from countries that have developed sound legal and educational structures (2) to others where these do not exist (3). Furthermore, the damaging effects on health of recent wars, continuing unrest and conflict in the countries in transition, and the economic hardships faced by their populations have influenced the shifting societal frameworks and the transformation of fundamental societal values and patterns of behavior where many relationships, including those between physicians and patients, are undergoing fundamental changes. Better education will reinforce a moral commitment to patients' rights, equal access to healthcare, quality of care, solidarity, and protection of vulnerable populations, as well as promote general well-being. Developing ethics awareness in particular will help to articulate the human values underlying all healthcare activities.

The Andrija Štampar School of Public Health has recognized the importance of ethics education at all levels of the medical curriculum. With support of the Council of Europe and its Social Cohesion initiative as part of the Stability Pact for SEE (4), the school initiated the new Master's program for Health, Human Rights, and Ethics, which aims to improve ethics education at both the postgraduate and undergraduate levels. This project is part of a loan from the Council of Europe Bank of Development to aid curriculum development and reconstruction of the school. The project has also been supported by the WHO and the SEE Public Health Network.

Ethics Committees

European countries have seen different levels of progress regarding the institutionalization of bioethics and the development of ethics committees. In particular, the development of research ethics committees has been more pronounced—almost all countries have legal provisions and research ethics committees mandated by law (5). The status of clinical ethics committees, however, varies with regard to approach, organization, and legal foundation (6).The process of institutionalization of bioethics is regarded by some as especially important to those European societies in transition. In particular, development of clinical and healthcare ethics committees could encourage the growth of professional bioethics and the creation of important networks (7). However, such institutionalization, if not carefully thought through within a specific context, can generate skepticism and bureaucracy (8).

In Croatia, the first steps toward bioethics institutionalization through ethics committees began in the 1970s with the creation of what were referred to as the "commissions for drugs," which were established for the purpose of joint Croatian-international clinical research projects. In the 1990s, ethics committees became required by law, with articles 51 and 52 of the 1997 Law on Health Protection devoted to setting the framework for their duties. According to this law, each healthcare institution in Croatia should have an ethics committee consisting of five members, two of whom should be from outside the medical field. Committee functions include:

- following the implementation of ethical principles of the medical profession
- approving research activities (protocols) within the health institution
- overseeing drug and medical device trials
- overseeing organ procurement, and
- solving other ethical issues in the health institution.

In 2001, the National Bioethics Committee for Medicine of the Government of the Republic of Croatia was founded. This independent advisory and multidisciplinary body is involved in policymaking, education, and debates on ethical issues on the national level. It has 20 members, seven of whom are women, representing a variety of specialties: hematology, internal medicine, clinical and basic pharmacology, epidemiology, public health, gynecology, history of medicine, gastroenterology, basic medical sciences, and genetics. There is also a veterinarian, a biologist, a molecular biologist, a philosopher, an experimental psychologist, and a Catholic moral theologian. The committee acknowledges and inculcates in its work the values expressed in numerous international declarations and documents.

In 2002, the National Bioethics Committee conducted research on the functioning of Croatian ethics committees. Of particular interest were the number of members, structure of

membership, themes discussed during meetings, reports drafted on the work of the committees, number of meetings to date, policies, and guidelines. Excluding pharmacies and homecare institutions, 241 healthcare institutions took part in the study. Of the participating healthcare institutions, 111 reported having an ethics committee. Of four medical faculties in Croatia, three have an ethics committee. There are also ethics committees at the Faculty of Veterinary Medicine and the Faculty of Pharmacy and Biochemistry in Zagreb, at the Institute for Anthropology, Institute for Medical Research, Institute Rudjer Boškovic, and at the Croatian Medical Chamber and Croatian Medical Association, Croatian Dentists' Chamber, Croatian Pharmacists' Chamber, and Croatian Chamber of Biochemists. The response rate was between 100% and 75%, depending on the type of the institution (100% response rate for clinical hospitals, 91% for regional and local general hospitals, 80% for clinics and policlinics, 75% for medical faculties, and approximately 77% for all other healthcare institutions, including public health institutes, primary care facilities, and ER facilities. Ethics committees tend to have from five members as required by law to ten (though two did not state the number of members, four have only three members, and two have four members).

All of the committees have physicians as members, and 34 committees include a nurse. Only one committee had a philosopher.

Almost all committees stated that reviewing research protocols was their main task, though some deal with other issues as well, mainly concerning "the promotion of the ethical values in their institutions." In 19 institutions, a "commission for drugs" also reviews clinical protocols, which creates additional confusion about the tasks of ethics committees. Other committees, such as those of the Croatian Medical Chamber and Croatian Medical Association, the Croatian Dentists' Chamber, the Croatian Pharmacists' Chamber, and the Croatian Chamber of Biochemists, deal primarily with deontological values and issues of the specific professions they represent and do not function in a research oversight capacity. Of all institutions involved in this research we received only 22 procedural guidelines for the conduct of meetings. Only in three cases were international documents and declarations cited (e.g., the Helsinki Declaration, Tokyo Declaration, Guideline for Good Clinical Practice). Other documents cited included the Ethical Codex of the Croatian Medical Association, the law on the protection of the mentally ill, the law on healthcare protection, and the law on health insurance.

Recently, the National Bioethics Committee proposed changes to the existing legal provisions for ethical committees in particular, a division was proposed between ethics committees, which now by law perform both tasks of research ethics committees and institutional review boards, and clinical ethics committees. According to this proposal, the functions of the

research ethics committees and clinical ethics committees would be split. The research ethics committees would be in charge of the review of research protocols. They would be organized on the regional level according to the European guidelines and would have legal responsibility for their decisions. 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, policymaking, and clinical case consultations. Unfortunately, this proposal was not accepted by governmental bodies.

Other Ethical Issues and Developments

A number of new healthcare laws have been established or are being drafted in the Republic of Croatia for example, the recently drafted Law on Patients' Rights. The Convention on Human Rights and Biomedicine of the Council of Europe together with the additional protocol on cloning as well as the new law on drugs are due to pass Parliament by the end of 2003.

However, some remaining issues have been a continuing source of legal and ethical problems. Croatia has no law on artificial insemination, for example. There was an initiative by the National Bioethics Committee to begin drafting a law to regulate this field, but for a variety of administrative and political reasons this process has not come very far. Hopefully, in the future there will be some improvements in this area.

In conclusion, one could say that developments regarding ethics issues in medicine have gone far in Croatia, but a lot of work remains to be done, especially on the educational and legal levels.

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Chapter 4

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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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
TOTAL	7	23	15	196
Did not respond	0	2	3	43
Non response rate	0%	9%	20%	21 %
Responded	7	21	12	153
Response rate	100%	91%	80%	77 %
Do not have an ethics committee	0	0	0	82
Have an ethics committees	7	21	12	71

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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Chapter 5

Education of ethics committee members: experiences from Croatia

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ABSTRACT

Objectives: To study knowledge and attitudes of hospital ethics committee members at the first workshop for ethics committees in Croatia.

Design: Before/after cross-sectional study using a self administered questionnaire.

Setting: Educational workshop for members of hospital ethics committees, Zagreb, 2003.

Main outcome measurements: Knowledge and attitudes of participants before and after the workshop; everyday functioning of hospital ethics committees.

Results: The majority of the respondents came from committees with at least five members. The majority of ethics committees were appointed by the governing bodies of their hospitals. Most committees were founded after the implementation of the law on health protection in 1997. Membership structure (three physicians and two members from other fields) and functions were established on the basis of that law. Analysis of research protocols was the main part of their work. Other important functions—education, case analysis, guidelines formation—were neglected. Members' level of knowledge was not sufficient for the complicated tasks they were supposed to perform. However, it was significantly higher after the workshop. Most respondents felt their knowledge should be improved by additional education. Their views on certain issues and bioethical dilemmas displayed a high level of paternalism and over protectiveness, which did not change after the workshop.

Conclusions: The committees developed according to bureaucratic requirements. Furthermore, there are concerns about members' knowledge levels. More efforts need to be made to use education to improve the quality of the work. Additional research is necessary to explore ethics committees' work in Croatia especially in the hospital setting.

INTRODUCTION

Ethics education is important for the work of ethics committees. Many argue that the main function of ethics committees is to provide ongoing education on ethical issues at every level of health care—for ethics committees themselves and for the general medical community (1). Thus education of members of ethics committees as the first step in fulfilling the educational function of an ethics committee becomes an important issue.

Ethics committees in Croatia are a relatively new phenomenon. (2). Their existence is required by the law on health protection. (3). We undertook a survey of the work of ethics committees in Croatia. This looked at 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 the work of the committees. The response rate was between 75% and 100%, depending on the type of healthcare institution.

According to the results of this survey 46% of the healthcare institutions in Croatia (excluding pharmacies and homecare institutions) have an ethics committee. Eighty nine per cent of ethics committees have five members, three of whom are from medical professions and two of whom come from other fields. Physicians, theologians, hospital lawyers, and nurses were likely candidates for membership of an ethics committee, while philosophers, hospital staff who worked outside of the hospital, and patients' representatives were not. Forty nine per cent of those committees said their main function was the analysis of research protocols. Ethical case analysis was often practised as well. Education was confirmed as an ethics committee's function in only a few cases; the same was true for policy making (2). As a result of those findings, the National Bioethics Committee for Medicine held the first workshop for members of hospital ethics committees in Croatia in 2003. The aim of the workshop was to educate members of the ethics committees and prepare them for their everyday work. Topics covered were: types and functions of ethics committees in the world and Croatia; introduction to the analysis of a research protocol; introduction to case consultations; introduction to biomedical ethics as a discipline, and information about relevant literature. Participants in the workshop were invited to take part in a survey in order to test their knowledge and attitudes before and after the workshop, and to explore in depth their everyday working practices.

METHODS

Participants

Members of hospital ethics committees as well as members of ethics committees at medical and dental schools and research institutes were invited to participate in this workshop. The invitations were sent by post and asked each of the ethics committees to send at least two members. A total of 107 participants attended the workshop, 25 of whom were not members of an ethics committee in a hospital institution. Of 73 hospital institutions (clinical centres, local and regional hospitals, special hospitals, clinics and polyclinics) whose members were invited to the workshop, 52 sent members. The number of members that came from each hospital varied from one to five. Sixty six participants filled in the questionnaire at the beginning of the workshop. Out of these 66, 31 completed the questionnaire at the end of the workshop as well.

The participants from medical schools and research institutes did not participate in the survey.

Instrument

The instrument used for this survey was a questionnaire consisting of four parts. The first part concentrated on obtaining demographic data about the age, sex, and occupation of the respondents; information about the number of members on an ethics committee; possible educational practices in the work of a committee; the frequency of meetings; the issues they dealt with in everyday practice, and the respondents' views on their position in a committee as well as on the work of the committee.

The second part was dedicated to a self assessment of the knowledge of each respondent in the field of biomedical ethics. For this part we adapted the model of self evaluation questionnaire presented by Judith Wilson Ross in her book, *Health Care Ethics Committees—the Next Generation* (1). This second part of the questionnaire consisted of 42 questions. The respondents had to assess their knowledge by using a Likert type scale with grades from one to five: (1 = yes I am familiar with this topic and would feel comfortable teaching others about it; 2 = yes, I am familiar with this topic, but do not think I could answer questions about it; 3 = yes I am familiar with this topic in a general way, but not any of the specific issues; 4 = no, I do not know much about the topic, and 5 = I have never even heard of this topic).

The third part consisted of 23 questions that tested the participants' knowledge of the filed of biomedical ethics.

The fourth and final part of the instrument consisted of 19 statements on different bioethical issues that the respondents could grade by using a Likert type of scale from one to five (1 = I completely disagree, 5 = I completely agree). For this part we adapted the "bioethics consensus statements", also taken from the book by Judith Wilson Ross, *Health Care Ethics Committees—the Next Generation* (1).

Statistical analysis

The results were statistically analysed using the statistical program SPSS version 11.5. Descriptive statistics, non-parametric tests (Mann-Whitney, Wilcoxon Signed Ranks Test), and Spearmans ϱ were used for data analysis.

RESULTS

Hospital ethics committees: structure and function

The mean age of the respondents was 48.65 (95% CI = 46.25–51.04). There were 27 male and 39 female respondents. Fifty one of the respondents were physicians; three were pharmacists; three were psychologists; four were nurses with a higher education degree; two were lawyers; one was a sociologist, and three did not state their profession. Structure, everyday work, and functions of hospital ethics committees can be seen from table 1. Respondents were also asked a few questions regarding their views on their work as a member of an ethics committee. The majority of the respondents (64) felt their views were respected in the everyday work of the committee. Fifty seven respondents felt the views of the members of their committees reflected the views of Croatian society. Forty nine respondents felt that so far the work of their ethics committee had been efficient.

Table 1 – Data on the structure, functions and everyday work of ethics committees according to the respondents answers

Year started		1991-2003
Median number of months of committee existence		24 (interquartile range 45)
Structure		
Number of members		1- 9 members 5 members on average
Members' occupation	All committees had physician (median 3, interquartile range 1)	
	theologian	49
	lawyer not employed by the hospital	26
	nurse	20
	hospital lawyer	8
	social worker	5
	member of hospital executive board	5
	local official	1
	hospital administration official	1
	No patient representatives, philosophers or ethicists as members.	
Functions		
Analysis and approval of research protocols *		56
*(Median time spent on the analysis of a research protocol was 2 hours (interquartile range 2))		
Education of the members of the ethics committees and hospital staff		12
Policies and guidelines formation		11
Ethical case analysis		37
Review of complaints made by patients and physicians		35
Everyday work		
Most frequent issues dealt with in everyday practice		
	clinical research	48
	informed consent	28
	communication problems between patients and physicians	28
	communication problems among hospital staff	26
	confidentiality of medical data	26
	principles of ethical decision making	25
	patients' rights	24
	assessing the competency of patients	21
Median number of annual meetings		4 (interquartile range 6)
Total number of annual meetings		7.5 (interquartile range 16)
Decision making process	consensus formation	37
	public voting	22
	secret voting	1
Average grade of influence on decision making process of hospital		
3.27 (95% CI = 3.00- 3.55)		
Average grade of work that committee performed so far		
3.44 (95% CI = 3.20-3.70)		

Ethics committee members' knowledge

Fifty four respondents felt competent to be a member of an ethics committee; only 13 had attended special educational courses and conferences related to bioethical issues. However, 61 respondents felt they needed additional education in the field of bioethics. We tested how the respondents themselves assessed their knowledge of different bioethical issues (table 2).

Table 2 – Level of self-assessment of respondents' knowledge about different bioethical issues (tested on 66 respondents before the workshop; 1= yes, I am familiar with this topic and would feel comfortable teaching others about it; 2= yes, I am familiar with this topic , but do not think I could answer questions about it, 3= yes, I am familiar with this topic in a general way, but not with any of the specific issues; 4= no, I do not know much about the topic; 5= I have never− heard of this topic).

FIELD	C ± Q
procreation and genetics	3.00 ± 0.88
transplantation	3.00 ± 1.00
research	2.00 ± 1.00
ethics committees	3.00 ± 1.00
resource allocation	3.00 ± 1.00
patients' rights	2.50 ± 1.13
end-of-life issues	3.10 ± 1.00
legal provisions	2.72 ± 1.07

How respondents self assessed the level of their knowledge of different bioethical issues before and after the workshop was also tested (table 3). We found significant difference ($p = 0.011$ Wilcoxon Signed Ranks Test; C±Q before = 2.6±0.87; C±Q after = 2.68±0.7) between the self evaluation of knowledge results before and after the workshop. No significant correlation was found between self evaluation of knowledge results and sex

Table 3 – Level of self-assessment of respondents' knowledge before and after the workshops about different bioethical issues (n =31) (1= yes, I am familiar with this topic and would feel comfortable teaching others about it; 2= yes, I am familiar with this topic , but do not think I could answer questions about it, 3= yes, I am familiar with this topic in a general way, but not with any of the specific issues; 4= no, I do not know much about the topic; 5= I have never heard of this topic).

FIELD	BEFOREC ± Q	p*	AFTERC ± Q
procreation and genetics	3.13 ± 0.69	0.517	3.00 ± 0.56
transplantation	3.00 ± 1.00	0.564	3.00 ± 1.33
research	3.00 ± 1.00	0.040	2.00 ± 1.00
ethics committees	3.00 ± 1.00	0.021	2.33 ± 1.00
resource allocation	3.00 ± 1.00	0.019	3.00 ± 0.50
patients' rights	2.75 ± 0.63	0.132	2.63 ± 0.94
end-of-life issues	3.30 ± 1.05	0.004	2.90 ± 0.65
legal provisions	2.72 ± 1.14	0.001	2.43 ± 0.86

*Wilcoxon Signed Ranks Test

The level of knowledge of the respondents was also tested. The highest number of correct answers, 68% and higher, was obtained on the questions that dealt with functions, work, and types of ethics committees and patients' rights issues. The level of correct answers to questions related to research issues was a bit confusing. On the one hand almost all of the respondents knew about the Declaration of Helsinki, however, less than one per cent of respondents gave the right answers to the question related to informed consent. The level of knowledge regarding other ethical issues, especially legal provisions regulating those issues in Croatia and the world, was not that high (less than 68% on average) and incomplete.

We found significant difference ($p = 0.001$ Wilcoxon Signed Ranks Test) between the level of knowledge before and after the workshop (C±Q before = 0.47±0.17; C±Q after = 0.61±0.09). The level of the respondents' knowledge before and after the workshops was tested on 31 respondents. No significant correlation was found between level of knowledge and sex or age of the respondents.

Attitudes of ethics committee members toward bioethical issues

Respondents' agreement or disagreement with certain statements regarding bioethical issues is shown in table 4.

Table 4– Level of agreement with statements regarding bioethical issues (tested on 66 respondents before the workshop) (1 = I completely disagree, 5 = I completely agree)

STATEMENT	C ± Q
The goals of medical care are to cure disease, restore function, eliminate suffering and prevent illness.	5.00 ± 0.00
In spite of highly developed technological achievements, today's modern medicine cannot always be successful because it cannot always help to cure disease, restore function, eliminate suffering and prevent illness.	5.00 ± 1.00
The competent and informed patient has the right to refuse any form of treatment, regardless of whether he or she is terminally ill.	5.00 ± 1.00
A diagnosis of mental illness does not by itself justify a judgment that the patient lacks decision-making capacity.	2.00 ± 2.50
The physician has a duty to recommend the course of treatment that in his or her judgment reflects the patient's best interest.	5.00 ± 0.00
The physician should not respect the patient's refusal of a certain medical treatment if this, according to the judgment of the physician, could lead to serious consequences for the patient's health.	3.00 ± 2.00
If a patient lacks decision-making capacity, a family member or significant other may act as the patient's surrogate.	5.00 ± 1.00
If the patient's wishes about a medical treatment are known they should be respected.	5.00 ± 1.00
If the patient's wishes about a medical treatment are not known an attempt should be made to determine what the patient would probably have wanted.	4.00 ± 2.00
Any quality of life consideration is to be assessed form the patient's perspective (for example, the patient's perceived experience of burden and benefit).	4.00 ± 1.00
Parents have the right and duty to make treatment decisions for their children and may be presumed to be acting in their child's best interests.	4.00 ± 1.00
Similar medical cases should be treated similarly.	4.00 ± 0.50
There is a psychological and moral difference between withholding and withdrawing treatment under the same circumstances.	4.00 ± 1.00
It is more reasonable to withhold treatment on the grounds that it might not achieve the patient's desired goals than to try a treatment and then stop if the treatment does not achieve the patient's desired goals.	4.00 ± 2.00
Treatment recommendations should clearly articulate the goals of the treatment so that patients/ surrogates can be clear as to whether the treatment meets their desired goals.	5.00 ± 1.00
Advanced directives are not helpful in encouraging dialogue among patient, family and physician about the patient's values and preferences with respect to the treatment until such time as they are no longer able to make decisions.	5.00 ± 1.00
The rationing of healthcare (decisions about limiting availability of medical care to individual patients) should be explicitly addressed at the policy level, whether at the institutional, professional or governmental level.	4.00 ± 1.00
Rationing decisions in the healthcare system should be made by individual physicians for individual patients	2.00 ± 2.00
Patients may want to use economic factors in making their own decisions but surrogates' use of economic factors in making decisions for others is controversial.	4.00 ±2.00

Wilcoxon Signed Ranks Test

We found no significant difference ($p = 0.37$ Wilcoxon Signed Ranks Test C±Q before = 3.86±0.25; C±Q after = 3.89±0.32) between the level of agreement or disagreement with statements regarding bioethical issues before and after the workshop and no significant correlation was found either with sex or age of the respondents.

DISCUSSION

The current survey provides more detailed insights into the everyday work of ethics committees and their position within the hospital structures. According to the literature, members of ethics committees have identified four key factors for success: (a) support from the administration; (b) committee composition; (c) committee leadership, and (d) committee structure, function, and process. The level of administrative support should be good but a good working relationship implies that the administration will not attempt to control the committee and that committee is autonomous in its work. Multidisciplinary and diverse membership is also important for the success of an ethics committee in a hospital institution, together with strong leadership, which guarantees equality and creates a good atmosphere for the committee's work. Clarity of purpose, regular meetings, an emphasis on the committee's functions, especially the educational one, with a clear recognition of the importance of self evaluation orientation, is the fourth factor identified as important for ethics committees' success (4).

Administrative support for ethics committees and their members was not lacking in our case, according to the data obtained. The respondents were quite satisfied with the committee's influence on the hospital's decision making practices and with the overall work of their committees. The committees were founded after the implementation on the law on health protection in 1997. Membership structure (three physicians and two members from other fields) and functions were based on those legal provisions. The same pattern regarding the formation of ethics committees was also observed in a 2002/2003 survey carried out by the National Bioethics Committee (2). However, this raises the concern that the implementation of ethics committees in the hospital system in Croatia is not a "grass root" process, as it has been in the USA (1), but has, instead, been prompted by the bureaucratic behaviour of the hospital administration, as can be observed in other European countries in transition (5). Further evidence for this is suggested by the fact that the majority of the members of ethics committees were appointed by the management of their hospitals, and some committees have hospital administration employees as members. The reasons for this require further investigation.

Multidisciplinarity of the membership of the committees was present to some extent. However, as in the survey carried out by the National Bioethics Committee in 2002/2003,

physicians, theologians, hospital lawyers, and nurses were likely candidates for membership for an ethics committee, while philosophers, lawyers who worked outside of the hospital, and patients' representatives were not. The reason for this can probably be found in the perceived social value of different professions in the Croatian society. However, one might wonder whether every theologian and lawyer, and in some cases, as we have found out in our survey, even every hospital lawyer, is a suitable candidate for the membership of a hospital ethics committee (6, 7). In our opinion it is highly unlikely that just because someone is a member of a certain profession they are therefore going to be suitable candidates for membership of a hospital ethics committee. We feel that expertise and competency in the field of bioethics should be the prime criterion for membership of an ethics committee, taking also into consideration the criterion of multidisciplinarity of its membership (8).

The notion of equality and the significance of a good atmosphere in the committee's work were perceived by respondents. Committee members were satisfied with their position as members of the committee and they felt their views were well respected. The positive perception of the committees' work is related to the age of the respondents and the length of time spent on the committee, as well as to the profession of the members (theologians, nurses, and physicians rated the success of their committees very highly) (9). Since the average age of our respondents was 48.65 years and the majority of them were either nurses, physicians, or theologians the high satisfaction rate was not unexpected. Also the role of ethics committees is often not well perceived in a hospital environment (10, 11). However, the respondents were quite satisfied with the committee's influence on the hospital's decision making practices.

Research protocol analysis was a dominant function of the committees. Ethical case analysis was often practised as well. Education was confirmed as an ethics committee's function only in 12 cases, and policy making in only 11. This feature of prioritisation of the research protocol analysis in the work of ethics committees can be observed in the committees of mixed type (those combining functions of an IRB and HEC) such as Belgian ethics committees (12). Croatian ethics committees are of the mixed type. In countries such as the UK and Australia, where ethics committees do not combine the functions of IRBs and HECs, policy formation seems to be the dominant function of hospital ethics committees (13, 14).

A high proportion of ethics committee members were confident about the level of their knowledge and their level of competency. This is probably the reason why they did not attend a lot of educational workshops or lectures that could help them in their work. However, the results of knowledge self assessment and the results of actual knowledge level in our study show a different picture. The average level of self assessed knowledge before the workshop

was three, meaning: “yes, I am familiar with this topic in a general way, but not with any of the specific issues”. This level significantly improved after the workshop. The level of knowledge before the workshop was less than satisfactory, especially in regard to issues such as informed consent, research ethics, transplantation, and legal provisions in Croatia and other countries. This level significantly improved after the workshop as well. However, the majority of respondents felt that they needed additional education for their work as members of an ethics committee. Self education and self assessment constitute the corner stone of the work of a successful ethics committee (8,15). Educational efforts are important and can improve the knowledge level of ethics committee members (16). There is, however, a need for further investigation into the influence of education on the moral reasoning, moral competency, and moral development of medical professionals and ethics committee members (17,18).

The attitudes of members of ethics committees in our survey did not change much after the educational workshop. The respondents were, so to say, paternalistic in their approach to the patient. They would overrule a patient’s refusal of a treatment if they regarded the treatment as beneficial for the patient. Moreover, patients who were mentally ill were regarded as incompetent. They found a moral difference in favour of withholding treatment as opposed to discontinuing the ongoing treatment of a patient. Attitudes and behavioural dimensions are important for ethics education and thus are important for the education of ethics committee members. It is not easy, however, to change attitudes and behaviours via education (19).

One should, however, be cautious in interpreting the data we have presented: it is evident that our survey presents only snapshots regarding the work of ethics committees in hospitals in Croatia. The participants were those members that were officially delegated to come. Thus, they were either selected by their committees as more versed in the subject or were highly motivated to come as this was a field that interested them. A more detailed analysis, including a larger number of members, should be carried out. Moreover, one can see that any real follow up of the workshop cannot be carried out because only 31 participants filled in the questionnaire both before and after the workshop. Thus, this survey cannot prove for certain whether the educational workshop was successful or not. This was just, one might say, a short pilot test in anticipation of further investigations in this field in Croatia. We feel that such investigations are important because quality control should be implemented in this area of hospital work (20, 21). Croatia should follow any recommendations arising from further investigations in order to improve quality control within the hospital setting.

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Chapter 6

A critical analysis of Croatian hospital ethics committees: opportunity or bureaucratic cul-de-sac?

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ABSTRACT

Objective: To study the work and membership structure of the hospital ethics committees in Croatia.

Design: A cross-sectional study using a self-administered questionnaire specially developed for this purpose.

Setting: Croatian hospitals.

Main outcome measurements: Knowledge and attitudes of participants and everyday functioning of hospital ethics committees.

Results: The structure and composition of the hospital ethics committees are highly legalistic and formal. Most of them were established after the introduction of the legal provisions for ethics committees in Croatia (after 1997). In the majority of cases, the number of members and their occupation are an exact replica of the structure of the committees required by law (3 physicians together with 2 other professionals, of whom lawyers and theologians were the most likely candidates for membership). Consistent with previous surveys, our data also shows that the main task of ethics committees in hospitals was an analysis of research protocols, thus neglecting the other functions important for a hospital ethics committee: education, case analysis, and guidelines formation. The level of the members'knowledge is average but insufficient for the complicated tasks that they are supposed to perform in their everyday work. Their views on certain issues and bioethical dilemmas display a high level of paternalism and overprotectiveness of their patients. The majority of the members who participated in our survey are 50 years and older with, in most cases, no formal education in the field of bioethics.

INTRODUCTION

Ethics committees have long been a feature of medical practice in North America, especially in the clinical setting. The emergence of ethics committees occurred in the 1960s and 1970s with the emergence of the discipline of bioethics. Ever since the first ones were established, two types of ethics committees have been present: IRBs (Institutional Review Board, or research ethics committee), whose only function is the analysis of research protocols, and HECs (Healthcare Ethics Committee or hospital ethics committee or clinical ethic committee).

IRBs emerged as a consequence of many cases of widely publicized revelations of physician researchers who were using patients as their subjects without the patients' knowledge or their understanding of the risk involved. The function and purpose of the research ethics committee is to ensure that the research is designed in conformity to relevant ethical standards. However, it also has the task of assessing the adequacy of the design of the study reviewed. As a result of those requirements, the IRB is both an ethics committee and a professional review board. This is also reflected in its membership structure. The number of members may vary from 5 to 20. The membership structure is interdisciplinary. However, membership selection in an IRB is also focused on the competencies of the members to assess the acceptability of research in terms of legal standards, professional practice and community acceptance (1).

HECs (healthcare ethics committees) are important for the hospital setting in the United States. They deal with ethical issues in clinical settings and have three functions: education, creation and revision of hospital policies and guidelines, and ethical case analysis. Born out of a grass-root process in the American hospitals, they have become a necessity for the hospitals (2); hospitals are expected to have them in order to receive required professional accreditation (3). HECs, like IRBs, have a multidisciplinary membership structure aimed at enabling thorough discussion and debate among representatives of different perspectives. The number of members may vary from 5 to 20. In setting up an HEC a balanced membership should be aimed at (4).

Ethics committees are also emerging across Europe. Here the development of research ethics committees has gone the furthest. Now, in almost all European countries there are legal provisions and research ethics committees are mandated by law (5). However, the type, level and mode of establishment of clinical ethics committees varies from country to country (6) In some European countries ethics committees that combine both the functions of HECs and IRBs can be found (7). Such ethics committees are of the "mixed" type (8).

Ethics committees in the Croatian healthcare institutions are also of the "mixed" type. This can be seen from the Law on the Health Protection from 1997 and 2003 (9,10).

Until recently, there was no systematic research done on ethics committees in Croatia. In 2002 and 2003, the National Bioethics Committee conducted a study of ethics committees in Croatia (11).

As a follow up action of this study in 2003, the first workshop was held for the members of ethics committees in healthcare institutions in Croatia. The majority of the participants came from hospital ethics committees. The aim of the workshop was to educate the members of ethics committees and prepare them for their everyday work. At that occasion, with the help of the National Bioethics Committee, it was decided to perform a pilot study concentrated on the work of hospital ethics committees with a specially developed instrument (12). We concentrated on the members of hospital ethics committees in our analysis because their response rate in the first study done by the National Bioethics Committee in 2002/2003 was the highest. Secondly, almost all hospital ethics committees had a participant in the workshop. However, our main reason for selecting those committees was our belief that those committees had the most complex tasks. While committees in other healthcare institutions were practically non-existent, or met only intermittently to deal with research protocol analyses due to the nature of the everyday work in those institutions, we believe that hospital ethics committees had to be prepared to deal with all the tasks of an ethics committee (analyses of research protocols, education, policy-formation, ethical case analyses).

These findings prompted us to start an in-depth analysis of the situation regarding ethics committees in Croatian hospitals using the same instrument and methodology that we tested in the pilot study. This paper highlights those findings.

METHODS

Participants

A questionnaire was sent by mail to all members of hospital ethics committees in Croatia. From the data obtained by the 2002/2003 survey of the National Bioethics Committee we were able to calculate that the total number of members of hospital ethics committees in Croatia was 241.

Instrument

The instrument used for this survey was a questionnaire composed of 3 parts.

The first part concentrated on obtaining demographic data about age, sex, and occupation, as well as information about the number of members in the committee, possible educational practices in the work of the committee, frequency of meetings, issues dealt with in

everyday practice, and the respondents' views on their position in the committee as well as on the work of the committee.

The second part was dedicated to the self-assessment of the knowledge in the field of biomedical ethics by each respondent. For this part we adapted the model of the self-evaluation questionnaire presented by Judith Wilson Ross (13) comprising 42 questions. The respondents had to assess their knowledge by using a Likert-type scale with grades from 1 to 5 (1= yes, I am familiar with this topic and would feel comfortable teaching others about it; 2= yes, I am familiar with this topic, but do not think I could answer questions about it, 3= yes, I am familiar with this topic in a general way, but not with any of the specific issues; 4= no, I do not know much about the topic; 5= I have never heard of this topic).

The third part included 23 questions that tested the knowledge of the participants in the area of biomedical ethics. The final part of the instrument consisted of 19 statements on different bioethical issues that the respondents could grade by using a Likert scaling from 1-5 (1 = "I completely disagree" to 5 = "I completely agree"). For this part we adapted the "bioethics consensus statements" also taken from Judith Wilson Ross (13).

Statistical analysis

The results were statistically analyzed using the statistical program SPSS version 11.5. Descriptive statistics were used for data analysis

RESULTS

Of 241 members of hospital ethics committees in Croatia 147 members returned the questionnaire (the response rate was 61%). The mean age of the respondents was 50. 93 years (95% CI= 49. 33 – 52. 54). There were 74 male and 73 female respondents. 73% of the respondents were physicians.

Hospital ethics committee structure and function

73% of the respondents stated that their ethics committees had five members and only a few committees had fewer (1) or more (up to 9) members. The committees were established between the years 1972 and 2003, the majority in 1998. The mean time that our respondents spent as committee members was 36. 57 months (95% CI = 31. 24-41.89). The majority of the members were appointed by the management of their hospitals. All respondents replied that their committees had physicians as members (median 3, interquartile range 1), 119 committees had a theologian, 80 had a lawyer (not employed by the hospital), 34 had a nurse, 12 had a hospital lawyer, 7 had a hospital administration official, 6 had a social worker, 5 had a philosopher, 3 had

a local official, and 1 had an ethicist. None had patient representatives as members. Committees existed from less than 1 to 168 months (median 24, interquartile range 48). The median number of annual meetings was 5 (interquartile range 7), and the total number of meetings since their establishment was 7 (interquartile range 16). In the majority of cases (86) the decision-making process was based on consensus formation, in 2 cases on secret voting, and in 59 cases on public voting. The average duration of the committee meetings was 1 hour (60 minutes). 90 respondents stated that their committees had standing orders. The functions that the committees performed in their everyday work and the issues that they dealt with are shown in Table 1 and 2.

Table 1 – The functions that ethics committees performed in their everyday work

FUNCTIONS OF ETHICS COMMITTEES	ANSWERS
Analysis and approval of research protocols	114
Ethical case analysis	77
Review of complaints made by patients and physicians	64
Policies and guidelines formation	19
Education of members of ethics committees and hospital staff	16
Education of patients and their families	5

The median time spent on the analysis of a research protocol was 1 hour (interquartile range 2).

Table 2 - Issues dealt with in the everyday work of ethics committees

ISSUES	ANSWERS
Clinical research	108
Principles of ethical decision-making	58
Informed consent	50
Communication problems between patients and physicians	48
Communication problems among hospital staff	46
Confidentiality of medical data	41
Assessing the competency of patients	39
Patients' rights	34
Conflict of interests	20
Treatment of pain in terminally ill patients	19
Economic problems concerning maintenance of a certain level of healthcare	13
Palliative medicine	13
Abortion	10
Euthanasia	10
Ethical questions concerning HIV infected patients	9
Organ transplantation	7
DNR orders	6
Resource allocation	5

The questions related to the respondents' views on their work as members and the general views on the work of their committees are presented in Table 3.

Table 3 – Questions about the everyday work of the committees

QUESTION	YES	NO
Do the opinions of your committee's members reflect the views of Croatian society?	125	22
Do you feel competent enough to be a member of your ethics committee?	132	15
Do you feel that your opinion is respected in the work of your ethics committee?	145	2
Did you attend any special educational courses or conferences related to bioethical issues?	25	122
Do you feel that you need additional education in the field of bioethics?	124	23
Do you feel that the work of your ethics committee is efficient?	121	26

When grading the influence of their ethics committees on the decision-making process of the hospitals, respondents gave the mean grade of 3. 49 (95% CI = 3. 31 – 3. 67).
Respondents graded the work that their committees had performed so far with the mean grade of 3. 64 (95% CI = 3.49 - 3.80).

Knowledge self-assessment and knowledge level of ethics committee members

The level of the self-assessment of the respondents' knowledge about bioethical issues is indicated in Table 4.

Table 4 – The level of self-assessment of respondents' knowledge about different bioethical issues (tested on 147 respondents; 1= yes, I am familiar with this topic and would feel comfortable teaching others about it; 2= yes, I am familiar with this topic, but do not think I could answer questions about it; 3= yes, I am familiar with this topic in a general way, but not with any of the specific issues; 4= no, I do not know much about the topic; 5= I have never heard of this topic).

FIELD	C ± Q
Genetic counselling	3.00 ± 1.00
Ethical issues related to the beginning of life and abortion	3.00 ± 1.00
Ethical issues concerning artificial procreation	3.00 ± 1.00
Surrogate motherhood	3.00 ± 1.00
Counselling women with HIV infection about pregnancy and abortion	3.00 ± 1.00
Treatment of seriously ill newborn babies	3.00 ± 1.00
Legal provisions for children born with severe genetic and chromosomal abnormalities and inborn organ deficiencies	3.00 ± 1.00
Anencephalic newborn babies as organ donors	3.56 ± 1.00
Definition of brain death and cortical death	3.00 ± 1.00
Ethical issues related to the transplantation of organs	3.00 ± 1.00
Patients' rights	2.00 ± 2.00
Confidentiality of patient data	2.00 ± 2.00
Breach of patient confidentiality when there is evidence of danger to others	2.00 ± 2.00
Informed consent in minors	2.00 ± 2.00
Informed consent and HIV testing	3.00 ± 1.00
Informed consent in innovative therapeutic procedures	2.00 ± 1.00
Treatment termination in competent terminally ill patients	3.00 ± 1.00
Treatment termination in competent non-terminally ill patients	3.00 ± 1.00
Treatment termination in non competent terminally ill patients	3.00 ± 2.00
Treatment termination in non competent non-terminally ill patients	3.00 ± 2.00
Proxy consent in incompetent patients	3.00 ± 2.00
Advanced directives	4.00 ± 2.00
Medical criteria of futile treatment	3.00 ± 2.00
DNR orders	3.00 ± 2.00
Double effect	3.10 ± 2.00
Euthanasia	2.00 ± 2.00
Palliative medicine	2.00 ± 1.00
Refusal of transfusion for religious reasons	2.00 ± 2.00
Sterilization	3.00 ± 2.00
Ethics committees (history, functions, importance, and types)	3.00 ± 1.00
Hospital ethics committees	2.00 ± 1.00
Institutional review boards	3.00 ± 2.00
Clinical research and research on humans in general	2.00 ± 1.00
Helsinki declaration	3.00 ± 1.00
Universal declaration on the human genome UNESCO	3.00 ± 2.00
Council of Europe Convention and additional protocols concerning ethical issues	3.00± 1.00
Hippocratic oath	3.00 ± 2.00
Nuremberg codex	1.00 ± 1.00
Ethical codes of Croatian Medical Association and Croatian Medical Chamber	2.00 ± 2.00
Resource allocation and justice issues in healthcare systems	3.00 ± 0.00
Conflict of interests	3.00 ± 1.00

No significant correlation was found between the knowledge self-evaluation results and the sex or age of the respondents.

Table 5 – The level of knowledge of the respondents regarding bioethical issues; frequencies of correct answers

QUESTION AND CORRECT ANSWERS T-true, F-false	CORRECT ANSWERS
Ethics committees in healthcare institutions are called Healthcare Ethics Committees or HECs. **T**	106
A healthcare ethics committee undertakes the same tasks as an IRB (Institutional Review Board). **T**	37
In the Republic of Croatia the work of ethics committees is regulated by the Law on Health Insurance. **F**	69
Members of HECs have a legal liability for their decisions. **F**	67
The functions of HECs are: analyseis of research protocols, education of their members and hospital staff, and ethical case analyses. **T**	138
The HEC Forum is a scientific journal that deals with the work of ethics committees. **T**	50
The Helsinki Declaration gives ethical guidelines for research on humans. **T**	122
Tom L. Beauchamp and Albert Jonsen have written the book "Principles of Biomedical Ethics". **F**	48
Autonomy, beneficence, and justice are the principles of biomedical ethics. **T**	110
Casuistry is a method of ethical analysis. **T**	75
Today it is certain that Hippocrates did not write the Hippocratic oath. **T**	50
In the Republic of Croatia a physician can only break confidentiality if a court requests it. **T**	128
Informed consent is the only form by which a patient can give his or her consent for a certain medical procedure, and this can only be done in writing. **F**	34
Patients have the right to refuse medical treatment. **T**	145
In the Republic of Croatia there is a Law on patients' rights **F***	58
Croatia has an "opt out" system for organ donation. **T**	74
Brain death and PVS are the same. **F**	70
According to Dutch law, physicians and members of a patient's family can perform euthanasia. **F**	47
In Europe, only Belgium and the Netherlands have legal acts that regulate euthanasia. **T**	102
Abortion is permitted in Croatia. **T**	120
Croatia has a law on artificial procreation. **F***	76
Croatia has a law on conflict of interests. **F ***	77
According to the law in Croatia, HIV infection is regarded as a quarantine disease.**F**	102

* At the time of the survey there were no legal documents regulating this field; now there is one either in place or at the end stage of approval.

No significant correlation was found between the level of knowledge, sex, and age of the respondents.

Attitudes towards bioethical issues of ethics committee members

The respondents' agreement or disagreement with certain statements regarding bioethical issues is shown in Table 6.

Table 6 – The level of agreement with statements regarding bioethical issues (tested on 147 respondents) (1 = "I completely disagree", 5 = "I completely agree")

STATEMENT	C ± Q
The goals of medical care are to cure disease, restore function, eliminate suffering, and prevent illness.	5.00 ± 0.00
In spite of highly developed technological achievements, today's modern medicine cannot always be successful because it cannot always help to cure disease, restore function, eliminate suffering, and prevent illness.	5.00 ± 1.00
The competent and informed patient has the right to refuse any form of treatment, regardless of whether he or she is terminally ill.	5.00 ± 1.00
A diagnosis of mental illness does not, by itself, justify a judgment that a patient lacks decision-making capacity.	2.00 ± 3.00
The physician has a duty to recommend the course of treatment that, in his or her opinion, reflects a patient's best interests.	5.00 ± 0.00
The physician should not respect a patient's refusal of a medical treatment if, according to the opinion of the physician, this could lead to serious consequences for the patient's health.	4.00 ± 2.00
If a patient lacks decision-making capacity, a family member or significant other may act as the patient's surrogate.	5.00 ± 1.00
If a patient's wishes about a medical treatment are known they should be followed.	4.00 ± 1.00
If a patient's wishes about a medical treatment are not known an attempt should be made to determine what a patient would probably have wanted.	4.00 ± 1.00
Any quality of life consideration is to be assessed from the patient's perspective (for example, the patient's perceived experience of burden and benefit).	4.00 ± 1.00
Parents have the right and duty to make treatment decisions for their children and may be presumed to be acting in their child's best interests.	4.50 ± 1.00
Similar medical cases should be treated similarly.	4.00 ± 0.75
There is a psychological and moral difference between withholding and withdrawing treatment under the same circumstances.	4.00 ± 1.00
It is more reasonable to withhold treatment on the grounds that it might not achieve a patient's desired goals, than to try a treatment and then stop if the treatment does not achieve the patient's desired goals.	4.00 ± 2.00
Treatment recommendations should clearly articulate the goals of a treatment so that patients/ surrogates can be clear as to whether the treatment meets their desired goals.	5.00 ± 1.00

Advanced directives are not helpful in encouraging dialogue among a patient, their family, and a physician about the patient's values and preferences with respect to treatment until such time as they are no longer able to make decisions.	3.50 ± 2.00
Rationing of healthcare (decisions about limiting availability of medical care to individual patients) should be explicitly addressed at the policy level, whether at the institutional, professional, or governmental level.	4.00 ± 1.75
Rationing decisions in the healthcare system should be made by individual physicians for individual patients.	3.00 ± 2.00
Patients may want to use economic factors in making their own decisions, but surrogates' use of economic factors in making decisions for others is controversial.	4.00−± 2.00

DISCUSSION

The study of the work of hospital ethics committees enabled us to get a clear picture of the committees' composition, functions, and everyday work. Consistent with the previous two studies, the same pattern of membership structure emerged. Committees had 5 members of whom 3 were physicians and 2 came from other professions (4). Although 5 is the number usually required for the formation of an ethics committee, according to the bioethics literature, it is not uncommon for ethics committees in hospitals to have more than 5 members (2). More members, especially from different fields and professions, promote an interdisciplinary approach and exchange of different approaches and opinions in the everyday work of a committee (14). A larger number of members can lead to a division of the committee's work between different subcommittees that have special tasks, thus distributing the work of the committee and making it more efficient (15). However, some authors suggest that the committees should not have more than 10 members in order to be expedient and focused on their tasks (2). In the Croatian case we can observe that the majority of the committees have membership structures which exactly follow the membership structure required by the Health Protection Law. Here we can observe a certain legalistic and formal approach in the formation of ethics committees. Except for the fact that the majority of the committees had a legalistic approach to membership structure, most of them were founded during 1998, after the first implementation of legal provisions for ethics committees in Croatia by the Health Protection Law from 1997, and most committee members were elected by hospital administrations. This legalistic approach is further corroborated by the selection of professions participating in the work of the committee. Again, as in the Health Protection Law, we have 3 physicians and 2 other members from different fields. The profiles of the 2 non-physician members show, as in the previous two studies, that nurses, theologians (priests), and lawyers (from outside, or in a minority of cases, from within hospital administrations) are likely candidates for membership in a hospital ethics committee. Hospital administration officials and social workers are more likely candidates for membership

than philosophers and ethicists. Patient representatives in hospital ethics committees, although important (16), are non-existent in Croatia. Such a selection of professions for membership in a hospital ethics committee might be a matter of convenience. Sometimes, especially in the hospitals of smaller towns, it is easier to find lawyers, nurses, and theologians (priests) who are willing to participate in the work of the committee, than other professions. Another reason for selecting someone as a member of a committee can be the perceived value of a profession in a society, or its value as a profession in a society as perceived by physicians, as they are represented in hospital administrations, and it is the hospital administrations that selects and appointes the members of the committees. Nevertheless, whatever the reason for selecting certain professions over others for the membership of hospital ethics committees in Croatia, sometimes these choices do not do justice to the potential benefits certain professions could bring to the committees' work. For instance, theologians who were mainly participating in the committees' work were predominantly priests form the local communities or priests who were hospital chaplains. At present, in Croatia there are a number of lay theologians being educated and working in the field of religious education in communities all over the country. They could also be potentially important members of hospital ethics committees. Moreover, a need for pastoral care was expressed recently in the agreement between the Croatian state and the Catholic Church, officially establishing the post of hospital chaplains. They could play an important part in the work of hospital ethics committees as well. There is certainly a need for the participation of theologians in hospital ethics committees. However, one can wonder whether every theologian and lawyer, or even a hospital lawyer, is an adequate candidate for membership in a hospital ethics committee (17,18). In our opinion, it is highly unlikely that just because people are members of certain professions this makes them good candidates for membership in a hospital ethics committee. We feel that expertise and competency in the field of bioethics should be the prime criteria for membership in an ethics committee, besides taking into consideration the criterion of multidisciplinarity of its membership (19).

This brings us to the question why only one single member of the hospital ethics committees in Croatia regarded him or herself as an ethicist. By ethicist we mean a person coming from any field of study (theology, philosophy, law, medicine, sociology, psychology), who has a thorough knowledge of bioethics and has received some sort of formal education in this field. . The answer is evident. Croatia is lacking a sufficient number of experts in biomedical ethics, comprising all the previously mentioned fields, so it is no wonder that none of the participants in our survey (with a single exception) felt comfortable with the level of their knowledge and the level of education that they had received in the field of biomedical ethics.

This is corroborated by the need for further education in the field of bioethics that the members expressed in our survey.

Furthermore, the exclusion of patient representatives as members of ethics committees leads to serious doubts concerning the purpose of those committees and the respect for patients' opinions in a society that promotes such membership structure in hospital ethics committees. Moreover, we know of the existence of NGOs dealing with patients' rights in Croatia. Another puzzling fact that emerged in our survey is that the majority of respondents believed that their views reflect the views of Croatian society, which is highly unlikely, as the majority of the members are well-educated and come from the fields of medicine, law, and theology, which is not true for the majority of the Croatian population (20).

According to our survey, the analysis of research protocols is the main function performed by ethics committees. This was also noticed in our pilot study and the study of the National Bioethics Committee from 2002/2003. This can be explained by looking at the background of the development of ethics committees in Croatia. The first steps towards the institutionalization of bioethics through ethics committees in Croatia were made in the 1970s, when the first IRBs (Institutional Review Boards) were created. These committees were called "hospital drug commissions", and were formed in the larger clinical hospitals in Croatia. They were involved in the methodological and ethical analysis of clinical drug trials (21). Thus it is not surprising that ethics committees are most often identified with the analysis of research protocols. However, this situation recently changed with the introduction of the new Law on Drugs and Medicinal Products in 2003 (22). The analysis of research protocols is now centralized at the independent central ethics committee at the Ministry of Health. This will probably lead to the transformation of hospital ethics committees in Croatia into classical HECs with education, guideline-formation, and ethical case analysis as the main functions of their work. In some hospitals one can still find both IRBs under the name of "hospital drug commissions" as well as hospital ethics committees, sometimes performing the same function - research protocol analysis. With the introduction of the new Law on Drugs and Medical Products, such confusion has been avoided by centralizing the reviews. In this new model "hospital drug commissions" are likely to be transformed into commissions for the control of rational drug prescription policies, thus improving the quality level of hospital treatments.

Our survey also showed that case analysis was quite often practiced as a function. However, one can see from the list of issues discussed by the committees that the majority of the problems were related to communication problems between patients and physicians, physicians and physicians, or to patients' rights issues. At the same time the education of the

members as a function was neglected. Thus it follows that the members could not get involved in more complicated cases and that they mostly dealt with communication problems and problems related to patients' rights. Furthermore, as the policy formation function was also rarely practiced, regulatory mechanisms of hospital decision-making were not developed. In such circumstances serious ethical problems were not discussed as there was no regulatory mechanism to fall back on in the decision-making process. The lack of education and policy-formation efforts also led to the creation of more problems at the communication level between hospital staff and patients and among hospital staff themselves. These findings can be corroborated by the fact that the level of knowledge of the members was average but insufficient for the complicated tasks that they were supposed to perform in their everyday work. Our survey showed that the average level of self-assessed knowledge was 3, meaning "yes, I am familiar with this topic in a general way, but not with any of the specific issues". The level of knowledge was less than satisfactory, especially in regard to issues such as informed consent, research ethics, transplantation, or legal provisions in Croatia and other countries. However, although confident about their knowledge, members of hospital ethics committees expressed the need for further education in the field of bioethics. What should this further level of education comprise? Members of hospital ethics committees in Croatia should at least have a good understanding of important national and international legal frameworks and issues in the field of bioethics. They should be able to fully understand basic concepts and notions like informed consent, patients' rights, issues at the end and the beginning of life, research ethics issues. In the near future, the education of hospital ethics committee members should become the most important function of their work. Education should be the main tool for not only raising the level of the members' knowledge but concurrently changing the ethical climate in the Croatian hospitals as well.

In regard to the everyday work of ethics committees, another observation can be made. The views of the members on certain issues and bioethical dilemmas demonstrated a high level of paternalism and overprotectiveness of their patients. This can be explained by the fact that the majority of the members who participated in our survey were 50 years and older with, in most cases, no formal education in the field of bioethics.

In conclusion, our analysis of the work of hospital ethics committees showed a bureaucratic approach to the establishment and everyday work of the committees. Although the committees were satisfied with their position in the hospitals, the question arises concerning their real purpose within the hospital structure. Probably the answer is partly to satisfy legal requirements. The reasons for this situation are found in the general atmosphere within the

healthcare system in Croatia before the 1990s. This is not uncommon and is to be expected in healthcare systems that used to be monitored and regulated by the government in a highly bureaucratic manner with no sensitivity to the real situations in the everyday work of healthcare professionals. In such a context healthcare professionals were usually required to conform to bureaucratic requirements, putting their better judgment in conflict with the requirements of the system. Such an approach is still present and creates many problems for the development and implementation of healthcare reforms in countries undergoing transition (23).

Another bioethical trait that is characteristic in countries undergoing transition is a strong paternalistic tendency, especially among the older healthcare personnel with a more traditional view on the physician-patient relationship and medical ethics (24). The majority of our respondents were physicians around 50 years of age. The reason for this tendency was probably the view that a member of an ethics committee should be an experienced older physician whose experience can be equated with the level of his or her competency in medical ethics. Here we find a traditional approach to medical ethics: older, more experienced physicians are competent enough to converse about ethical issues by virtue of the fact that they have a lot of experience and practice to draw their knowledge from.

All of these observations prompted us to conclude that our analysis of the work of hospital ethics committees could explain structural ethics issues in a given healthcare system. Because hospitals are healthcare structures made of intricate webs of relationships between people, they have attributes relevant to ethics. They promote values embodied in medical ethics; they reinforce certain kinds of behaviour and discourage transgressions. They create and promote ethical cultures within their walls. Hospitals have purposes; they protect the well-being of patients, foster their healing process, and help them and their families to cope with health problems. On the basis of these purposes, responsibilities towards patients and their families are attributed. Hospital ethics committees are the structures that epitomize organizational ethics within a hospital. By observing how they function one can “read” a hospital. Hospitals and hospital ethics committees are intertwined into the patchwork of a healthcare system as are other institutions and organizations. Thus by observing the work of hospital ethics committees one can tell a lot about the ethical climate of the healthcare system itself. Further investigations will be undertaken in this direction.

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Chapter 7

Ethics and the structures of health care in the European countries in transition: hospital ethics committees in Croatia

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ABSTRACT

Hospital ethics committees are a recent phenomenon in countries in transition. Croatia's example shows they are staffed mainly by older doctors with no specialist knowledge of ethical issues. The importance of professional relationships and the educational function of ethics committees have been ignored.

INTRODUCTION

Healthcare structures, organisations, and institutions have ethical characteristics that are about relationships. These groups are composed of individuals and groups of people with moral obligations. Healthcare structures embody particular organisational cultures that, good or bad, affect people and reflect values. Also, healthcare structures have certain purposes, and they can be evaluated and held accountable whether or not they fulfill their purposes, particularly those affecting and effecting health care. For these reasons, healthcare structures have ethical attributes, and ethical analysis of the healthcare system could be performed (1).

We use hospitals ethics committees in Croatia to explore the issues connected with structural ethics in healthcare institutions in the countries in transition, and we present it as an example that applies also to other countries in transition. We chose hospital ethics committees because we believe that such an analysis can explain structural ethics issues in a healthcare system.

Hospitals and structural ethics

Hospitals are healthcare structures made of intricate webs of relationships between people. They have attributes relevant to ethics: they promote values embodied in medical ethics, reinforcing certain kinds of behavior and discouraging transgressions. Hospitals create and promote ethical cultures within their walls. Hospitals have purposes: they protect the wellbeing of patients, foster their healing process, and help patients and their families to cope with disease. On the basis of these purposes, hospitals have responsibilities towards patients and their families. Observing how hospital ethics committees function makes it possible to "read" a hospital. Hospitals and hospital ethics committees are part of the patchwork of a healthcare system, as are the other institutions and organisations. Thus by observing the work of hospital ethics committees one can tell a lot about the ethical climate of the healthcare system itself.

European countries in transition, ethics, and healthcare structures

Countries in transition in central, eastern, and southeastern Europe have a similar path of development and historical background (2). The healthcare structures in countries in transition were regarded as health factories. The number of beds, the number of patients processed, the level of technical sophistication in these healthcare factories were most important in evaluations of their work. Little if any attention was paid to the age, personal characteristics, religious beliefs, and gender differences of patients or to ethical problems that arose in the process of providing health care. The bureaucratic approach in health care was omnipresent. Unfortunately,

the legacy of such an approach can still be seen in healthcare structures in the countries in transition. Thus the process of institutionalisation of bioethics is regarded by some authors as especially important to European societies in transition. The development of hospital ethics committees, especially, could encourage the development of ethical professional behaviour and the creation of important networks within a specific country (3). However, if institutionalisation is carefully implemented, it can produce scepticism and bureaucratic behaviour (4).

Croatian ethics committes and healthcare structures

Ethics committees in Croatia are a relatively new phenomenon (box).

History of ethics committees in Croatia

1970s: First steps towards bioethics institutionalisation (hospital drug commission, institutional review boards) for international multicentre trials

1990s: Ethics committees formed in medical schools, medical associations

First legal requirements for ethics committees in healthcare institution (Law on Health Protection from 1997): committees must combine the functions of institutional review boards and hospital ethics committees; they are to have five members, of whom two are not from the medical field

2001: Formation of the National Bioethics Committee for the Medicine of the Government of the Republic of Croatia (20 members; issues recommendations, guidelines, and reports on various ethical issues)

Committees are found in scientific institutes and the schools of dentistry, veterinary medicine, and pharmacy, along with National Bioethics Committee and committees in healthcare institutions, medical schools, and professional regulatory bodies

In 2002 and 2003, the National Bioethics Committee for Medicine conducted a study of ethics committees in Croatia, asking about the number of members, structure of membership, issues discussed during meetings, number of meetings so far, standing orders, working guidelines, and documents related to their work. The survey had a response rate of 82% and showed a highly formal and legalistic approach to the formation of ethics committee (5). Those findings prompted us to further analyse the situation, especially regarding ethics committees in hospitals in Croatia, because we felt that analysing the work of hospital ethics committees would provide information about structural ethics issues within a healthcare system.

Survey and results

We sent a questionnaire to 241 members of hospital ethics committees. Their names were obtained from the 2002-3 survey of the National Bioethics Committee. The questionnaire had four parts: data on age, sex and occupation, number of members in the committee, educational practices, frequency of meetings, issues dealt with in everyday practice; a 42 question self-

evaluation questionnaire (assessed on a Likert scale); 23 questions testing knowledge of ethical issues; and 19 "bioethics consensus statements" (agreement measured on a Likert scale).

The survey had a response rate of 61% (74 men, 73 women); mean age of the respondents was 51; 73% of respondents were doctors. The survey showed that the structure and the composition of hospital ethics committees followed the legal requirements. Most committees were formed after 1997, when the legal provisions for ethics committees in Croatia were introduced. The number of members and their occupation was an exact replica of the structure of the committees required by the law: three doctors and two members from other professions, of whom lawyers and theologians were the most likely candidates.

The main task of ethics committees in hospitals was an analysis of research protocols, thus neglecting the other functions important for a hospital ethics committee: education, case analysis, and development of guidelines. The level of knowledge of the members was average, but not sufficient for the complicated tasks that they were supposed to perform in their everyday work. Their views on the doctor-patient relationship and bioethical dilemmas showed a high level of paternalism and overprotectiveness of their patients. These results may be due to the fact that most of those who participated in our survey were 50 years and older and had no formal education in the field of bioethics.

A bureaucratic approach

The legalistic approach to the formation of ethics committees, as in the Croatian case, is not uncommon, and transforms ethics committees into bureaucratic bodies (4).Hospital ethics committees exist only to fulfill the legal requirement. This is a drawback in developing a healthcare institution or a healthcare system with ethical standards.

This top down approach is common in countries in transition (6), where the development of civil society has been constrained by a former totalitarian government. Those societies feel more at ease when the regulatory frameworks in all areas as well as in health care are implemented by the state. This is to be expected in healthcare systems which were monitored and regulated by the government in a highly bureaucratic manner with no sensitivity to the reality of the everyday work of healthcare professionals. In such a climate, healthcare professionals were usually required to conform to bureaucratic requirements, thus putting their judgment in conflict with the requirements of the system (7).

The top down approach and highly legalistic framework has created confusion about the tasks of ethics committees in hospitals. Although the committees combine the functions of institutional review boards and hospital ethics committees, they have made the analysis of

research protocols their main function. This is also not uncommon, since in other countries in transition institutional review boards have been present for many years in one form or another because of multicentre trials (8). Thus members of ethics committees have considerable knowledge from this field. However, this jeopardises the other, more important, functions of an ethics committee in hospital: education about ethical issues, development of guidelines, and analysis of cases that raise ethical questions (9,10).

This lack of recognition of the broad range of functions of a hospital ethics committee, especially the educational function, can be seen in the insufficient level of knowledge of the committees' members. This draws attention to the need for developing bioethics education on all levels in the countries in transition; efforts to improve the level of knowledge have been made in Lithuania, Estonia, Latvia, Poland, Slovenia, Czech Republic, Slovak Republic, Hungary, Romania, Bulgaria, and Croatia (3,6).

Another trait is a strong paternalistic tendency, especially among older healthcare staff who have a more traditional view on the doctor-patient relationship and medical ethics (6). This is reflected in the work of ethics committees, which are often made up of older doctors, as in the Croatian case—probably because the experience of older doctors is equated with their competence in medical ethics. Here we find a traditional approach to medical ethics: older, more experienced doctors are thought to be competent enough to converse about ethical issues just because they have considerable experience to draw their knowledge from.

CONCLUSIONS

The work of ethics committees in Croatia can be viewed as one of satisfying norms and requirements within a healthcare system. However, healthcare systems are also about people and relationships, and when that is ignored it can create a lot of strain on both providers and users, creating unresolved issues and tensions as well as ethical problems. Healthcare organisations should be based on webs of relationships and interactions between people, promoting ethical values, trying to foster patients' best interests, and having responsibilities.

Summary points

In European countries in transition, like Croatia, the healthcare system has a bureaucratic climate and approach

Ethics committees in such a climate are bureaucratically constituted entities whose functions consist mainly of analysing research protocols

Members of hospital ethics committees have insufficient knowledge of ethical issues and a paternalistic approach

Ignoring people and relationships can strain both providers and users, creating unresolved issues and tensions and ethical problems.

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Chapter 8

Worldwide experiences of hospital ethics committees' education- lessons for Croatian healthcare system reality

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ABSTRACT

The article gives an overview of worldwide experiences in hospital ethics committees' education with the description of current problems and approaches. Croatian situation of ethics committees' education is also discussed. Possible solutions and approaches in ethics committees' education for transitional societies with special emphasis on Croatian healthcare system are discussed.

Educating hospital ethics committees worldwide

Ethics education of members of ethics committees is an important part of their work with apparently well-established benefits for committees' work. Judith Willson Rosss states that *raison d'ętre* of ethics committees work is their educational function: first of all education of its own members via different methods and means and after that education of hospital staff, patients and the community (1).

Different authors present different views on how this education should be done. Curricula for ethics committees' self-education have been presented by some authors. These curricula usually aim to educate committee members in a number of subjects from basic ethical theories and concepts to specific bioethical issues like informed consent, DNR orders, PVS, issues at the end and the beginning of life and legal, religious and cultural aspects of providing healthcare (2). The strategies applied for education of hospital ethics committees vary from formal courses in bioethics, morality and theology, continuing education seminars, ethics ground rounds and seminars, clinical clerkships to eat and learn sessions and variety of audiovisual materials for individual learning (3). The education of ethics committees' members can be done by committee members themselves or additional help can be sought from experts, usually clinical ethics consultants (4).

The majority of authors view hospital ethics committees primarily as fora for conscious and reflective consideration of significant and often ambiguous value issues in patient care as certain level of bioethical knowledge is deemed to be essential for its everyday functioning. It is from this basic level of knowledge and function that an ethics committee can than embark onto more difficult tasks of policy formation, clinical case consultation and its transformation into the fora for multidisciplinary discussion of ethical issues (5). Judith Willson Ross favors hospital ethics committees' involvement in this ethical decision-making. Her model presents a committee as a multidisciplinary body in the role of hospital's main resource for ethical guidance in individual cases. Other authors like LaPuma and Toulmin feel that this task should be undertaken by clinical ethics consultants while ethics committees should be restricted to the education, policy-formation and multidisciplinary discussions on specific topics within hospitals rather than clinical case analysis. There is also a middle approach presented by some authors that tries to combine both models, thus creating a two-layer model of clinical ethics. In this model there is a close connection with the work of clinical ethicists, hospital ethics committees and institution itself in creating education and ethical reflection on the ward (6). This classic view derived from US experiences of hospital ethics committees formation has been prevailing

all over the world. In the USA and Canada there are now a number of consortium ethics programs whose main function is education of different ethics committees' members and creation of permanent regional ethics networks of hospital ethics committees (7, 8). Committee structure, function and process, and within this framework especially education, are considered to be among the key factors when talking about successful institutional implementation of hospital ethics committees (9). Education of ethics committee's members thus aims at creating significant mass of experts within the structure of a healthcare institution.

Problems with hospital ethics committee's education

Although the education of ethics committees seems to be regarded as the cornerstone of their activity, the studies have failed to uncover any significant effects of ethics education on the moral reasoning, moral competency and /or moral development of medical professionals (10). It is evident that education of ethics committee members can contribute to the improvement of the level of their knowledge about certain bioethical issues and there have been some positive results of specialized ethics committees training courses (11). However, it is not clear if there is any relationship between ethics education and either moral competence, moral development or projected behavior in clinical ethics context. Adrian Bardon has shown in his study that the effects of non-moral personal, societal and institutional factors on moral reasoning of members of hospital ethics committees could play a significant role, that further investigations into this areas should be undertaken, and that ethics education for medical professionals and ethics committee members should be rethought (10). Furthermore, John McMillan and Annett Baier are also worried that, if people are given a brief version of theoretical options for moral theory, as it is often done in ethics education practices, for ethics committees' members it may result in a stunted parody of an ethical decision. To McMillan it is evident that ethics committees members should be knowledgeable of current new developments in medical law, they should be provided with the best available clinical information and they could discuss major moral arguments for particular practices that are discussed. However, he is not sure how far we should go with making ethics committees members up to date in moral theories (12).

Additional problem with ethics committees' education could also be institutional climate towards the committee. There is evidence that ethics committees are popular with those in hospital who use them, usually those who already have an awareness of ethical issues and some sort of ethical training (13). Moreover, among many criticisms of hospital ethics committees' work, the notion that committees do not make good teachers is often present. It is not clear why ethics committees' members, who in majority of cases have no experience in

teaching and developing ethics problems, should be in charge of ethics education in hospitals. Furthermore, sometimes committee members lack the adequate knowledge in ethical issues and therefore their role of educators cannot be seen as a favorable one. However, its is often said that those who have no experience in education can sometimes create adequate environment for the educational process by using informal methods of education as informal education through practice by their peers, which is common practice within clinical settings (12).

Croatian hospital ethics committees and education

Croatia has decided for the top down approach of implementation of hospital ethics committees. Hospital ethics committees have been in placed since 1997 by legal provisions (14). The provision of the local review of research protocols and at the same time presence of ethical reflection in the clinical settings, were the reasons for the establishment of the mixed type of ethics committees (those combining functions of the IRBs and HECs).

We have decided to investigate their composition and work in a number of studies undertaken from 2000-2003. The studies reviled a lot of problems with mixed type of hospital ethics committees. Among the problems observed, the presence of domination of the research protocols review, among other functions that ethics committees were supposed to perform, presented a serious drawback in their everyday work. A significant segment of the studies was also concentrated on educational practices in the committees and the level of ethics knowledge of the committee members. One of the studies took place during the first educational workshop for ethics committee members in Croatia. The other study looked at the overall knowledge of hospital ethics committee members (15).

We found out that high proportion of ethics committee members were confident about the level of their knowledge and their level of competence. On the other hand, committee members did not attend many educational workshops or lectures that could help them in their work. The average level of self-assessed knowledge did not show more than familiarity with ethical topics in a general way, without any of the specific ethical issues. The majority of respondents felt that they needed additional education for their work as members of ethics committees. However, from our data we were not able to analyze the influence of education on moral reasoning, moral competence and moral development of medical professionals and ethics committee members. The attendance of the workshop for ethics committee members improved a little their level of knowledge, although not significantly, while it was not easy to change attitudes and behaviors through educational efforts of ethics committee members in Croatia. We also found out that the institutional climate and the climate within the healthcare system

ignored not only the educational function of ethics committees but also the importance of professional relationships. Since healthcare systems are also about people and relationships, when that is ignored, it can create a lot of strain on both providers and users, creating unresolved issues and tensions as well as ethical problems. Healthcare organizations should be based on webs of relationships and interactions between people, promoting ethical values, trying to foster patients' best interests, and having responsibilities (15).

Throughout our studies, there was a need for further educational effort for ethics committees' members but having all that was so far said about ethics committees' educational function one is not sure what sort of educational effort the ethics committees in Croatia should embark on. As Richard A. Aschroft rightly observed, from our studies one is not sure what should be an educational ideal that we should strive for in Croatia, or what is an ideal or average level of knowledge that we should compare the knowledge of ethics committee members to and by whose standards (16). We have decided to take on this challenge and try to answer what would be an educational ideal that we should strive for when letting hospital ethics committees in Croatia embark on their educational function?

For an ethical function in the hospitals in Croatia

Croatian healthcare system presents itself as a hierarchical and bureaucratic entity. It is not uncommon that sometimes the therapeutic aim of an institution (in our case a hospital) risks to be subordinated to the bureaucratic organizational aims (15, 17). In institutions like hospitals there is always a risk for institution violence. This risk can be even greater in the transitional societies like Croatia. The power games, even political involvement in medical decision-making, are not uncommon in transitional settings. Furthermore, the legalistic and bureaucratic organization is the characteristic of the legal regulation of healthcare as a whole and the healthcare professions in transitional countries like Croatia. Ethical regulations are taken lightly and their breach is not uncommon (18). Thus, there is no wonder that the work of ethics committees in hospitals is confusing and that educational practices are scarce. The situation is further deteriorated by the loss of trust in medicine, by the corruption, low education level of patients, misunderstandings and manipulations with patient rights issues.

On the other hand, with the development of medical practice, physician's professional behavior has been constantly changing from a mostly paternalistic attitude to more teamwork by involving other medical professions and patients in decision-making. However, this does not occur without problems. In some European countries the physicians are looking at this occurrence with reserve. The ideas that ethics committees are unnecessary, that ethics is

already discussed in hospital words, that it has always been present in everyday practice, that the majority of ethics issues can be solved or prevented by present legal standards or their improvement and that physicians and hospital staff do not have time for participation in yet another committee are strongly present (19). Furthermore, sometimes the work of ethics committees in the hospital is viewed as a sort of crisis management, a useful tool for helping with patients' requests for clearing out medical mismanagement issues (20).

However, none of these views give justice to the real potential and influence that hospital ethics committee can have in the creation of important changes in the hospital environment, especially in a transitional country like Croatia. The rethinking of the role of hospital ethics committees in the Croatian healthcare system, especially through their educational function, can prove to be a possible remedy.

The HECs in general, are keen on having educative function, thus raising the level of ethical awareness in their institution. According to this generalized view, educational function of hospital ethics committees should include education of hospital managers, clinicians, hospital professionals and patients themselves. This approach could improve respect for patients' rights, consensus formation with hospital support, ethically-oriented decisions, as well as foster dispute and conflict resolution, establish some form of local democratic procedures (in our opinion deemed necessary in transitional societies.) However, this classical view of the role of ethics committees' education, with a strong emphasis on procedures and policy- formation in hospital setting as necessary component and aim of educational practices of hospital ethics committees, runs a risk of turning ethics committees into procedural and bureaucratic entities (21). It is easy to imagine that in a highly bureaucratic hospital structure as in Croatian hospitals, ethics education, if not carefully thought of, would turn ethics committees into superficial quick-fix entities for preserving the status quo.

Authors like Pierre Boitte emphasize that the reality that governs healthcare institutions whose prime example is an everyday life of a hospital, is primarily a clinical one, meaning that clinical judgments and decisions are the focal point of everyday interactions within hospital walls. Clinical judgment enables health professionals to make decisions in given situations case by case. This judgment constitutes of balance between theoretical knowledge and the unknown factors of the illness itself. The quality of this judgment is achieved by the experience and practice. Sometimes within this clinical reality there are cases and situations that create areas of uncertainty, where clinical judgment needs to be complemented with certain additional qualities that can only be found in ethical reflection (22). Thus the healthcare ethics committees

are there to help create space for ethical reflection and/or case consultation within hospital institutions and their education is a prerequisite for this function.

He is of the opinion that the primary goal of ethics committee's work is not the procedural and practical problem-solving aspect of its educational practices, but the creation of an ethical function in a hospital setting. This means that our educational process should try to avoid putting emphasis on ethical-procedural practices in hospitals, but work more on the things that are deemed to be ethical-substantive. "To defend the role of an ethical function in hospitals means in this perspective to agree to take into account this critical reflection in the biomedical practices, considering at the same time the outside parts of the critical reflection, the proximity of actual caring and research practices and the institutionalization of those two activities," states Boitte. For Boitte the critical reflection does not consist in formulating regulations in order to try containing or bringing limits to practice (which very often do not take care of those normative processes) but rather in promoting commitment of the persons who are fully acting in biomedical innovations, especially those who practice medicine and care for people. This will enhance the ethical aspects of the decision-making process. In other words, we have to avoid only medical logic or managerial logic to be taken into account when decisions concerning specific cases are made or when problems arise. In order to be relevant, ethics must consist of more than just an intervention at the last moment. It must be present in every department with each patient to help other occupations – doctors or nurses and cared for to take responsibility (17).

We find that this is exactly what we are aiming to in promoting the educational process of hospital ethics committees in Croatian hospitals. In an institutional setting like hospital one, it is only through gradual and permanent process of self-development of each participant in the caring process, that we can avoid that bureaucratic mentality and "window – dressing" tendencies in ethical decision- making. Educational ideal that we should strive for when encouraging educational function of hospital ethics committees in Croatia is to change the climate of an institution. This task is not easy and could take years. However, it is the only sound and permanent choice for Croatia or any other transitional country in order to avoid pitfalls of bureaucratic mentality of the healthcare system. Ethics committees should concentrate on the use of education as a tool for changes in order to establish ethical function in hospitals. In such approach, there are no quick fixes but carefully planned and consistent process of change of attitudes and structure and the institution (hospital) as a whole.

Nevertheless, this creation of an ethical function in hospitals should only be regarded as a small part of the creation of the ethical function in the healthcare system itself. In order to

start real changes in an ethical climate in a transitional healthcare system, changes should be made on all levels. Therefore, educational efforts should be aimed at healthcare providers, form the beginning of their university education to the level of permanent professional education where ethics committees could play an important role. Patient education should also be undertaken within this framework. All of the available materials and methods of ethics education should be used in order to achieve this aim. The emphasis is not on methods and materials but on continuity. One cannot finish an educational course and workshop and say: “Fine, now I am competent to make ethical decisions”. It is by personal all encompassing approach that non-moral personal, societal and institutional factors influencing moral development could be better interwoven into the intricate web of ethical decision-making.

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Chapter 9

Conclusion and discussion: the future of ethics committees in Croatia

In many countries, ethics committees are currently well established as useful components of healthcare. However, some authors are reporting a "failure to thrive" syndrome, especially of the healthcare ethics committees (1). Moreover, some authors are pointing out that committees can also provide a context in which decisions potentially damaging for patients' welfare can be made, and for which no one takes ultimate responsibility. This is most likely to be the case in settings where most members of the committee are relatively removed from clinical practice, where conflict of interest with administrative needs exists and where the group dynamics is bureaucratic (2). This pattern has also been observed in countries in transition. In Lithuania the "failure to thrive" syndrome and bureaucratic climate are well known to researchers in this field (3). Albania is also one of the examples where this pattern is found; although attempts to reform the healthcare system have been made, old habits in the healthcare system have continued to exist , or have even created new problems like corruption (4). Georgia and Azerbaijan as well as Russia also have difficulties with the transformation of their healthcare systems. Thus the formation of ethics committees in these countries is very slow, with an extremely legalized approach (5, 6, 7). Poland, the Czech Republic, Hungary and Slovakia could not prevent these top-down bureaucratic approaches in the formation of their ethics committees either. The usual scenario of the creation of ethics committees was through adopting a number of legal provisions; then, according to general opinion, the process of implementation would usually start (8,9,10,11).

As we have shown in our studies, the Croatian situation regarding ethics committees can certainly be characterized as a "failure to thrive" situation. Although established in 1997 (12), ethics committees in Croatia are still struggling in their everyday work.

The first reason for this difficult situation can be found in inadequate and often confusing legal provisions. Croatia basically has only one type of ethics committee: this is the so-called "mixed type", which functions both as healthcare ethics committee and research ethics committee; it usually operates in different healthcare institutions. Research ethics committees as such can only be found in research institutes and medical schools. There are also ethics committees in professional organizations, but they only deal with professional issues (13). These last two types of committees constitute only a small portion of the total number of committees, which are predominantly of the "mixed type". In 2003 the new Law on Drugs and Medical Products was implemented (14). According to this law the review of research protocols has now been transferred to the independent central research ethics committee. This approach is in accordance with tendencies reported in the literature on IRB establishment and territorial organization practices (15). The future of IRBs seems to be bright now, with an increasing

number of IRBs in place and a growing number of legal provisions that stipulate their implementation even in the less developed countries of the world (16). In regard to research ethics committees there is an ongoing debate as to whether a more centralized approach should be taken to research protocol reviews, as is the case now in Croatia. International guidelines suggest to create one or more central research ethics committees per country that will be responsible nationally or regionally for the review of all research protocols (CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, the Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Application of Biology and Medicine of the Council of Europe). This approach of centralization of the review of research protocols can make the process more expedient. Moreover, this would prevent having several committees on the local level concurrently reviewing the same research protocol giving different opinions about it. Furthermore, this centralized approach could foster impartiality and avoid local pressure groups influencing the review process. Finally, this approach helps to bring together the best experts in one committee, which is especially important in smaller or underdeveloped countries.

Therefore, with the implementation of the new Law on Drugs and Medical Products in 2003, Croatia is trying to follow these developments in the field of research ethics. Additional ethical standards have also been created with the formation of the National Bioethics Committee for Medicine of the Government of the Republic of Croatia in 2001. Now, there is a basis for quality ethical counseling in the drafting of new laws necessary to regulate sensitive bioethical fields and the promotion of societal debate on bioethical issues. However, the relationship between the Croatian government and the National Bioethics Committee was not without its drawbacks and troubles. In the future there is a need for a better understanding of the function of the National Bioethics Committee from part of the governmental authorities, who must accept the independence of the committee without political interference in its work.

The most troubling legal aspect in regard to ethics committees in Croatia is related to the work of ethics committees in hospitals. As demonstrated in these studies, ethics committees in hospitals, as well as in other healthcare institutions, are of the “mixed type”. Our research regarding their work has shown that they have actually been working as IRBs, thus neglecting the HEC functions in the majority of cases. Their transformation into healthcare ethics committees has now begun with the implementation of the new Law on Drugs and Medical Products. This new law was implemented in order to regulate all the activities connected with the marketing, production and research of drugs and medical devices. According to the new Law on Drugs and Medical Products, research protocols should be reviewed by an independent

central research ethics committee at the Ministry of Health. At the same time, the articles in the Law on Health Protection from 2003 which have been providing the legal framework for the work of ethics committees in healthcare institutions still state that the review of research protocols could be done locally as part of the functions of an ethics committee. This creates confusion and duplication of work since a research protocol can possibly be reviewed on a national and local level at the same time. By excluding hospital ethics committees from the practice of research protocol review, this confusing situation could be avoided and legal requirements for the transformation of hospital ethics committees into real healthcare ethics committees could be established. Furthermore, one should be careful with establishing legal requirements for outpatient healthcare institutions to have an ethics committee. Although there are tendencies, especially in the United States, to create healthcare ethics committees in outpatient healthcare institutions (17), the situation in the Croatian case will be more problematic. The lack of ethical expertise and the ongoing reforms of the healthcare system, where the role of outpatient healthcare facilities is not yet clear, can create problems in the formation and organization of healthcare ethics committees. It is no wonder that in our research we found a low percentage of ethics committees in outpatient healthcare institutions, while in inpatient facilities this proportion was significantly higher.

Nevertheless, improving legal provisions is not the only guarantee of a successful establishment of healthcare ethics committees in Croatia. Our investigation has shown that the bioethical knowledge of the members of hospital ethics committees in Croatia is in need of enhancement. Thus it is necessary to establish extensive educational practices. Educational workshops as suggested in our research are important for improving the level of knowledge of ethics committee members. Another knowledge improvement strategy is the improvement of graduate or postgraduate courses in bioethics in professional education and university programmes. In Croatia, the subject of medical ethics (or bioethics at some universities) was introduced in the medical curriculum at the beginning of the 1990s (18). Nevertheless, even before the 1990s efforts were made in the field of medical ethics. One was the creation of a centre for medical ethics at the Andrija Štampar School of Public Health in the 1980s and the establishment of annual workshops on human rights and medicine at the Interuniversity Centre in Dubrovnik. Other efforts include a number of elective undergraduate courses at the Andrija Štampar School of Public Health with an emphasis on various topics such as “Right to life” and “How to implement the Hippocratic Oath”. However, there is still a lack of skilled professionals in the field of bioethics, although the number of scholars is growing. The same situation can be observed in other countries in Central and South East Europe. The situation

from country to country varies from adequate legal provisions and educational structures to poor or no legal provisions and educational structures. Furthermore, the damaging effects on health of the recent wars, continuing unrest and conflict in the countries of South East Europe and the economic hardship faced by the populations have influenced the societal frameworks and the transformation of fundamental societal values. These disastrous events have also had a negative impact on many human relationships, including the one between physician and patient. The countries of South East Europe (Croatia, Bosnia and Herzegovina, Moldova, Bulgaria, Romania, Serbia-Montenegro, Albania, Former Yugoslav Republic of Macedonia) have all accepted the challenge to strengthen the fundamental human rights in their societies and the rights of vulnerable populations and individuals to effective healthcare, social wellbeing and human development as a part of these societal changes. The principles guiding this challenge have been formulated by the World Health Organisation, UNESCO and the Council of Europe. Within the framework of the Stability Pact for South East Europe, initiatives have been taken to further social cohesion and to increase access to appropriate, affordable and high-quality healthcare. Recognising that health is an integral determinant of social cohesion, it is important to assess all efforts to improve health within a humane framework, emphasising the interrelationship of health and peace, health care and human rights. Better education will contribute to reinforcing the moral commitment to patients' rights, equal access to healthcare, the quality of care, solidarity, the protection of vulnerable populations, the promotion of wellbeing. Ethics in particular will help to articulate the human values underlying all healthcare activities.

The Andrija Štampar School of Public Health of the University of Zagreb Medical School has recognised the importance of ethics education on all levels of the medical curriculum. With the support of the Council of Europe and its Social Cohesion Initiative as part of the Stability Pact for South East Europe (19), the School started the development of the new master program "Health, Human Rights and Ethics**"**. This program aims at improving ethics education not only on the postgraduate level, but through its capacity building efforts (creating a new generation of professionals with bioethics expertise) it also aims at improving ethics education on the undergraduate level. This project has been financed by the Council of Europe Bank of Development with part of the loan which, besides the reconstruction of the Andrija Štampar School of Public Health, aims at curriculum development. The project has also been supported by the World Health Organization and the SEE Public Health Network. Two curricula are being developed within this project: one on environmental and occupational health and another focused on the interrelations of health, human rights and ethics (20).

Educational policies and good legal provisions can nourish the development of good quality ethics committees. However, an adequate level of development of civil society and democratic mentality within a society are essential for their success (3). Our research into the work of Croatian ethics committees has shown a bureaucratic mentality of satisfying norms and requirements within a healthcare system. However, healthcare systems are also about people and relationships and when that is ignored a lot of strain will result both for the providers and users, creating unresolved issues and tensions, as well as ethical problems. Healthcare organizations should be based on networks of relationships and interaction among people, promoting ethical values, trying to foster the patients' best interests and taking responsibilities (21). The same pattern can be observed in other countries in transition. In Hungary the transparency of the selection criteria for ethics committees seems to be an important issue (10). In Poland, a plethora of ethics committees exists, but at the same time there seems to be a lack of coordination of their work (8). Romania has also instituted ethics committees but except for the review of research protocols one does not get a lot of information about the other aspects of their work (22). It seems that research protocol review is a preoccupying task for the majority of ethics committees in transition countries like Slovakia, Slovenia, Russia, Georgia, Romania (11, 23, 7, 5, 22). However, the situation in Croatia will probably be improved with the further development of civil society, the implementation of healthcare reforms and European integration processes. Furthermore, the development of ethics committees itself will contribute to the enhancement of democratic decision-making procedures and to the dissemination of democratic values in the society (24).

With the necessary changes in the Croatian healthcare system, hospital ethics committees could become the means for improving quality standards in healthcare delivery. Hospital ethics committees can indirectly improve the quality of care by providing support to clinicians and managers as they face difficult clinical decisions. They could help to create the kind of reflective and critical culture within the healthcare institutions, which would be essential for clinical governance to be a genuine rather than a cosmetic change (25). In contemporary healthcare institutions financial, clinical and professional issues are so interrelated that they cannot be separated (26). From the standpoint of quality control, ethics committees can also be good catalysts for the improvement of physician-patient communication. Now, with the implementation of the new Law on Patients' Rights (27) in Croatia, and the extensive development of patient rights NGOs, physicians, patients and government seem to be confused about the practical application of the new legal standards. Hospital ethics committees could be transformed into forums for debates on this issue. By educating both hospital staff and patients

with the help of patient rights NGOs, they could be responsible for changing physician-patient encounters in healthcare institutions. This will require a transformation of the membership structure of committees, allowing representatives of patient rights NGOs and representatives of the local community to be members, which is not the case in Croatia at the moment, as our research has shown. Improvements in this direction could also be made regarding the age of the committee members. The current average age of committee members is 50 years. Renewing membership with younger physicians, who have different approaches and experiences when encountering their patients than their older colleagues, who according to our research tend to be more paternalistic, could transform hospital ethics committees into more patient-orientated structures.

Not only could hospital ethics committees be instrumental in improving the quality of care in healthcare institutions, but they themselves should follow quality standards (28).Such an approach would also include the selection criteria for their members, putting emphasis on knowledge and expertise rather than on the social perception of the status of members in their professions or preferences of the hospital administration, which is now in the majority of cases decisive for the election of members of hospital ethics committees in Croatia, according to our data.

Adequate legal provisions, educational efforts, the introduction of mechanisms of quality control and orientation to patient rights will transform Croatian hospital ethics committees into bodies that are able to address policy formation and case consultation, functions that are now almost non-existent in the everyday work of Croatian ethics committees. The case-consultation practice of Croatian ethics committees can be further improved by the creation of databases of cases that have been subjected to ethical analysis and consultation in various hospitals. These databases could be created locally on the hospital level, where an ethics committee could register the case deliberation process and its outcomes in specific cases without identifying the committee members or patients involved. Such databases could provide a log book of committee case-consultation work. These local databases could be interconnected on the national level so that every hospital ethics committee member, when working on a specific case, can consult the database and see what the other committees recommended in similar cases. This could be a practical educational tool for committee members in the case-deliberation process. It should be underlined that the purpose of these databases would not be to interfere with the decision-making process of other committees, but rather to provide educational guidance.

In conclusion, with the changes proposed here the situation of ethics committees in Croatia could be adequately improved. Since the Croatian case, in our opinion, shows a number of similarities with other countries in transition, the proposed solution for the Croatian ethics committee problems may possibly provide a paradigm for solving similar problems in other countries in transition in Europe and the world as well.

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Summary

SUMMARY

In this thesis the work of ethics committees in Croatia is being investigated for the first time. The 1997 Law on Health Protection introduced legal standards for the establishment of the so-called "mixed" type of ethics committees in healthcare institutions. Our study aims to examine whether this top-down approach of ethics committee implementation was the right approach for Croatia and what the consequences of this approach were for the work and formation of Croatian ethics committees. The investigation is focused on the types of committees, the functions they perform in their everyday work, their membership structure. Special emphasis has been placed on the analysis of ethics committees in healthcare institutions, especially hospitals, in Croatia. Data was collected using questionnaires.

Chapter 1 provides a general background on the history, development and different types of ethics committees worldwide. It addresses specific characteristics of the Croatian situation in regard to ethics and ethics committees. The aim of the thesis is presented.

Chapter 2 gives an overview of the situation and development regarding ethical issues in medicine in the European countries in tranisiton.

Chapter 3 gives an overview of the situation and development regarding ethical issues in Croatian medicine. In Croatia, the subject of medical ethics, or bioethics, was introduced into the curriculum at the medical schools of the Universities of Rijeka and Zagreb in the early 1990s. Today, bioethics education has become a basic part of undergraduate medical education not only in Rijeka and Zagreb but also in Osijek. In 1997 legal provisions for the establishment of ethics committees in healthcare institutions were provided by the Law on Health Protection. In 2001 the National Bioethics Committee of the Government of the Republic of Croatia was founded. However, some issues have been a continuing source of legal and ethical problems. In future, improvements can be made in this area. We conclude that developments regarding ethics issues in medicine are well on track in Croatia, but a lot of work remains to be done, especially on the educational and legal levels.

Chapter 4 presents the first of the three surveys into the work of Croatian ethics committees described in this thesis. This first exploration was undertaken in 2002/2003 by the National Ethics Committee for Medicine of the Government of the Republic of Croatia. In Croatia, ethics committees are legally required in all healthcare institutions by the Law on Health Protection. A cross-sectional survey of healthcare institutions (excluding pharmacies and home care institutions) was undertaken to identify all the ethics committees six years after the implementation of the Law on Health Protection. This first survey studied the structure,

functions and legal provisions as well as the different types of ethics committees in Croatian healthcare institutions. The data was obtained from the replies of the committees to a circular letter and a questionnaire distributed by the National Bioethics Committee. The results show that 46% of the healthcare institutions in Croatia (excluding pharmacies and home care institutions) have ethics committees. 89% of the ethics committees have 5 members, 3 of whom are from medical professions and 2 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. Although there are legal provisions for ethics committees in healthcare institutions in Croatia, there is evidence of discrepancies between what happens in practice as opposed to what is required by the Law on Health Protection, suggesting the need for a revision of the law. There is also a need for creating separate networks of HECs and IRBs in Croatia. In comparison with other countries, the development of ethics committees in Croatia demonstrates some similarities with other transitional societies in Europe.

Chapter 5 deals with the education of ethics committee members in Croatia. It presents the first educational workshop ever for members of ethics committees in healthcare institutions, held in Zagreb in 2003, together with the survey that was performed during this workshop. The objective of this survey was to study the knowledge and attitudes of hospital ethics committee members who attended the first workshop for ethics committees in Croatia (all of them came from hospital ethics committees). This survey was a pilot-study project with the purpose to test a specially designed questionnaire and highlight the main problems and issues in the work of hospital committees. It took the form of a before/after cross-sectional study using a self-administered questionnaire specially developed for this purpose. The main outcome measurements were the knowledge and attitudes of the participants before and after the workshop, and the everyday functioning of hospital ethics committees. The majority of the respondents came from committees with at least 5 members (at least two physicians). The majority of the ethics committees were elected by the governing bodies of their hospitals. Most committees were founded after the implementation on the Law on Health Protection in 1997. The membership structure (3 physicians + 2 members from other fields) and functions were copied from these legal provisions. Analysis of research protocols was the main part of their work (in 56 cases), thus neglecting the other functions important for a hospital ethics committee: education, case analysis, guidelines formation. The level of knowledge of the members was average, but not sufficient for the complicated tasks that they were supposed to perform in their everyday work. However, it was significantly higher after the workshop. The

majority of respondents felt that their knowledge should be improved by additional education. Their views on certain issues and bioethical dilemmas displayed a high level of paternalism and over-protectiveness of their patients, and that did not change after the workshop. The data presented provides some impressions on the current situation in Croatia regarding the knowledge and attitudes of the members of hospital ethics committees. A bureaucratic pattern of the development of the committees was observed. Furthermore, concerns are raised about the knowledge levels of members of hospital ethics committees. More effort needs to be made to use education as a possible factor in improving the quality of their work. The findings regarding the everyday work of the committees were consistent with the findings of the 2002/ 2003 study of the National Bioethics Committee for Medicine in the Republic of Croatia.

Chapter 6 presents an in-depth analysis of the work of hospital ethics committees in Croatia. A specially designed questionnaire was used for this purpose. This was the third survey performed into the work of ethics committees in Croatia. The objective of the survey was to study the work and membership structure of hospital ethics committees in Croatia. It was a cross-sectional study using a self-administered questionnaire specially developed for this purpose. The questionnaire was sent by mail to all members of ethics committees in Croatian hospitals. The response rate by mail was 60%. The main outcome measurements were the knowledge and attitudes of the participants as well as the everyday functioning of hospital ethics committees. The results show that the structure and composition of the hospital ethics committees are highly legalistic and formal. Most of them were formed after 1997, in the wake of the introduction of legal provisions for ethics committees in Croatia. In the majority of cases, the number of members and their occupation were an exact replica of the structure of the committees required by the law (3 physicians + 2 members of other professions, of whom lawyers and theologians were the most likely candidates for membership). As in previous surveys, our data also show that the main task of the ethics committees in hospitals was an analysis of research protocols, thus neglecting the other functions important for a hospital ethics committee: education, case analysis, guidelines formation. The level of knowledge of the members was average, but not sufficient for the complicated tasks that they were supposed to perform in their everyday work. Their views on certain issues and bioethical dilemmas displayed a high level of paternalism and over-protectiveness of their patients. The majority of the members who participated in our survey were 50 years and older with, in most cases, no formal education in the field of bioethics.

Chapter 7 comprises the evaluation of the results of the three previously described surveys in this thesis. The aim was to analyse the structural ethics issues observed in the work

of ethics committees in Croatia. On the basis of bioethics literature discussed in Chapter 1 and experiences from other countries, the findings regarding ethics committees in Croatia are critically examined. The findings show that in the European countries in transition, like Croatia, the healthcare system has a bureaucratic climate and approach. Ethics committees in such a climate are bureaucratically constituted entities whose functions mainly comprise the analysing of research protocols. The members of hospital ethics committees tend to have insufficient knowledge of ethical issues as well as a paternalistic approach. Ignoring human relationships and treating patients insufficiently as persons can strain both the providers and users of healthcare, creating unresolved issues and tensions as well as ethical problems.

Chapter 8 gives an overview of worldwide experiences in hospital ethics committees' education with the description of current problems and approaches. Croatian situation of ethics committees' education is also discussed. Possible solutions and approaches in ethics committees' education for transitional societies with special emphasis on Croatian healthcare system are discussed.

Chapter 9 concludes the thesis with a discussion on the findings obtained from the previously described studies. It also provides recommendations for further improvement of the work of ethics committees in Croatia. Possible changes in policies and legal frameworks are also discussed.

Samenvatting

SAMENVATTING

In dit proefschrift wordt voor het eerst het werk van ethiek commissies in Kroatië onderzocht. De Wet op Gezondheidsbehoud (*Law on Health Protection*) uit 1997 introduceerde wettelijke richtlijnen voor het vestigen van zogenaamde 'gemengde' ethiek commissies in gezondheidszorginstellingen. Onze studie wil onderzoeken of deze top down benadering van implementatie van ethiek commissies de juiste benadering was voor Kroatië, en wat de gevolgen van deze benadering waren voor het werk en de vorming van Kroatische ethiek commissies. Het onderzoek richt zich op het type van commissies, functies die deze vervullen in het dagelijks werk alsmede de structuur van lidmaatschap. Speciale nadruk is gelegd op de analyse van ethiek commissies in gezondheidszorginstellingen, in het bijzonder ziekenhuizen. Gegevens werden verzameld door middel van vragenlijsten.

Hoofdstuk 1 biedt een algemene achtergrond van de geschiedenis, ontwikkeling en verschillende typen ethiek commissies wereldwijd. Het behandelt specifieke kenmerken van de Kroatische situatie met betrekking tot ethiek en ethiek commissies. Het doel van het proefschrift wordt gepresenteerd.

In hoofdstuk 2 wordt een overzicht gegeven van de ontwikkeling en de huidige situatie betreffende ethische kwesties in de geneeskunde in postcommunistische Europese landen.

Hoofdstuk 3 geeft een overzicht van de situatie en ontwikkeling met betrekking tot ethische kwesties in de Kroatische geneeskunde. In Kroatië werd het onderwerp medische ethiek, of bio-ethiek, in het curriculum ged'ntroduceerd in het begin van de jaren 90 op de medische faculteiten van de universiteiten van Rijeka en Zagreb. Vandaag de dag is bio-ethiek een basaal onderdeel van het preklinisch onderwijs geworden, niet alleen in Rijeka en Zagreb, maar ook in Osijek. In 1997 werden wettelijke voorzieningen getroffen voor het oprichten van ethiek commissies in gezondheidszorginstellingen in de Wet op Gezondheidsbehoud. In 2001 werd de Nationale Ethiek Commissie van de Regering van de Republiek Kroatië opgericht. Echter, sommige onderwerpen zijn een voortdurende bron van wettelijke en ethische problemen geweest. In de toekomst kunnen verbeteringen op dit gebied doorgevoerd worden. Onze conclusie is dat ontwikkelingen op het gebied van medisch ethische kwesties goed op koers zijn in Kroatië, maar dat er nog veel werk verzet moet worden, in het bijzonder op het vlak van educatie en wetgeving.

Hoofdstuk 4 presenteert het eerste van drie onderzoeken naar het werk van ethiek commissies in Kroatië die in dit proefschrift beschreven worden. De eerste verkenning werd ondernomen in 2002-2003 door de Nationale Medische Ethiek Commissie van de Republiek Kroatië. Ethiek commissies zijn wettelijk verplicht in Kroatië voor alle gezondheidszorg

instellingen vanwege de Wet op Gezondheidsbehoud. Er werd een inventariserend onderzoek gedaan van de gezondheidszorginstellingen (met uitsluiting van apotheken en thuiszorg instellingen) om alle ethiek commissies in kaart te brengen, zes jaar na het van kracht worden van de Wet op Gezondheidsbehoud. Dit eerste onderzoek bestudeerde de structuur, functies en wettelijke voorzieningen en verschillende soorten van ethiek commissies in Kroatische gezondheidszorginstellingen. De gegevens werden verkregen uit antwoorden van de commissies op een rondschrijven en vragenlijst die werd verstuurd door de Nationale Bio-ethiek Commissie. Uit de resultaten wordt duidelijk dat 46% van de gezondheidszorginstellingen in Kroatië (met uitsluiting van apotheken en thuiszorg instellingen) ethiek commissies hebben. 89% van de ethiek commissies hebben 5 leden, waarvan 3 uit de medische beroepsgroep en 2 uit andere velden. 49% van deze commissies berichtten dat hun belangrijkste functie bestaat uit de analyse van onderzoeksprotocollen. Slechts een klein deel van die ethiek commissies stuurde statuten, richtlijnen voor het werk of andere documenten die aan hun werk gerelateerd zijn in. Hoewel er wettelijke voorzieningen zijn voor de ethiek commissies in de gezondheidszorginstellingen in Kroatië, blijkt dat er discrepanties zijn tussen de praktijk en de Wet op Gezondheidsbehoud, die vragen om een herziening van de wet. Er is behoefte aan het opzetten van gescheiden netwerken van HEC's en IRB's in Kroatië. In vergelijking met andere landen, zijn er bepaalde overeenkomsten tussen de ontwikkeling van ethiek commissies in Kroatië en andere overgangssamenlevingen in Europa.

Hoofdstuk 5 handelt over de scholing van leden van ethiek commissies in Kroatië. Het doet verslag van de eerste scholingsbijeenkomst die ooit gehouden is voor leden van ethiek commissies in zorginstellingen in Zagreb in 2003, samen met het onderzoek dat tijdens deze workshop werd uitgevoerd. Het doel van dit onderzoek was om de kennis en attitude in kaart te brengen van de leden van ethiek commissies van ziekenhuizen die aanwezig waren bij de eerste workshop voor ethiek commissies in Kroatie (allen afkomstig uit ethiek commissies van ziekenhuizen). Dit onderzoek was een pilot-study om een speciaal ontworpen vragenlijst te testen en de belangrijkste problemen en onderwerpen in het werk van de ziekenhuiscommissies naar voren te halen. Het was een voor/na inventariserend onderzoek aan de hand van een zelfrapporterende vragenlijst die speciaal voor dit doel ontwikkeld werd. De belangrijkste uitkomstmetingen betroffen de kennis en attitude van de deelnemers voor en na de workshop, het dagelijks functioneren van ethiek commissies van ziekenhuizen. De meerderheid van de respondenten was afkomstig uit commissies met minstens vijf leden (minstens twee artsen). De meerderheid van ethiek commissies werd gekozen door de besturen van hun ziekenhuizen. De meeste commissies waren opgericht nadat de Wet op Gezondheidsbehoud van 1997 van

kracht was geworden. De structuur van het lidmaatschap (3 artsen en 2 leden uit andere velden) en functies werden overgenomen uit de wettelijke voorzieningen. De analyse van onderzoeksprotocollen was het belangrijkste deel van hun werk (in 56 gevallen), waarbij andere functies die voor ethiek commissies in ziekenhuizen van belang zijn, worden veronachtzaamd: scholing, casus-analyse, het opstellen van richtlijnen. Het kennisniveau van de leden was gemiddeld maar niet voldoende voor de ingewikkelde taken die zij geacht werden uit te voeren in hun dagelijks werk. Het was echter beduidend hoger na de workshop. De meerderheid van de respondenten was van mening dat hun kennis verder verbeterd zou moeten worden door verdere scholing. Hun meningen over bepaalde onderwerpen en bio-ethische dilemma's toonde een hoge mate van paternalisme, en over-bescherming van hun patiënten en zij veranderden niet na de workshop. De gegevens die gepresenteerd zijn geven enige indruk van de huidige situatie in Kroatië met betrekking tot de kennis en attitudes van de leden van ethiek commissies in ziekenhuizen. Er werd een bureaucratisch patroon van ontwikkeling van de commissies waargenomen. Verder werden er zorgen uitgesproken over het kennisniveau van de leden van ethiek commissies in ziekenhuizen. Er moeten meer pogingen ontwikkeld worden om scholing in te zetten als een mogelijke factor om de kwaliteit van het werk te verbeteren. De bevindingen met betrekking tot het dagelijks werk van de commissies waren in overeenstemming met de bevindingen van de studie uit 2002/2003 van de Nationale Bio-ethiek Commissie voor geneeskunde in de Republiek Kroatië.

In hoofdstuk 6 wordt een diepteanalyse gepresenteerd van het werk van ethiek commissies van ziekenhuizen in Kroatië. Voor dit doel werd een speciaal ontworpen vragenlijst gehanteerd. Dit was het derde onderzoek naar het werk van ethiek commissies in Kroatië. Het doel van het onderzoek was het werk en de structuur van lidmaatschap bestuderen van ethiek commissies in ziekenhuizen in Kroatië. Het was een inventariserend onderzoek waarbij een zelf rapporterende vragenlijst werd gebruikt die speciaal voor dit doel ontwikkeld was. De vragenlijst werd per post verstuurd naar alle leden van ethiek commissies in Kroatische ziekenhuizen. Van 60% werd per post een antwoord ontvangen. De belangrijkste uitkomst van de metingen waren kennis en attitudes van deelnemers en het dagelijks functioneren van ethiek commissies van ziekenhuizen. De resultaten laten zien dat de structuur en de samenstelling van ethiek commissies in ziekenhuizen zeer legalistisch en formeel zijn. De meeste van hen werden opgericht na de invoering van de wettelijke voorzieningen voor ethiek commissies in Kroatië (na 1997). Het aantal leden en hun beroep weerspiegelden in de meeste gevallen exact de structuur van de commissies die door de wet vereist zijn (3 artsen en 2 andere beroepen, waarvan juristen en theologen de meest voor de hand liggende kandidaten voor lidmaatschap zijn). Evenals in

eerdere onderzoeken laten onze gegevens ook zien dat de belangrijkste taak van ethiek commissies in ziekenhuizen de analyse van onderzoeksprotocollen was, waarbij andere functies die voor ethiek commissies in ziekenhuizen van belang zijn worden veronachtzaamd: scholing, casus-analyse, het opstellen van richtlijnen. Het kennisniveau van de leden was gemiddeld maar niet voldoende voor de ingewikkelde taken die zij geacht werden uit te voeren in hun dagelijks werk. Hun meningen over bepaalde onderwerpen en bio-ethische dilemma's toonde een hoge mate van paternalisme, en over-bescherming van hun patiënten. De meerderheid van de leden die aan ons onderzoek meededen waren 50 jaar en ouder met, in de meeste gevallen, geen officiële opleiding in het veld van de bio-ethiek.

Hoofdstuk 7 bestaat uit de evaluatie van de resultaten van de drie hierboven in dit proefschrift beschreven onderzoeken. Het doel was om de structurele ethische kwesties te analyseren die waargenomen werden in het werk van ethiek commissies in Kroatië. Op basis van de bio-ethische literatuur die in Hoofdstuk 1 is besproken en ervaringen van andere landen worden de bevindingen met betrekking tot ethiek commissies in Kroatië kritisch onderzocht. De bevindingen tonen dat in Europese landen in een overgangsperiode, zoals Kroatië, het gezondheidszorgsysteem een bureaucratisch klimaat en benadering kent. Ethiek commissies in een dergelijk klimaat zijn bureaucratisch gevormde grootheden waarvan de functie voornamelijk bestaat uit het analyseren van onderzoeksprotocollen. Leden van ethiek commissies van ziekenhuizen hebben doorgaans onvoldoende kennis van ethische kwesties en hebben een paternalistische benadering. Het veronachtzamen van menselijke relaties en het fenomeen dat patiënten niet voldoende als personen behandeld worden levert spanning op voor zowel zorgverleners als zorgontvangers, hetgeen onopgeloste kwesties en spanningen en ethische problemen schept.

In hoofdstuk 8 wordt een overzicht gepresenteerd van de wereldwijde ervaringen in het onderwijs aan medisch ethische commissies samen met een beschrijving van de huidige problemen en benaderingen. De Kroatische situatie voor wat betreft onderwijs aan medisch ethische commissies wordt ook bediscussieerd. Tevens worden mogelijke oplossingen en benaderingen aangaande onderwijs aan medisch ethische commissies in postcommunistische Europese landen (met name Kroatië) bediscussieerd.

Hoofdstuk 9 sluit het proefschrift af met een bespreking van de bevindingen die werden verkregen door middel van de beschreven onderzoeken. Het biedt ook aanbevelingen voor verdere verbetering van het werk van ethiek commissies in Kroatië. Mogelijke veranderingen in beleid en wettelijk raamwerk worden besproken.

Sažetak

SAŽETAK

U ovoj se tezi studiji po prvi puta istražuje rad etičkih povjerenstava u Hrvatskoj. Zakon o zdravstvenoj zaštiti iz 1997. godine prvi je puta postavio pravne standarde za osnivanje i rad tzv. „mješovitih" etičkih povjerenstava u zdravstvenim ustanovama. Naše istraživanje ima za cilj istražiti je li ovakav pristup osnivanju etičkih povjerenstava bio primjeren za Hrvatsku i koje su posljedice takvoga pristupa na daljnje djelovanje hrvatskih etičkih povjerenstava. Istraživanje se bavi tipovima povjerenstava, njihovim zadaćama koje obavljaju u svakodnevnom radu, strukturom članstva. Posebna je pažnja posvećena analizi etičkih povjerenstava u zdravstvenim ustanovama, napose bolnicama u Hrvatskoj. Podatci su skupljeni na osnovi upitnika.

Prvo poglavlje daje opći uvod u povijest, razvoj i različite tipove etičkih povjerenstava širom svijeta. Ovo se poglavlje također bavi i specifikumom hrvatske situacije u odnosu na rad etičkih povjerenstava, te se ukratko izlaže i cilj ove teze.

Drugo poglavlje daje pregled razvoja biomedicinske etike uz pregled značajnih problema iz tog područja u Europskim tranzicijskim zemljama.

Treće poglavlje daje pregled vezan uz etička pitanja u Hrvatskoj medicini. U Hrvatskoj je nastava iz medicinske etike prvi put uvedena 1990-ih godina na Medicinskome fakultetu Sveučilišta u Rijeci i medicinskome fakultetu Sveučilišta u Zagrebu. Danas je bioetička edukacija postala sastavnim dijelom dodiplomske nastave ne samo u Rijeci i Zagrebu nego i u Osijeku. Godine 1997. je Zakon o zdravstvenoj zaštiti donio pravne osnove za uspostavu etičkih povjerenstava u zdravstvenim ustanovama. Godine 2001. osnovano je Nacionalno bioetičko povjerenstvo za medicinu Vlade Republike Hrvatske. Ipak, neka pitanja i dalje su izvor niza etičkih i pravnih problema. Možemo zaključiti da je razvoj brige o etičkim pitanjima u medicini u Hrvatskoj krenuo u pravome smjeru, ali ostalo je još dosta posla za obaviti, posebice u području edukacije i pravne regulative.

Četvrto poglavlje prvo je od triju istraživanja rada hrvatskih etičkih povjerenstava koja su opisana u ovoj tezi. Prvo istraživanje provelo je 2002./2003. Nacionalno bioetičko povjerenstvo za medicinu Vlade Republike Hrvatske. Zdravstvene ustanove, prema hrvatskom zakonu, trebaju imati etička povjerenstva. Presječna studija zdravstvenih ustanova (isključujući ljekarne i ustanove za njegu u kući) provedena je šest godina nakon implementacije Zakona o zdravstvenoj zaštiti kako bi se identificirala sva etička povjerenstva. Ova prva studija bavila se strukturom, zadaćama, zakonskom regulativom i različitim tipovima etičkih povjerenstava u hrvatskim zdravstvenim ustanovama. Podatci su dobiveni na osnovi odgovora povjerenstava na pitanja postavljena u cirkularnome pismu koje je uputilo Nacionalno bioetičko povjerenstvo.

Rezultati pokazuju da 46 zdravstvenih institucija u Hrvatskoj (izuzev ljekarni i ustanova za njegu u kući) ima etičko povjerenstvo. Među njima 89% etičkih povjerenstava ima 5 članova, od kojih su 3 iz medicinskih profesija, a 2 iz drugih područja; 49% povjerenstava svojom osnovnom funkcijom navodi analizu protokola kliničkog istraživanja. Samo je mali dio povjerenstava poslao svoje statute, poslovnike ili slične dokumente koji usklađuju njihov rad. Iako u Hrvatskoj postoji pravna regulativa vezana za rad etičkih povjerenstava, postoje naznake o razlikama između svakodnevne prakse u radu povjerenstava i Zakona o zdravstvenoj zaštiti. Stoga je nužna revizija postojeće zakonske regulative iz toga područja. Postoji potreba za stvaranjem odvojenih mreža kliničkih etičkih povjerenstava i istraživačkih etičkih povjerenstava u Hrvatskoj. U usporedbi s drugim zemljama, razvoj etičkih povjerenstava u Hrvatskoj ima sličnosti s razvojem etičkih povjerenstava u nekim europskim tranzicijskim zemljama.

Peto se poglavlje bavi edukacijom članova etičkih povjerenstava u Hrvatskoj. Ono prikazuje prvu edukacijsku radionicu za članove etičkih povjerenstava u zdravstvenim ustanovama, održanu u Zagrebu u 2003., te istraživanje koje je provedeno tijekom te radionice. Cilj je tog istraživanja bio istražiti znanje i stavove članova bolničkih etičkih povjerenstava koji su sudjelovali u radu prve radionice za članove etičkih povjerenstava u Hrvatskoj (većina sudionika bili su članovi bolničkih etičkih povjerenstava). To je istraživanje ujedno bilo i pilot-studija namijenjena testiranju posebno sastavljenog upitnika. Studijom se nastoji upozoriti na glavne probleme u radu bolničkih etičkih povjerenstava. Bilo je to prije/poslije presječno istraživanje u sklopu kojega je upotrebljavan posebno za tu svrhu sastavljen upitnik. Glavne mjere ishoda bili su znanje i stavovi sudionika prije i poslije radionice, te svakodnevni rad bolničkih etičkih povjerenstava. Većina ispitanika bili su članovi povjerenstava koja su imala 5 članova (s najmanje 2 člana liječnika). Većinu članova etičkih povjerenstva birala su upravna vijeća bolnica. Većina je povjerenstava osnovana nakon donošenja Zakona od zdravstvenoj zaštiti 1997. godine. Struktura članstva (3 liječnika + 2 člana iz drugih struka) te zadaće povjerenstava preslikana je iz pravne regulative. Analiza protokola kliničkih istraživanja bila im je osnovna zadaća (u 56 slučajeva), te su tako zapostavljali svoje ostale zadaće važne za bolnička etička povjerenstva: edukaciju, analizu slučajeva i pisanje naputaka. Razina znanja članova povjerenstava bila je zavidna, ali ne i zadovoljavajuća s obzirom na kompleksnost njihovih svakodnevnih zadaća. Većina ispitanika bila je mišljenja da bi se njihovo znanje trebalo usavršiti dodatnom edukacijom. Stavovi članova povjerenstava o raznim bioetičkim pitanjima pokazivali su visoku razinu paternalizma i pretjerane brige za pacijente. Njihovi se stavovi nisu bitno promijenili nakon radionice. Skupljeni podatci daju određene dojmove o sadašnjoj situaciji u Hrvatskoj vezanoj uz znanje i stavove članova bolničkih etičkih povjerenstava. Zamijećen je

bio birokratski pristup osnivanju povjerenstava. Također, razina znanja članova bolničkih etičkih povjerenstava daje razloga za zabrinutost. Više bi pažnje u budućnosti trebalo posvetiti edukaciji, čimbeniku koji bi moga povoljno utjecati na rad bolničkih etičkih povjerenstava. Podatci o svakodnevnom radu povjerenstava bili su konzistentni s onima prikupljenim u studiji 2002./ 2003. Nacionalnog bioetičkog povjerenstva za medicinu u Republici Hrvatskoj.

Poglavlje šesto obuhvaća podrobnu analizu rada bolničkih etičkih povjerenstava u Hrvatskoj. Posebno sastavljen upitnik upotrijebljen je u tom istraživanju. To je treće istraživanje vezano uz rad etičkih povjerenstava u Hrvatskoj. Cilj je istraživanja bio analizirati rad i strukturu članstva bolničkih etičkih povjerenstava u Hrvatskoj. Bilo je to također presječno istraživanje u kojem je upotrijebljen posebno sastavljen upitnik. Upitnik je bio poslan svim članovima bolničkih etičkih povjerenstava u Hrvatskoj – njih 60% sudjelovalo je u tom istraživanju ispunivši upitnik. Glavne mjere ishoda bili su znanje i stavovi sudionika, te svakodnevni rad povjerenstava. Istraživanje pokazuje da su struktura i sastav povjerenstava krajnje legalistički i formalni. Većina ih je osnovana nakon uvođenja pravne regulative za rad etičkih povjerenstava u Hrvatskoj (nakon 1997.). Broj članova pojedinog povjerenstva i njihova zanimanja točna su preslika strukture članstva koja je propisana zakonskom regulativom (3 liječnika + 2 iz druge struke, od kojih su pravnici i teolozi česti članovi povjerenstva). Kao i u prethodnim istraživanjima, i ovi podatci upućuju na to da je glavna zadaća povjerenstava analiza protokola kliničkih istraživanja, te de se zanemarene ostale zadaće važne za rad bolničkih etičkih povjerenstava: edukacija, analiza protokola i pisanje naputaka. Razina znanja članova povjerenstava bila je zadovoljavajuća, ali nedostatna za slojevite zadaće koje oni trebaju svladavati u svojemu svakodnevnom radu.Njihovi pogledi na određene bioetičke dileme pokazuju visoku razinu paternalizma. Većina članova povjerenstava koja je sudjelovala u ovom istraživanja u životnoj je dobi od pedeset godina ili više, te nema formalne edukacije iz bioetike.

Poglavlje sedmo sastoji se od evaluacije prethodnih triju istraživanja u ovoj tezi. Cilj je toga poglavlja analizirati strukturalna etička pitanja u radu etičkih povjerenstava u Hrvatskoj. Na osnovi bioetičke literature prikazane u prvome poglavlju te na osnovi iskustava drugih zemalja kritički su razmotreni podatci dobiveni istraživanjem rada etičkih povjerenstava u Hrvatskoj. Istraživanja pokazuju da u europskim tranzicijskim društvima poput Hrvatske zdravstveni sustav odiše birokratskom klimom i pristupom. Etička povjerenstva u takvoj su klimi birokratski konstituirana tijela čija je osnovna zadaća analiza protokola kliničkog istraživanja. Članovi etičkih povjerenstava često nemaju dovoljno znanja i često imaju paternalistički pristup pacijentu. Ignoriranje ljudskih odnosa i nedovoljno posvećivanje pažnje

pacijentima kao osobama, može imati opterećujući učinak i na korisnike i na pružatelje zdravstvenih usluga stvarajući tako niz neriješenih pitanja, tenzija i etičkih problema.

Poglavlje osmo daje preglde svjetskih iskustava vezanih uz edukaciju etičkih povjerenstava uz opis percipiranih problema i raznih pristupa njihovu riješenju. Razmatra se i hrvatska situacija vezana uz edukaciju etičkih povjerenstava. Moguća riješenja i pristupi edukaciji etičkih povjerenstava raspravljeni su uz poseban naglasak na tranzicijskim društvima.

Deveto poglavlje završno je poglavlje teze u kojemu se analiziraju podatci prije toga opisanih studija. Također, u tomu se poglavlju nalaze i prijedlozi za daljnje unapređenje rada etičkih povjerenstava u Hrvatskoj. Razmatraju se i moguće promjene pravne regulative.

CURRICULUM VITAE

Ana Borovečki was born on in Zagreb, Croatia on 9 October 1973. She graduated from secondary school (Gymnasium Classicum Zagrabiense) in 1992. In 1998 she graduated from the University of Zagreb Medical School with a Doctor of Medicine degree. In 2000 she also obtained her degree in Philosophy and Comparative Literature from the University of Zagreb Faculty of Philosophy. During her medical studies she received the Rector's award of the University of Zagreb in 1998 for her research paper *Philosophical influences of Gjuro Armeno Baglivi in «De fibra motrice et morbosa»*. As a member of EMSA (European Medical Students' Association), she was the GFTD (General Task Forces Director) in the EMSA European Board in 1997 and the EMSA Zagreb coordinator from 1992 to 1998. She was also the founder and international secretary of the Students' Section of the Croatian Medical Association. In the course of 1998 and 1999 she completed her one-year internship in medicine in Croatia and passed the medical licensure exam. From 1999 to 2001 she worked as a research assistant at the Department of History of Medicine of the Croatian Academy of Sciences and Arts. From 2002 to 2004 she participated in the European Master in Bioethics programme organized conjointly by the Universities of Nijmegen, Leuven, Basel and Padova; she obtained the Master in Bioethics degree with *magna cum laude*. In 2003 she started her PhD studies at the University Medical Center Nijmegen at the Department of Ethics, Philosophy and History of Medicine, where she conducted the research described in this thesis. She is currently working as a research assistant at the Andrija Štampar School of Public Health of the University of Zagreb Medical School. She is in her fourth year of specialty training in clinical pharmacology. She is a member of the Croatian Medical Association and the Croatian Philosophical Society.