



A CRITICAL ANALYSIS OF CROATIAN HOSPITAL ETHICS COMMITTEES: OPPORTUNITY OR BUREAUCRATIC *CUL-DE-SAC*?

Ana BOROVEČKI
"Andrija Štampar" School of Public Health, Zagreb
Henk ten HAVE
Radboud University Medical Centre Nijmegen, Nijmegen
Stjepan OREŠKOVIĆ
"Andrija Štampar" School of Public Health, Zagreb
UDK: 614.253(497.5)
174:61](497.5)
Izvorni znanstveni rad
Primljeno: 20. 6. 2005.

The objective of our investigation was to study the work and membership structure of the hospital ethics committees in Croatia. The main goals were examining the knowledge and attitudes of participants and everyday functioning of hospital ethics committees. Results show that 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. 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. 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. The level of the members' knowledge is average but insufficient for the complicated tasks that they are supposed to perform. Their views on certain issues and bioethical dilemmas display a high level of paternalism and overprotectiveness of their patients. The majority of respondents are 50 years and older with, in most cases, no formal education in the field of bioethics.

Key words: hospital ethics committees, Croatia

✉ Ana Borovečki, "Andrija Štampar" School of Public Health,
Medical School, University of Zagreb, Rockefellerova 4,
10 000 Zagreb, Croatia.
E-mail: abor@mef.hr

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 ethics 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 (Levine, 2004).

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 (Drane, 1994); hospitals are expected to have them in order to receive required professional accreditation (JCAHO, 1996). 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 (Wilson Ross et al., 1993a).

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 (Tschudin, 2001). However, the type, level and mode of establishment of clinical ethics committees varies from country to country (Lebeer, 2002). In some European countries e-

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

ethics committees that combine both the functions of HECs and IRBs can be found (Glasa, 2000a). Such ethics committees are of the "mixed" type (Carbannelle, 2002).

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

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 (Borovečki et al., 2004).

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. On 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 (Borovečki et al., 2006). 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 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 (Wilson Ross et al., 1993a) 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 (Wilson Ross et al., 1993a).

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

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

🔍 TABLE 1
The functions that
ethics committees
performed in their
everyday work

🔍🔍 TABLE 2
Issues dealt with in the
everyday work of
ethics committees

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.

| 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).

| 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 |

TABLE 3
Questions about the everyday work of the committees

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.

| 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

TABLE 4
The level of self-assessment of respondents' knowledge about different bioethical issues

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

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

| 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 |

| Field | C ± Q |
|---|-------------|
| 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 |

TABLE 4 (continued) (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).

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: analysis 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 |

| Question and correct answers (T-true, F-false) | Correct answers |
|---|-----------------|
| 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 |

TABLE 5 (continued) * 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

TABLE 6
The level of agreement with statements regarding bioethical issues

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

| 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 |

| Statement | C ± Q |
|---|-------------|
| 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 |

TABLE 6 (continued) (Tested on 66 respondents before the workshop; 1 = "I completely disagree", 5 = "I completely agree")

DISCUSSION

1229

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 (Wilson Ross et al., 1993a). 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 (Drane, 1994). 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 (Millspaugh, 1995). A larger number of members can lead to a division of

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

the committee's work between different subcommittees that have special tasks, thus distributing the work of the committee and making it more efficient (Jiwani, 2001). However, some authors suggest that the committees should not have more than 10 members in order to be expedient and focused on their tasks (Drane, 1994). 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 (Craig et al., 1998), 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 select and appoint 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 from the local communities or priests who were hospital chaplains. At present, in Croatia there

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

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 (Smith, 1998 and Buehler, 1998). 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 multidisciplinary of its membership (Slomka, 1998).

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 (Census from 2003).

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

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 (Vrhovac, 1998). 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 Medical Products in 2003 (*Zakon o lijekovima i medicinskim proizvodima*, 2003). The majority of analyses of research protocols are now centralized at the Drug Agency and 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 edu-

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

cation 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

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

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 (Orešković, 1998).

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 (Glasa, 2000b). 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.

ACKNOWLEDGEMENTS

1234

Many thanks to Darko Hren and the National Bioethics Committee for Medicine of the Government of the Republic of Croatia, without whose support and help with data analysis this paper could not have been written.

REFERENCES

- Borovečki, A., ten Have, H., Orešković, S. (2004), Developments Regarding Ethical Issues in Medicine in the Republic of Croatia, *Cambridge Quarterly of Healthcare Ethics*, 13 (3): 263-6.
- Borovečki, A., ten Have, H., Orešković, S. (2006), Education of ethics committee members: experiences from Croatia, *Journal of Medical Ethics*, 32 (3): 138-142.
- Buehler, D. A., DiVita, R. M., Yium, J. J. (1998), Hospital Ethics Committees: The Hospital Attorney's Role. In: S. F. Spicker (ed.), *The Healthcare Ethics Committee Experience* (p. 185-194), Malabar Florida: Krieger Publishing Company.
- Carbonnelle, S. (2002), Belgian hospital ethics committees: from law to practice. In: G. Lebeer (ed.), *Ethical Function in Hospital Ethics Committees* (p. 19-34), Amsterdam Berlin Oxford Tokyo Washington DC: IOS Press.
- Craig, R. P., Middleton, C. L., O'Connell, L. J. (1998), What is an ethics committee and who are its members: membership and structure. In: R. P. Craig, C. L. Middleton, L. J. O'Connell; *Ethics committees [in Croatian]* (p. 5-11), Zagreb (Croatia): Pergamena.
- Drane, J. F. (1994), Basic Facts about Health Care Ethics Committees. In: J. F. Drane, *Clinical Bioethics* (p. 1-16), Kansas City; Sheed and Ward.
- Glasa, J. (2000a), Bioethics and the Challenges of a Society in Transition: The Birth and Development of Bioethics in Post-Totalitarian Slovakia, *Kennedy Institute of Ethics Journal*, 10 (2): 165-170.
- Glasa, J. (ed.) (2000b), *Ethics committees in Central and Eastern Europe*. Bratislava: Charis IEMB.
- Jiwani, B. (2001), *An Introduction to Health Ethics Committees: A Professional Guide for the Development of Ethics Resources*. Provincial Health Ethics Network.
- Joint Commission for Accreditation of Healthcare Organizations. 1996 Comprehensive manual for hospitals. Chicago, IL: JCAHO; 1996: 95-97.
- Levine, R. J. (2004), Research Ethics Committees. In: W. T. Reich (ed.), *Encyclopaedia of Bioethics*, Vol. IV (p. 2311-2316), New York; Macmillan Simon and Schuster.
- Lebeer, G. (2002), *Ethical function in hospital ethics committees*. Amsterdam, Berlin, Oxford, Tokyo, Washington DC: IOS Press.
- Millspaugh, D. (1995), From anonymity to respect: lessons in the establishment of bioethics forum, *HEC Forum*, 7 (1): 3-12.
- Orešković, S. (1998), New Priorities for Health Sector Reform in Central and Eastern Europe, *Croatian Medical Journal*, 39 (3): 225-233.
- Popis stanovništva 2001*. Republika Hrvatska – Državni zavod za statistiku, 2. izdanje, 2003.
- Slomka, J. (1998), The Ethics Committee: Providing Education for Itself and Others. In: S. F. Spicker (ed.), *The Healthcare Ethics Committee Experience* (p. 101-108), Malabar Florida: Krieger Publishing Company.
- Smith, M. L., Burleigh, M. D. (1998), Pastoral Care Representation on the Hospital Ethics Committee. In: S. F. Spicker (ed.), *The Healthcare Ethics Committee Experience* (p. 159-166), Malabar Florida: Krieger Publishing Company.

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

Tschudin, V. (2001), European experiences of ethics committees, *Nurs Ethics*, 8:142-51.

Vrhovac, B. (1998), *Stanje i problemi etičke regulacije u hrvatskom zdravstvu – predgovor*. In: R. P. Craig, C. L. Middleton, L. J. O'Connell, *Etički komiteti – praktični pristup* (p. 5-11), Zagreb: Pergamena.

Zakon o lijekovima i medicinskim proizvodima. *Narodne Novine* 121/2003.

Zakon o zdravstvenoj zaštiti. *Narodne Novine* 1/1997.

Zakon o zdravstvenoj zaštiti. *Narodne Novine* 121/2003.

Wilson Ross, J., Glaser, J. W., Rasinski-Gregory, D., Gibson McIver, J., Bayley, C. (1993), Taking Stock: Where Ethics Committees Originated and Where They Are Now. In: J. Wilson Ross, J. W. Glaser, D. Rasinski-Gregory, J. Gibson McIver, C. Bayley (eds.), *Health Care Ethics Committees – The next Generation* (p. 1-10), American Hospital Association.

Wilson Ross, J., Glaser, J. W., Rasinski-Gregory, D., Gibson McIver, J., Bayley, C. (1993a), Evaluation and Self-Assessment: Determining How Much Ethics Committees Need to Do. In: J. Wilson Ross, J. W. Glaser, D. Rasinski-Gregory, J. Gibson McIver, C. Bayley (eds.), *Health Care Ethics Committees – The next Generation* (p. 113-132), American Hospital Association.

KRITIČKI OSVRT NA BOLNIČKA ETIČKA POVJERENSTVA U HRVATSKOJ: NOVA PRILIKA ILI BIROKRATSKA SLIJEPA ULICA?

Ana BOROVEČKI

Škola narodnog zdravlja "Andrija Štampar", Zagreb

Henk ten HAVE

Medicinski centar Sveučilišta Radboud, Nijmegen

Stjepan OREŠKOVIĆ

Škola narodnog zdravlja "Andrija Štampar", Zagreb

Cilj istraživanja bio je proučiti rad i strukturu članstva etičkih povjerenstava zdravstvenih ustanova u bolnicama u Hrvatskoj, uz provjeru znanja i stavova ispitanika te analizu svakodnevnoga funkcioniranja bolničkih etičkih povjerenstava. Rezultati pokazuju da je pristup strukturi i sastavu bolničkih etičkih povjerenstava izrazito legalistički i formalan. Većina povjerenstava osnovana je nakon uvođenja zakonske regulative za etička povjerenstva. Struktura članstva povjerenstava preslikana je iz zakonske regulative. Kao što su pokazala i neka prethodna istraživanja, glavna funkcija bolničkih etičkih povjerenstava jest analiza protokola kliničkih istraživanja, zanemarujući ostale važne funkcije koje bi ona trebala obavljati. Ispitanici su pokazali

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

zadovoljavajući stupanj znanja s područja bioetike, ali je razina znanja još uvijek preniska za složene zadatke koje bi oni kao članovi povjerenstva trebali svakodnevno obavljati. Stavovi ispitanika o nekim bioetičkim pitanjima pokazivali su visok stupanj paternalizma i pretjerana zaštitničkog odnosa prema pacijentima. Većina članova bolničkih etičkih povjerenstava koja je sudjelovala u ovome istraživanju pripadala je dobnoj skupini od 50 godina i više i nije imala formalnog obrazovanja s područja bioetike.

Ključne riječi: bolnička etička povjerenstva, Hrvatska

Kritische Stellungnahme zur Einführung von Ethikausschüssen an kroatischen Krankenhäusern: Neue Chancen oder eine bürokratische Einbahnstraße?

Ana BOROVEČKI

Schule für Gesundheitswesen "Andrija Štampar", Zagreb

Henk ten HAVE

Radbout University Medical Centre, Nijmegen

Stjepan OREŠKOVIĆ

Schule für Gesundheitswesen "Andrija Štampar", Zagreb

Mit dieser Arbeit sollten die Tätigkeit und das Profil der Mitglieder von Ethikausschüssen an kroatischen Krankenhäusern untersucht werden. Die Hauptpunkte der Untersuchung waren Wissensstand und Ansichten der Befragten, ferner eine Analyse des Arbeitsalltags von Ethikausschüssen. Die Untersuchungsergebnisse zeigen, dass man bei der Zusammensetzung und Struktur der Ethikausschüsse an Krankenhäusern ausgesprochen legalistisch und formalistisch verfahren hatte. Die meisten Ausschüsse wurden nach Verabschiedung der entsprechenden Gesetzesgrundlage zur Regelung der Tätigkeit von Ethikausschüssen ins Leben gerufen. Die Zusammensetzung der Ausschüsse lehnt sich an die Empfehlungen der Gesetzesgrundlage an. Wie bereits aus einigen früheren Untersuchungen hervorging, besteht die Hauptfunktion von Ethikausschüssen an Krankenhäusern in der Analyse von Protokollen zu klinischen Untersuchungen, wobei aber andere wichtige Aufgaben beiseite gelassen werden. Die Befragten zeigten zufriedenstellende Kenntnisse aus dem Bereich der Bioethik, doch reicht dieses Wissen nicht aus, um den komplexen Aufgaben, mit denen die Mitglieder von Ethikausschüssen tagtäglich konfrontiert sind, gewachsen zu sein. Die Ansichten der Untersuchungsteilnehmer zu einigen bioethischen Fragen zeigten ein hohes Maß an Paternalismus und ein übertriebenes Beschützerverhältnis bezüglich der Patienten. Die meisten

DRUŠ. ISTRAŽ. ZAGREB
GOD. 15 (2006),
BR. 6 (86),
STR. 1221-1238

BOROVEČKI, A., TEN
HAVE, H., OREŠKOVIĆ, S.:
A CRITICAL ANALYSIS...

Mitglieder von Ethikausschüssen an Krankenhäusern, die an dieser Untersuchung teilnahmen, gehören zur Altersgruppe der etwa 50-Jährigen und haben keine formale Ausbildung auf dem Gebiet der Bioethik.

Schlüsselwörter: Ethikausschüsse an Krankenhäusern, Kroatien