

Developments Regarding Ethical Issues in Medicine in the Republic of Croatia

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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 structures² 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 Bošković, 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 polyclinics, 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 ethic 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.

Notes

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