

CLINICAL ETHICS IN CROATIA: AN OVERVIEW OF EDUCATION, SERVICES AND RESEARCH (AN APPEAL FOR CHANGE)

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SUMMARY – The aim of this paper is to delineate current position of clinical ethics in the Croatian healthcare system by analyzing the following: representation of clinical ethics contents in the curricula of medical and associated schools; composition and role of clinical ethics consultations; and establishment of an ethical/legal framework for the conduct of research. Curriculum investigation, literature review, and analysis of the Croatian Act on the Protection of Patients' Rights were performed. The contents of clinical ethics are offered through 63 obligatory and elective subjects at 12 institutions. It is wrongly placed either too early or too late within the curriculum. Continuity at all levels of health professional education is needed. Croatian experience with clinical ethics consultations is shaped only by ethics committees. Problematic is the review of research protocols indicated as their main activity. Inclusion of team and individual consultations would increase the availability and facilitate the usage of ethics support services. The Act on the Protection of Patients' Rights is based on the principles of humanity and availability, ensuring the right to protection when participating in clinical trials. Unfortunately, the outdated paradigm of paternalistic medicine aggravates the respect for patients' rights in cure, care and research. A shift towards the patient/person-centered healthcare system would put the Act into everyday practice. Although clinical ethics has entered the Croatian healthcare system in a formal and practical way, the authors wish to emphasize the need to approach the European and other international standards regarding the recent Croatian accession to the European Union.

Key words: Ethics, clinical; Ethics consultation; Education; Research; Croatia

Introduction

In the past decades, bioethics has indeed lived a very rich and complex history, and today clinical ethics represents its most prominent and dynamic segment. Taking into account clinical ethics' most important charac-

teristics (focus on questions of ethics in the continuous, daily care for the patient, discussions about different models of ethical decision-making in practice and the importance of education and research), Fletcher and Brody have identified three focal points of any clinical ethics program in a healthcare institution:

- education;
- services (models of ethical decision-making in clinical practice, such as consultations and policy formulation); and
- research¹.

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The aim of this paper is to delineate current position of clinical ethics in the Croatian biomedicine and healthcare system. It will focus on three key developmental moments of clinical ethics in Croatia whilst referring to the aforementioned focal points:

- representation of clinical ethics contents in the curricula of medical and associated schools;
- the composition and role of clinical ethics consultation; and
- the establishment of a moral-legal framework for the conduct of research, with special reference to the Croatian Act on the Protection of Patients' Rights from 2004.

Materials and Methods

Representation of clinical ethics contents and its position within the curricula of medicine, dentistry, organization and health management, sanitary engineering, nursing, midwifery, physiotherapy, laboratory medicine, radiology, and occupational therapy courses at 12 Croatian college and university institutions were investigated. Data were collected by analyzing curricula descriptions at official sites of the respective institutions.

Literature review on the composition and activities of clinical ethics consultation service, with special reference to the current situation in Croatian healthcare system was performed. The Croatian Act on the Protection of Patients' Rights was analyzed, with special reference to the informed consent and ethics of the research contents.

Results

Education in clinical ethics

The contents of clinical ethics is offered through the framework of 40 obligatory and 23 elective subjects regarding medical ethics, nursing ethics, healthcare ethics, bioethics and philosophy.

As the number of elective subjects significantly varies among institutions, analysis of the position within the curriculum was performed on obligatory subjects. The contents of clinical ethics is placed either at the very beginning (1st or 2nd year) in 33 (82.5%) subjects, or at the end of the curriculum (last year) in 6 (15%) subjects. The exception is the University of Split School of Medicine, which offers the contents

throughout the curriculum of medicine (2nd-6th year) in 1 (2.5%) subject (Table 1).

Clinical ethics consultations

Clinical ethics consultations (CEC) service consists of three elements: ethics committee, team consultations, and individual consultations. Each component has its own particularities (Table 2).

The Croatian experience with CEC services is shaped solely by ethics committees. Consultations by smaller consultation groups (team consultations) or consultations by individual consultants have not yet been developed. Current situation imposes reviewing scientific and clinical research protocols as an ethics committee's main activity (Table 3).

Ethics of research

The Croatian Act on the Protection of Patients' Rights from 2004 is based on two major principles: the principle of humanity and the principle of availability (articles 3-5). It regulates the following rights:

- the right of co-decision (articles 6-7),
- the right to information, and the right to refuse information (articles 8-15),
- the right to accept or refuse medical treatment or procedure (the right to informed consent in a narrower sense), with special reference to protection of rights of those incapable of consent (articles 16-18),
- the right to protection when participating in clinical trials (articles 19-21),
- the right to protection from modifications of human genome (article 22),
- the right of access to medical records (articles 23-24),
- the right to confidentiality (article 25),
- the right to maintain personal contacts (article 26),
- the right to voluntarily leave the hospital (article 27),
- the right to privacy (article 28), and
- the right to compensation (article 29).

In the system of protection of patients' rights, the Act refers to two basic levels:

- at the regional level, a committee is appointed to protect the rights of patients in each county (articles 30-37); and

Table 1. Clinical ethics contents in the curricula of medical and associated schools in Croatia

University/School	Department	Course/Subject*	Year/ECTS**
University of Zagreb School of Medicine	Divided among departments (including Andrija Štampar School of Public Health)	<u>Graduate</u> <u>Medicine</u> : Medical Ethics, <i>How to Apply Hippocratic Oath, Right to Life, Bioethics and Dignity of a Person</i> <u>Nursing</u> : Science, Philosophy and Theory in Nursing	6 th /2 1 st /10
University of Rijeka School of Medicine	Department of Social Sciences and Medical Humanities	<u>Graduate</u> <u>Medicine</u> : Medical Ethics, <i>How to Communicate (with Deaf Patients)?, Clinical Bioethics, On Health in a Different Way, Bioethics and Culture of Dialogue in Medicine, Introduction to Medical Ethics, Propaedeutics of Clinical Ethics, From Euthanasia to Dysthanasia, Medicine and Law, Media and Health Care</i> <u>Dentistry</u> : <i>Bioethics and Dental Ethics, How to Communicate (with Deaf Patients)?</i> <u>Organization and Health Management</u> : Medical Ethics, Bioethics, <i>How to Communicate (with Deaf Patients)?, On Health in a Different Way, Media and Health Care</i> <u>Sanitary Engineering</u> : <i>Bioethics</i> <u>Undergraduate</u> <u>Nursing</u> : Bioethics in Health Care <u>Midwifery</u> : Bioethics in Obstetrics with Communication Skills <u>Physiotherapy</u> : Health Ethics <u>Laboratory Medicine</u> : Medical Ethics <u>Radiology</u> : Ethics in Health Care	6 th /2 nd /2 ^{***} 1 st /3 1 st /2 1 st /5 1 st /2 1 st /2 1 st /1
University of Osijek School of Medicine	Department of Internal Medicine, Medical History and Medical Ethics	<u>Graduate</u> <u>Medicine</u> : Medical Ethics <u>Undergraduate</u> <u>Laboratory Medicine</u> : Ethics in Biomedicine	6 th /2 1 st /3
University of Split School of Medicine	Department of Medical Humanities	<u>Graduate</u> <u>Medicine</u> : Medical Humanities, <i>Historical and Ethical Aspects of Research on Human Subjects</i> <u>Dentistry</u> : Ethics and Bioethics in Dentistry, <i>Historical and Ethical Aspects of Research on Human Subjects</i> <u>Undergraduate</u> <u>Physiotherapy</u> : Ethics in Health Care <u>Nursing</u> : Philosophy and Bioethics in Health Care <u>Radiology</u> : Health Law and Ethics	2 nd -6 th /5 2 nd /2 3 rd /2 1 st /1 2 nd /1

University/School	Department	Course/Subject*	Year/ ECTS**
University of Split	Department of Health Care Studies	<u>Graduate</u>	
		<u>Nursing: Ethics in Health Care</u>	1 st /4
		<u>Physiotherapy: Ethics in Health Care</u>	1 st /4
		<u>Radiology: Ethics in Health Care</u>	1 st /4
		<u>Undergraduate</u>	
		<u>Nursing: Ethics in Health Care</u>	1 st /1.5
		<u>Midwifery: Ethics in Health Care</u>	1 st /1.5
		<u>Physiotherapy: Ethics in Health Care</u>	1 st /1.5
		<u>Radiology: Ethics in Health Care</u>	1 st /1.5
		<u>Laboratory Medicine: Ethics in Health Care</u>	1 st /1.5
University of Zadar	Department of Health Care Studies	<u>Graduate</u>	1 st /3
		<u>Nursing: Philosophy and Bioethics in Health Care</u>	
		<u>Undergraduate</u>	
		<u>Nursing: Philosophy and Bioethics in Health Care</u>	1 st /3
University of Dubrovnik	Department of Professional Studies	<u>Undergraduate</u>	
		<u>Nursing: Philosophy and Bioethics in Health Care</u>	1 st /3
University of Applied Health Studies	Divided among departments	<u>Graduate</u>	
		<u>Nursing: Clinical Nursing: Bioethics</u>	1 st /3
		<u>Nursing in Public Health: <i>Bioethics and Human Rights</i></u>	
		<u>Nursing in Psychiatry: Bioethics and Rights of Psychiatric Patients</u>	1 st /3
		<u>Nursing Management: <i>Bioethics and Human Rights</i></u>	
		<u>Undergraduate</u>	
		<u>Nursing: Ethics in Health Care</u>	1 st /2
		<u>Physiotherapy: Bioethics</u>	3 rd /2
		<u>Laboratory Medicine: Medical Ethics</u>	1 st /2.5
		<u>Radiology: Health Law and Ethics</u>	1 st /1
<u>Sanitary Engineering: <i>Bioethics</i></u>			
<u>Occupational Therapy: Bioethics in Occupational Therapy</u>	1 st /2		
Karlovac University of Applied Sciences	Department of Social Sciences and Medical Humanities of the University of Rijeka School of Medicine	<u>Undergraduate</u>	
		<u>Nursing: Bioethics in Health Care</u>	1 st /3
Lavoslav Ružička Polytechnic in Vukovar	Department of Physiotherapy	<u>Undergraduate</u>	
		<u>Physiotherapy: Bioethics</u>	3 rd /2
Polytechnic of Varaždin	/	<u>Undergraduate</u>	
		<u>Nursing: Philosophy and Bioethics in Health Care</u>	1 st /3
Polytechnic of Bjelovar	/	<u>Undergraduate</u>	
		<u>Nursing: Philosophy and Bioethics in Health Care</u>	1 st /3

ECTS = European Credit Transfer System; *courses are stated in underlying. Elective subjects are stated in *italic*; **applicable to obligatory courses; ***the subject of Medical Ethics is placed in the 2nd year of the curriculum; until the academic year 2012/2013, the subject was placed in the 6th year of the curriculum; currently, the education is offered both in the 2nd and 6th year of the curriculum.

Table 2. Main characteristics of the Clinical Ethics Consultations Service

Service	Composition	Activity	Activity contents	Environment	Time frame/limit	Administrative burden
Ethics Committee	Number varies (up to 10 members recommended)*	Retrospective and/or prospective	Education, consultations, guidelines	Far from the bedside	None	High
Team Consultation	2-3 members	Actual/current	Mainly consultations	Closer to the bedside	Low	Low
Individual Consultation	Single	In real time (here and now)	Consultations	By the bedside face-to-face	High	None

*Interdisciplinary membership is the main characteristic.

Table 3. Clinical Ethics Consultations Service in Croatia

Service	Composition	Activity	Activity contents	Environment	Time frame/limit	Administrative burden
Ethics Committee	Minimum 5 members (3 medical, 1 non-medical, 1 not from the institution)	Retrospective and/or prospective	Mainly research protocols review	Far from the bedside	None	High
Team Consultation	–	–	–	–	–	–
Individual Consultation	–	–	–	–	–	–

- at the national level, the Committee for Protection and Promotion of Patients' Rights of the Croatian Ministry of Health has been established (articles 38-40).

The concept of informed consent is considered central to the establishment of a medical-ethical-legal framework for the conduct of research. Thus, the contents regarding informed consent in a broader sense is presented all the way through articles 6-18, as an introduction to the contents of the ethics of research.

The right to protection when participating in clinical trials is regulated through articles 19-21. According to this Act, a patient should not be included in a clinical trial if the patient or his/her legal representative or guardian does not agree and sign the consent for this particular procedure. This implies that the patient/representative/guardian is fully informed about the nature, significance and type of clinical trial as well as about all the associated risks and consequences.

Discussion

Education in clinical ethics

Thanks to the efforts invested by Professor Ivan Šegota, the contents of clinical ethics was introduced to Croatian medical and nursing students at the beginning of the 1990s. He introduced the elective subject "Hippocratic Oath Today" into the curriculum for medical students of the University of Rijeka School of Medicine in the academic year 1991/1992². "Medical Ethics" as an obligatory teaching subject was introduced in the next academic year, as well as the obligatory subject "Nursing Ethics" for nursing students². This 'pioneering steps' in clinical ethics education were followed by the University of Zagreb School of Medicine in the academic year 1995/1996 and subsequently in other schools of medicine³. Currently, the contents of clinical ethics is offered through the framework of 63 obligatory and elective subjects at 12 Croatian college and university institutions⁴⁻¹⁶.

The situation in everyday clinical practice leaves space for redefining the educational method itself, although clinical ethics contents is offered through education in medical ethics, nursing ethics, health-care ethics, bioethics and philosophy. In the study conducted in 2007 by Sorta-Bilajac *et al.* on ethical dilemmas among physicians and nurses of the Rijeka University Hospital Center (UHC) (N=532), only a minority reported being somewhat confident (physicians 41 (36%), nurses 74 (32%)) or very confident (physicians 6 (5%), nurses 14 (6%)) about their knowledge in ethics^{17,18}.

The reason may lay in the fact that clinical ethics contents is placed within the curricula either at the very beginning (1st or 2nd year) or at the end of the curriculum (last year). The first situation imposes clinical ethics contents on students with very little or no clinical experience, depending on their high school education. In the latter case, these ethical concepts will be offered to soon-to-be independent healthcare providers with the already formed set of personal and professional values. In both cases, the clinical ethics contents is not in correlation with the students' actual needs.

Another reason could be that only a minority of both populations from the above mentioned survey by Sorta-Bilajac *et al.* reported attending other ethics training, such as medical ethics conference (physicians 19 (17%), nurses 25 (10%)), medical ethics case presentation (physicians 26 (23%), nurses 26 (11%)) or an intensive course in medical ethics (physicians 5 (4%), nurses 19 (8%))^{17,18}.

The third reason may lay in the fact that it was only in 2009 that clinical ethics contents formally entered the Croatian scientific system. It was positioned within and according to the Regulation on scientific and artistic fields and branches as follows: 3. Biomedicine and health-care; 3.02. Clinical medical sciences; 3.02.15. Medical ethics¹⁹.

A shift, or more precisely come-back towards William Osler's bedside ethics tradition would be needed²⁰. To emphasize, one should also be reminded of the definition of clinical ethics by Pellegrino *et al.*, who, among other, place the ethics teaching of medical students, interns, residents and clinicians exactly by the bedside²¹. Thus, clinical ethics contents should be offered continuously throughout the curriculum, which is similar to the efforts of the Split School of

Medicine. Also, clinical ethics programs should be appointed as mandatory by medical, nursing and associated chambers for the purposes of license renewal, according to the life-long-learning approach. As stated in the Encyclopedia of Bioethics, clinical ethics contents should be offered at all levels of health professional education, means at the preclinical, clinical, graduate and postgraduate levels, as well as within continuing education¹.

Clinical ethics consultations

There are two main problems regarding Croatian ethics support services. Firstly, a complete CEC service should consist of an ethics committee, team consultations and individual consultations²². The Croatian existing 'crippled' service discourages healthcare workers as well as patients from turning to ethics support service for help when facing an ethical dilemma^{17,18,23-25}. Namely, each component has its own particularities. Different component (i.e. committee, team or consultant) should be activated in a different morally-burdening clinical situation²⁶⁻²⁹. As shown in the aforementioned study by Sorta-Bilajac *et al.*, a minority of both populations reported ever using clinical ethics consultations service: physicians 14 (12%) and nurses 7 (3%)^{17,18}. These numbers are surely discouraging, since, as stated by Josipović-Jelić and Šoljan, clinical ethical dilemmas represent clinical problems where all potential solutions might require violation of some moral rule³⁰.

Secondly, the current Croatian situation imposes that the committees' main activity is reviewing scientific and clinical research protocols rather than other important functions, i.e. education, case analysis and consultations, as well as developing guidelines and institutional protocols^{17,18,22-25}. Through the amendments of the Croatian Act on Health Care from 2006, the institution of drug committees was identified to enable the shift towards a more advisory role of clinical ethics committees. The intention was to activate them in dealing with ethical issues arising in everyday care for the patient in a healthcare institution³¹. Unfortunately, they still represent the so-called 'mixed type' of committees, which combine the institutional review board's and ethics committee's functions³², monitoring the application of ethical and deontological principles of health professions in the provision

of health services, approval of scientific research in a medical institution, supervising organ removal after autopsy for medical, scientific and educational purposes, and solving other ethical issues in the provision of health services³³. This situation can be confirmed and illustrated by the analysis of the ten-year activity of the Ethics Committee of the Rijeka UHC. During the 1997-2007 period, the Committee processed 238 subjects: 217 (92%) reviews of research protocols, 8 (3%) developments of guidelines and institutional policies, 8 (3%) case analyses and consultations, and 5 (2%) educational activities³¹.

Due to a limited time-frame the Croatian biomedicine and health-care system has to meet the international standards, a widespread grass-root process of the CEC service development³² can no longer be implemented. The top-to-bottom approach might be of great help, with special emphasis on the place and role of ethics committees of medical, nursing and associated chambers. A strong stimulus from the aforementioned institutions should encourage healthcare institutions' managements to implement theoretical recommendations in daily clinical practice. Namely, the existing legal framework for the establishment and development of ethics support services will remain merely a declarative one without strong institutional support. It is extremely important that CEC service has accurately defined position within the institutional hierarchy, and that it has strong administrative support. Establishment of quality relationships with the existing services and compliance with institutional protocols on the one hand, and recognition of the service activities by the administration on the other hand provides good horizontal and vertical networking²² and enables activation of the CEC service.

Ethics of research

When framing concepts regarding the ethics of research, medical-ethical-legal guidelines are present in many international regulations, such as the Helsinki Declaration, the Declaration on the Promotion of Patients' Rights, the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine or the UNESCO's Universal Declaration on Bioethics and Human Rights³⁴. These guidelines

have already been, or are being interpolated in several Croatian documents, besides the aforementioned Act on the Protection of Patients' Rights, such as the Act on the Protection of Persons with Mental Illness, the Family Act, and the Criminal Code³⁴⁻³⁶.

The existence of a formal medical-ethical-legal framework does not ensure a satisfactory level of respect for patients' rights. On the contrary, great efforts are needed to approach the international standards at an active, not only declarative level. One of the greatest obstacles on this path might be the deontological model of bioethics, which is represented in countries of south Europe³⁷. This model offers space for an outdated paradigm of paternalistic medicine, which is still predominant in the Croatian society³⁷⁻³⁹. To illustrate it, Croatian research participants are predominantly inpatients. They are almost automatically enrolled in clinical trials since they are not inclined to refuse participation, just because they are patients. Namely, according to the deontological model, the patient has a positive duty to respect physician's instructions³⁷. Such a situation disables patients in expressing their full autonomy and reduces the informed consent doctrine to a merely theoretical issue.

In fighting this paradigm, the activities of the Croatian Association for the Promotion of Patients' Rights should be especially underlined. Among other, the Association has launched a counseling program for patients, under the auspices of the Croatian Ministry of Health⁴⁰. Also, current debate among Croatian bioethicists on the place and role of patients' ombudsman is particularly actual^{41,42}.

These efforts should facilitate the shift towards the new paradigm of the patient/person-centered system of biomedicine and healthcare⁴³. In this context, one ought to be reminded that, according to Ashcroft, "medical ethics scholars must take up the challenge of addressing the moral problems of social transition"⁴⁴.

Conclusion

Considering the three focal points of clinical ethics, the Croatian current situation leaves ample room for improvement, however, within a very limited time-frame. Establishment of continuous education in clinical ethics contents throughout the curriculum, as well as during residency, postgraduate training or

appointed by respective chambers, should create a shift towards the life-long-learning approach. A complete service of clinical ethics consultations, composed of an ethics committee, team consultations and individual consultations, would increase the availability and facilitate the usage of clinical ethics support services for healthcare workers as well as patients when solving morally burdening situations in their clinical surroundings. The need of stronger promotion of patients' rights among patients and healthcare providers regarding not only research, but also cure and care should be particularly underlined. Inclusion of the office of a patients' ombudsman into the Croatian healthcare system would be advised. These efforts would place the Act on the Protection of Patients' Rights into everyday clinical practice.

Finally, although clinical ethics has entered the Croatian biomedicine and healthcare system at the formal and practical level, the need to approach the European and other international standards regarding the recent Croatian accession to the European Union, should be strongly emphasized.

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Sažetak

KLINIČKA ETIKA U HRVATSKOJ: PREGLED IZOBRAZBE, KONZULTACIJA I ISTRAŽIVANJA
(APEL ZA PROMJENE)

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Cilj je ovoga rada utvrditi sadašnji položaj kliničke etike unutar hrvatskog zdravstvenog sustava analizirajući sadržaj iz kliničke etike u kurikulumima medicinskih fakulteta i srodnih institucija, sastav i ulogu kliničkih etičkih konzultacija, te uspostavu etičko/pravnog okvira za provođenje istraživanja. Korištene su metode pretraživanje kurikuluma, pregled literature, analiza Zakona o zaštiti prava pacijenata. Sadržaj iz kliničke etike poučava se kroz 63 obvezna i izborna kolegija na 12 institucija. Pogrešno je pozicioniran na početku ili na kraju kurikuluma. Potreban je kontinuitet na svim razinama izobrazbe zdravstvenih djelatnika. Hrvatska iskustva u kliničkim etičkim konzultacijama oblikovana su isključivo kroz etička povjerenstva. Problematična je činjenica što je analiza znanstveno-istraživačkih protokola identificirana kao njihova glavna aktivnost. Uključivanje timskih i individualnih konzultacija povećalo bi raspoloživost i olakšalo korištenje sustava etičke potpore. Zakon o zaštiti prava pacijenata Republike Hrvatske temelji se na načelima humanosti i dostupnosti, osiguravajući poštivanje prava na zaštitu pacijenta nad kojim se obavlja znanstveno istraživanje. Nažalost, zastarjela paradigma paternalističke medicine otežava poštivanje prava pacijenata pri njezi, liječenju i istraživanju. Pomak ka zdravstvenom sustavu usmjerenom na pacijenta/osobu aktivirao bi Zakon u svakodnevnoj praksi. Premda je klinička etika i formalno i sadržajno ušla u hrvatski zdravstveni sustav, autori naglašavaju potrebu za približavanjem europskim i drugim međunarodnim standardima povodom ulaska Hrvatske u Europsku Uniju.

Ključne riječi: *Etika, klinička; Etičke konzultacije; Izobrazba; Istraživanje; Hrvatska*