

■ PROFESSIONAL ISSUES

## Ethical approval for health research in central and eastern Europe: an international survey

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**ABSTRACT** – Research ethics committees in central and eastern Europe are increasing in importance as institutions in this region host a growing and more diverse range and volume of health-related research, with funding from an increasingly wide variety of sources.

**Aim:** To describe the arrangements for ethical supervision of research in eleven countries of central and eastern Europe, so as to identify examples of good practice and areas of weakness.

**Methods:** A questionnaire was sent to key informants known to be active in health-related research in Albania, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Lithuania, Poland, Romania, Russia, and Ukraine in October 2000. It sought information on the composition and functioning of ethics committees, their training and any public concerns about the ethics of health-related research.

**Results:** All countries except Ukraine confirmed that decision-making committee structures operate to oversee the ethics of research on human subjects. In all countries except Albania committees are comprised of medical and non-medical members. Members received specific training in bioethics in Estonia, Hungary, and Lithuania. Countries had made different degrees of progress in implementing arrangements for co-ordinating multi-site research and for monitoring research once it had commenced. Public concern about ethical issues arising from health-related research was rare.

**Conclusion:** The development of ethical supervision of health-related research in central and eastern Europe varies considerably. In some countries there are significant weaknesses that should be addressed. Other countries could serve as examples of good practice in the region. A major challenge is how the public can be involved in this process.

### Introduction

In response to abuses during the 1930s and 1940s, the World Medical Association adopted a code of practice known as the Declaration of Helsinki in

1964. Updated in 2000, it states that “*The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials*”<sup>1</sup>.

Research ethics committees thus have an important role to play in ensuring that scientific knowledge and understanding of disease are advanced and that these advances are made within a framework which preserves and protects the dignity and interests of research participants.

In the West over recent decades scientific, public, and media interest and anxiety relating to scientific conduct and misconduct have increased<sup>2</sup>. In many western industrialised countries this has resulted in reviews of arrangements to protect both the scientific community and the public from research misconduct.

Over the past decade the populations of eastern and central Europe have undergone seismic cultural, ideological, and socio-political shifts and the assertion of individual autonomy and the rejection of authoritarian structures is becoming embedded as it has in the West over the past 50 years. Allied to these social changes are complex changes in the provision of health care: decentralisation; autonomy of health care providers; and a growing emphasis on evidence-based medical practice<sup>3</sup>.

In addition to these factors, growth in the markets of large multinational pharmaceutical and medical technology industries is likely to result in the expansion of clinical research. This research will need to be co-ordinated and facilitated and, in addition, research participants and health-care recipients will need to be protected from misconduct.

Little research on the development, structure, and functioning of research ethics committees in central and eastern Europe has been published<sup>4–8</sup>. Research ethics committees in western Europe and the US

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have, broadly, dealt with scientific or medical misconduct by focusing upon preventive measures, investigated allegations of misconduct, or both<sup>2-9</sup>. This paper describes the structure and function of research ethics committees in eleven central and eastern European countries focusing largely, though not exclusively, upon their function as preventive bodies.

## Subjects and methods

A brief structured questionnaire was sent to key informants (individuals known to be active in health related research) in eleven countries of eastern and central Europe (Albania, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Lithuania, Poland, Romania, Russia, and Ukraine) in October 2000. The questionnaire posed eleven questions. They sought information on the presence of institutions for granting ethical approval for research involving human subjects, the structure of these decision-making bodies, and the selection/appointment process to committees where they existed. Other questions were related to training procedures for ethics committee members, the types of research which require ethical approval, structures and mechanisms for co-ordination of several ethics committees (if they exist), and monitoring of research.

Information was also sought on the extent of training in ethics in the undergraduate medical curriculum.

Finally, respondents were asked to describe briefly any examples where public concern had been shown in the realm of medical research.

## Results

All eleven questionnaires were completed and returned. All countries except Ukraine confirmed that decision-making committee structures operate to oversee the ethics of research on human subjects. National ethics committees operate in Albania, Bulgaria, the Czech Republic, Estonia, Hungary, Lithuania, Romania, and Russia (committees in Ministry of Health and Academy of Medical Science) (Croatia is in the process of drawing up a model national framework). In addition, there is a range of sub-national structures (Table 1). Mechanisms for co-ordination of individual committees are, however, weak. An

**Table 1. Sub-national research ethics structures.**

Country	Arrangements
Bulgaria	Committees in each university hospital
Czech Republic	Individual research institutes
Estonia	Separate committees based in Tallinn and Tartu for north and south of country
Hungary	Eleven regional committees, four of which are associated with universities, others with regional hospitals. Terms of reference accredited by Health Sciences Research Council
Poland	Individual research institutes
Russia	Regional committee in St Petersburg

## Key Points

**Research ethics committees have an important role to play in advancing scientific knowledge and protecting research participants**

**In central and eastern Europe there is a growing emphasis on evidence-based medical practice which is likely to result in an expansion of clinical research**

**Most countries of eastern and central Europe have in place national decision-making ethics committee structures, though mechanisms for co-ordination of their function are often poor**

**There has been little public debate of the complex ethical issues raised by research on human subjects in most countries**

exception was Hungary, where each committee must report annually to the Health Sciences Research Council and which was the only country in which institutional approval was the norm that had specific arrangements for multi-site studies. Estonia has established a committee specifically to review ethical aspects of a proposed Estonian genome project.

There was little information on the effectiveness of the arrangements described. One respondent noted, for example, that 'actually nobody controls some things really, but to officialise [*sic*] the results, you need the paper from certain people in the ministry'.

In all countries questioned with the exception of Albania research ethics committees have both medical and non-medical members; other members include lawyers, economists, psychologists, philosophers, theologians, medical students, sociologists, social workers, and bioethicists.

Special training in bioethics for members of research ethics committees was reported in Estonia, Hungary, and Lithuania. In contrast, all countries with the exception of Romania report that training in ethics is offered in undergraduate medical curricula, although in the Czech Republic it was described as minimal.

Respondents from all countries (except the Ukraine and Russia) stated that ethical committee approval is required for research where subjects are to receive an experimental treatment, and research in which samples are to be taken for screening or for diagnostic purposes. Committee approval was also needed in the Czech Republic, Estonia, Hungary, Poland, and on occasion in Lithuania for research which involves subjects completing questionnaires or being interviewed. When research involves information being extracted from clinical records committee approval is required in Estonia, Hungary, and in certain circumstances, Lithuania.

Ongoing monitoring of research results by ethics committees was reported in Albania, Bulgaria, Croatia, Estonia, and Hungary.

Public concerns about ethical issues in medical research in recent years were highlighted only by Croatia (several public scandals have resulted from the alleged unethical use of human

material in research). Most respondents indicated that this lack of public anxiety may be the result of a lack of 'awareness' by the public of the complex ethical issues in research on human subjects. For example, in Estonia it was noted that 'there has never been a deep and sophisticated general discussion on ethical issues in medical research. Mostly, individual wrongdoings in medical practice have been publicised.' Concerns which were highlighted included misconduct over issues of confidentiality, in the field of transplantation, and financial and clinical misconduct of doctors. For example, one respondent suggested that 'the only ethical issues of medical practice discussed openly in Soviet and Ukrainian mass media were under-the-table payments taken by medical workers and cases when medical workers have neglected their duties'.

## Discussion

The creation of national bioethics committees has been described by some as a 'revolutionary leap in the process of democratising decision-making'.<sup>10</sup> In 1997 eight members states of the European Union had created such committees, and two more were planning to do so. This survey shows that most countries of central and eastern Europe have in place national research ethics committees. In many countries these central structures have existed since the early 1990s; for example, the Czech Republic's Central Ethical Commission held its first meeting in 1990, only seven years after France's national body was instituted<sup>6</sup>. Of the countries surveyed, only Ukraine has no ethical committee structures in place to assess potential research on human subjects. Understanding how these structures work in practice clearly requires further research, but if one reflects that only five years ago, Husson and his colleagues suggested that most European Union countries have a 'tendency' to 'hide' cases of individual fraud because of the 'absence of precise and well codified rules'<sup>11</sup> and that as recently as 1999, Magne Nylenna suggested that 'despite a widely recognised need, most countries [of the European Union] still have no coherent system to deal with scientific misconduct'<sup>9</sup> it is clear great strides have been made in a short time in many countries of the former Soviet bloc.

One of the greatest challenges facing those contemplating the most effective and transparent workings of ethics committees is finding ways to involve the public<sup>10</sup>. In central and eastern Europe all ethics committees, except those in Albania, are comprised of medical and non-medical members, but public involvement remains limited. If increasing media and public awareness of the ethical issues involved in medical research along with a sophisticated public dialogue occurs this is likely to change. Yet clearly, at present, public debate regarding such issues is in its infancy. Clinical and financial misconduct seem to be provoking greater public anxiety at present, perhaps because

of the immediacy of the effects. But in the longer term the investment in undergraduate teaching of bioethics suggests some degree of professional awareness of the ethical issues surrounding research in humans, and this bodes well for the future.

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