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Scientific Contribution

Regulation of healthcare ethics committees in Europe

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Abstract. In this article, the question is discussed if and how Healthcare Ethics Committees (HECs) should be regulated. The paper consists of two parts. First, authors from eight EC member countries describe the status quo in their respective countries, and give reasons as to the form of regulation they consider most adequate. In the second part, the country reports are analysed. It is suggested that regulation of HECs should be central and weak. Central regulation is argued to be apt to improve HECs' accountability, relevance and comparability. To facilitate biomedical citizenship and ethical reflection, regulation should at the same time be weak rather than strict. Independence of HECs to deliberate about ethical questions, and to give solicited and unsolicited advice, should be supported and only interfered with by way of exception. One exception is when circumstances become temporary adversarial to ethical deliberation in healthcare institutions. In view of European unification, steps should be taken to develop consistent policies for both Eastern and Western European countries.

Key words: clinical ethics, deliberation, European unification, Healthcare Ethics Committee, legislation, regulation, subsidiarity

Introduction

Ethics committees are important interdisciplinary panels for the discussion of ethical questions. In the past 30 years, two types of ethics committees have become dominant in health care institutions: research ethics committees (RECs),[1] which focus on the review of medical research involving human subjects, and healthcare ethics committees (HECs), focussing on moral issues in patient care.[2] Remarkably, whereas for RECs regulatory structures have been developed on international and national levels, HECs have remained much less regulated.

This article analyses regulation of HECs in Europe. The descriptive aim of the study is to explore if and how HECs are being regulated in a select number of European countries; its normative aim is to discuss how HECs should be regulated.

Methods

Eight countries were chosen for this explorative study: Belgium, Croatia, France, Lithuania, The Netherlands, Poland, Slovakia and the United Kingdom. The choice of countries was not intended to be representative for Europe in its entirety. Rather, reflections from a limited sample of sufficiently diverse countries were to be analysed in order to demonstrate both the variety of concepts of clinical ethics facilities and possible tendencies as to the regulation of HECs. The countries can be divided into two groups: Belgium, France, The Netherlands and the United Kingdom have been democratic societies for a considerable amount of time. It was assumed that deliberation would not be entirely unknown in organisations of public life of these countries, e.g. in hospitals and

other health care institutions. Croatia, Lithuania, Poland and Slovakia are presently transitional countries that have undergone radical changes since the fall of Communism in 1989 and 1990. Other than in Western countries it was to be expected that deliberation, if practiced in health-care organisations, would rather be in a beginning stage.

The co-authors of this study are predominantly clinical ethicists from the countries chosen for the study. An exception is Poland, where no ethics committees appeared to have been implemented yet. However, it was decided not to exclude the Polish contribution in order to include its thoughts on future regulation of HECs in this country. Initially, all co-authors were asked to contribute a brief report about regulation of HECs in their countries, answering the following questions:

(1) What kind of regulation of HECs (legislation or other) exists?
(2) How should HECs ideally be regulated?
(3) What are the reasons for your preference?

Regulation is interpreted as a concern for HECs by authorities external to the committees themselves, expressed in rules of diverse latitude and bindingness. The authorities' concern may relate to both procedural and substantial questions. Procedural questions include the establishment and composition of HECs, succession of members, operating procedures, character of products (for example policy guidelines and procedures of moral case deliberation) and accountability issues. Substantial questions involve the moral advice given by the committee, most typical in the form of moral guidelines for the institution, sometimes in the form of conclusions of ethical case deliberation on the ward.

As to the different types of ethics committees, the main accent of this article lies on the level of healthcare institutions. National committees, which are mostly members of the European Conference of National Ethics Committees (COMETH) (see http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/COMETH/), accessed February 20, 2007), or regional committees will be mentioned when directly relevant for HECs and questions of HEC regulation.

The country reports were analysed in view of the status and reasons in favour and against models of regulation. All co-authors have commented on an earlier draft of this article, added missing information or made suggestions as to the discussion and conclusions.

Country reports

Belgium

Development

Since 1994, all general and psychiatric hospitals in Belgium have been legally required to establish a so-called 'local ethics committee' for tasks related to both RECs and HECs. The combination of research and clinical ethics in one single committee can be explained by the genesis of ethics committees in Belgium (Meulenbergs et al., 2005). In the remainder of this study, this type of committees will be called 'mixed committee(s)'. From as early as 1984, the Order of Physicians issued guidelines establishing research ethics committees. In 1992 the Order of Physicians' National Council broadened these committees' scope by appending systematic reflection on the ethical and philosophical aspects of healthcare practice to the range of committee tasks.

Regulation

Due to a ruling by the Belgian Court of Arbitration in 2000, the HEC-related tasks do not include ethics consultation any longer. The court decided that the Belgian federal lawmaker was unauthorised to set ethics consultation as a committee task since the competence to legislate on person-related issues in healthcare resides with the regional authorities.

In May 2004, the functioning of ethics committees changed owing to the new law on human experimentation that introduced the provisions of the EU Clinical Trials Directive 2001/20/EC (European Parliament, 2001). The already existing predominance of protocol review (Englert et al., 2001) over health care ethics tasks was reinforced, especially by setting competing time frames within which ethics committees have to review protocols (Trouet, 2004). The new law also introduced a funding system for ethics committees with regard to research ethics. Committees with a principal focus on healthcare ethics are not eligible for funding any more.

Apart from the specific tasks, the Royal Decree of 12 August 1994 also governs a committee's composition as well as its functioning. The current legal situation can be held inadequate. Allocating both REC and HEC related tasks to one single committee ignores the fundamental differences between research ethics and healthcare ethics, e.g. with regard to required expertise (Riis, 1998). Notwithstanding the legal framework, some

university hospitals and large hospital groups have established separate RECs and HECs (Vermylen and Schotsmans, 2000).

Future perspective

Today Belgian HECs are already regulated on a national scale. Due to this, every hospital has an ethics committee performing a multiplicity of committee tasks. In the past, this national character of HEC legislation has been shown to function as an important impetus to establish local ethics structures. Hence, the proposed integrative view on ethics committees should also be applied through national legislation. This bears not only the advantage that HECs have similar structures but also that quality management and concerted action among HECs can be effectively dealt with.

Croatia

Development

Since 1997, the Croatian Law on Health Protection has required the establishment/founding of ethics committees (Law on the health protection, 1997). A 2003 revision (Law on the health protection, 2003) left the legal requirements for the establishment of ethics committees unchanged. Each healthcare institution in Croatia is required to have an ethics committee consisting of five members (three medical, two non-medical). In 2001, the National Bioethics Committee for Medicine of the Croatian Government was founded (Directive on the establishment of the National Bioethics Committee for Medicine, 2001). This independent and multidisciplinary advisory body is involved in policymaking, education, and debates on ethical issues on a national level. Furthermore there are ethics committees at four medical faculties: at the Faculty of Veterinary Medicine and at the Faculty of Pharmacy and Biochemistry in Zagreb, at the Institute for Anthropology, the Institute for Medical Research, the Institute *Rudjer Boškovic* as well as other research institutions. All these committees basically deal with research.

Regulation

Croatia has decided for a top down approach for the implementation of ethics committees in healthcare institutions. These are ''mixed'' committees, a type of ethics committee which combines the tasks of both HECs and RECs. There are several problems with this type of regulation. First and foremost it does not relate to the committees in research institutions. Moreover, by the Law on Health Protection Pharmacies, homecare institutions and primary healthcare facilities are considered to be healthcare institutions as well. Having only 2–6 employees on average, separate ethics committees appear to be not feasible for these institutions.

The 2003 Law on Drugs and Medical Devices (Law on drugs and medical devices, 2003) has now centralised the review of research protocols at one specially established ethics committee on a national level. Following the Law on Health Protection, ethics committees in healthcare institutions are also required to review research protocols. This obviously creates confusion. Furthermore, research in hospital settings has shown that most ethics committees considered the analysis of research protocols as their main function, while the other tasks were neglected.

Further perspective

Both the Law on Health Protection and the Law on Drugs and Medical Devices will be revised. To improve regulation of ethics committees, research ethics and clinical ethics should be distributed to HECs and RECs respectively. Ethics committees in healthcare institutions should be transformed into HECs by changing the legal provisions. Additional efforts should be put in the members' education. Furthermore, HECs should be required in hospital settings, whereas for the other types of healthcare institutions moral problems could be directed to local or regional HECs.

France

Development

Healthcare ethics at a local level was not mentioned in French law until 2002, though many hospital-based ethical structures had been created. In 2002 and 2004, two legal steps concerning clinical ethics were taken. However, none of these relates to the 'committee' model. In 2002, the following sentence was inserted with no further specification: ''They [hospitals] perform, within their structure, a reflection on ethical issues related to the patient's reception and medical care'' (Art. L611 CSP, of the Law No. 2002-303, 2002). Strictly speaking, performing reflection does not mean setting up an ethics committee.

In August 2004, another insertion was placed following two official reports (a document about ethics and healthcare in France requested by the Ministry of Health, and an opinion of the latter by the National Ethics Committee (Cordier, 2003,

p. 13)): ''Forums for ethical reflection [*Espaces de réflexion éthique*] are created at the regional or interregional levels; they work in connection with university hospitals, and they are sites of education, documentation, interdisciplinary meetings and discussions on ethical issues in the field of health. They are also regional and interregional observatories with regard to healthcare practices. They participate in the organisation of public debate so as to foster information and consultation of citizens on bioethics issues'' (Art. L1412-6 CSP, added by law 2004-800 regarding bioethics, 2004). As of February 2007, however, *Espaces Éthiques* have still not been officially created. A working group has been set up at the Ministry to prepare specificatory decrees, allowing this law to become effective.

Regulation

The 2002 law is not a strict regulation. Neither has it led to any form of evaluation. Rather, hospitals are being encouraged to support various forms of healthcare ethics. Many of them already have an internal structure dedicated to clinical ethics. Probably about half of them sometimes perform ethics consultation and advisory work (Guerrier et al., 2004). The 2004 law directly refers to the *Espace Éthique of Assistance Publique Hôpitaux de Paris*, founded by Emmanuel Hirsch in 1995. For the first time, ''officially recognised'' bodies in healthcare ethics are about to be implemented in France. These bodies are not to be involved in decision-making on the ward. Rather, they support education and reflection. Since many and very diverse structures already exist, some operating at a regional level, their development and potential transformation is a possible source of difficulty.

Further perspective

The very first issue to be addressed in order to build up *Espaces Éthiques* is to identify, describe and foster existing initiatives. Many HECs could become part of *Espaces Éthiques*' network activities. As for the advisory work in this realm, no further regulation should be introduced at the moment because of two reasons. First, their prior goal is education and personal commitment in ethical reflection; second, a much better understanding of requests of such advisory procedures should be acquired prior to any regulation.

Lithuania

Development

The establishment of HECs (called 'medical ethics commissions') is based on two legal documents. First, the Health Care System Law of the Republic of Lithuania, passed by the Parliament in the early 90s, requires the establishment of HECs in the largest health care institutions (HCI). The same law has envisaged the founding of the Lithuanian National Bioethics Committee, which is responsible for co-ordinating and supporting HECs.

Second, the 'Model Guidelines for Medical Ethics Commissions', issued by the Ministry of Health in 1997, define the mission, functions, establishment and composition of HECs. These guidelines award an ethics committee with far-reaching competencies. For example, a HEC is required to monitor health care providers' compliance with principles of medical ethics. Furthermore, it may facilitate a HCI's decision-making in controversial ethical cases and in conflicts between health care professionals and patients.

Regulation

As to the establishment and composition, members of a HEC are being elected by secret vote during a general meeting of the employees of the HCI for a 3-year period. A committee regularly consists of 7–15 members, the exact number being decided upon by the general meeting. The appointment of a chairperson, deputy chair and secretary are left to the HECs self-regulation. These persons are elected by a simple majority vote at the committee's constituent meeting. Subsequently, each HEC may develop its own Guidelines in accordance to the Model Guidelines of the Ministry of Health. A HEC should receive technical support from the HCI's administration.

Future perspective

An anonymous evaluative study at the beginning of 2000 (Gefenas, 2001) showed that, instead of deliberating about medical ethical problems, most HECs had taken over the role of a sentinel. This means that HECs were limiting themselves to resolving difficult situations related to the health care professional – patient relationship as well as conflicts amongst health care professionals themselves, e.g. the refusal to participate in rounds with the chief of department, cases of caregivers being crude to patients and the like.

The most important issue related to the functioning of HECs in Lithuania is not to develop a certain type of regulation (e.g. national versus smaller scale), but to clarify the way medical ethics is conceptualised in and by HECs. Assigning ethics committees the role of a ''moral police'', and using them for disciplinary sanctions as well as a

substitute for legal or administrative regulations implies an authoritarian, non-deliberative concept of medical ethics. Attempts to ''implement'' such an interpretation of medical ethics by using HECs obviously give counterproductive results. Most likely the idea of committees as facilitators of ethical deliberation will be spoilt.

The strategy to issue Model Guidelines for HECs at the national level, however, can be considered an adequate step. The procedure to introduce these guidelines at each HCI leaves room for interpretation. Each HCI could modify those guidelines in a specific way, according to the local institutional needs. One of the most important missing elements has been the lack of a clear and realistic implementation strategy. Such a strategy should provide adequate financial resources (not only a ''technical assistance'') to establish a HEC's secretariat trained in health care ethics, and capable to sustain continuity of the committee's activities.

The Netherlands

Development

In The Netherlands, legal regulation solely exists for research ethics committees (REC). The 1999 *Medical Research Involving Human Subjects Act* (WMO) requires all scientific medical research involving human subjects to be reviewed by an officially recognised REC (Ministerie van Volksgezondheid, Welzijn en Sport, 2000). Recognition of RECs is granted by the *Central Committee Medical Research Involving Human Subjects* (CCMO). The CCMO is a national ethics committee exclusively dedicated to research ethics. Next to being entitled by law to guarantee recognition to local RECs, it is a committee of appeal.

HECs in The Netherlands date back to the beginning of the 1970s. During the first two decades, most of them were 'mixed committees'. Next to the review of research protocols, their responsibilities included the development of guidelines about moral questions in healthcare organisations (e.g. the hospital, the nursing home etc.), educative programmes for members, healthcare providers, patients and the public, and finally moral deliberation on the ward (van der Kloot Meijburg, 1990). Regulative as well as pragmatic reasons led to the differentiation of ethics committees into RECs and HECs. Pragmatically, research ethics tended to marginalise clinical ethics when both tasks belonged to the same committee. In this case, protocol review can turn out to be so time consuming as to become a committee's dominant or even its only activity. This development was intensified by regulation. The more administrative authority was granted to RECs, the more clinical ethics was neglected.

Regulation

HECs have been and continue to be a bottom-up enterprise. Next to the mixed committees, a number of committees were founded as separate HECs from the beginning. Without central regulation, statutes for HECs uniformly define the tasks of these committees according to the international consensus about what HECs are supposed to be doing. Locally, however, committees have accentuated their tasks differently, both according to agreements with the board of directors of the institution, and according to the consideration of requirements by hospital wards.

Future perspective

During recent years, the connection of HECs to patient care has become an issue (Ten Have, 2001). In 1999, the Dutch Association of Bioethicists (NVB) recommended to improve the connection of HECs to daily practice by maintaining the concept of ethics committees (Brom et al., 1999). A year earlier, the Centre for Ethical and Philosophical Aspects of Care (CELAZ) suggested transforming HECs into steering groups to improve integration of moral deliberation into the management, quality assurance programmes, and healthcare delivery on the wards (College voor Ethische en Levensbeschouwelijke Aspecten van de Zorgverlening, 1998).

Discussion papers like these are not yet regulation. Their first aim is to indicate problems and to inspire discussion. As a next step, a 'platform on moral deliberation' was set up at the Ministry of Health in 2004, in order to inventory concepts of moral deliberation on the ward. As of February 2007, discussions about implementation of healthcare ethics committees have been on the way within the working group of the Ministry of Health. As far as regulation is concerned, no distancing from the principle of self-regulation has been observed so far.

Poland

Development

HECs do not yet exist in Polish hospitals. Neither is there legal nor ethical regulation concerning HECs.

Regulation

The only ethics committees in Poland which could play, at least to some extent, a role similar to HECs, are medical ethical committees of medical councils or chambers of physicians and dentists. These committees operate at the national and regional level, and deal with issues of medical ethics (deontology). Their influence on health care policy and clinical decision-making is however very limited.

The Medical Ethics Committee of the Supreme Medical Council of the Polish Chamber of Physicians and Dentists (PCHPD) was set up in 1990, following a recommendation of the first General Medical Assembly, which is the highest authority of the PCHPD. The committee drafted the Code of Medical Ethics, which was finally adopted by the second General Medical Assembly in 1991. This code contains ethical norms that should be followed by all Polish physicians and dentists. Beyond this, the code has indirect legal significance.

Medical councils of regional chambers of physicians and dentists have set up their own Medical Ethics Committees. The role of regional committees is to monitor and give opinions on professional conduct of local physicians, to inform the Screeners for Professional Liability about norm violations, to propose solutions to conflicts, to take part in public discussions on bioethical issues, to deliver opinions on draft legislation concerning the protection of health and practicing as a physician, to table motions for legislative initiative and to promote bioethical education among young medical doctors.

All Medical Ethics Committees are monodisciplinary bodies, composed only of medical doctors. They gather 6–12 times a year. Each of the Medical Ethics Committees has its own statute, which governs in detail its functioning and internal organisation. The statutes differ significantly from each other in respect of particular regulations concerning organisational and functional issues.

Future perspective

Future HECs in Poland should be regulated and standardised on a national level in order to assure their accountability. Regulation, therefore, should address the following topics: (1) the tasks of HECs; (2) the size and composition of the committees; (3) membership requirements; (4) rules of appointing, financing and functioning of the committees; (5) case consultation procedures; (6) the storage of documentation of consults; and (7) review of committee processes and recommendations. These basic organisational and functional matters should be regulated by law, because the activities of the committees bear directly on patients' rights, enable and guide life-and-death decision-making, and provide ethical input into hospital policies and guidelines. HECs also play a significant role in the dialogue about medical futility and rationing of scarce medical resources. Legal acts and decrees should, however, leave room for HECs' self-regulation. Internal statutes of the committees should be consistent, not only with the law on HECs, but also with the norms of medical ethics as expressed in various national as well as international codes and recommendations.

Slovakia

Development

The "Velvet Revolution" of November 1989 marked a new start for the development of bioethics in the Slovak Republic. Since the very beginning, the idea of ethics committees in general has been supported by the Ministry of Health (MH). In the autumn of 1990, the Central Ethics Committee (CEC) was founded at the MH. At the same time, in the reform atmosphere following the "Velvet Revolution", several informal working groups on medical ethical issues were formed at the Faculties of Medicine, as well as in the teaching hospitals, research institutes, and also within several member societies of the Slovak Medical Association, and the Slovak Medical Chamber.

Later on, these groups were transformed into mixed committees. The "know-how" support for these review and ethics advisory bodies was provided mostly by the CEC: by means of consultations, informal recommendations and professional guidance. No reporting or hierarchical relationships were introduced. In June 1992, the "*Guidelines on Establishment and Work of Ethics Committees in Health Care Facilities and Biomedical Research Institutions*" (Guidelines) were elaborated by the CEC, and published in the form of the MH's recommendations. The Guidelines required and gave a specific guidance on the establishment and work of local ethics committees.

The new health law was adopted in 1994. Together with subsequent legislation, it helped to create a new legal milieu for medicine and health care. The "reform health legislation", approved in September 2004 by the Slovakian parliament, brought in more profound changes, however. It consisted of 7 new laws. The most important for ethics committees' issues were the Law No. 576/2004 Coll. on health care and the Law

No. 140/1998 Coll. on drugs and medical devices as later amended.

Regulation

The Law No. 576/2004 Coll., which became effective on January 1, 2005, requires all inpatient health care facilities in the Slovak Republic to have ethics committees established to deal with ethical problems connected with health care provision (and to review and monitor ethical aspects of 'in house' conducted biomedical research, including drug clinical trials). It also asks the regional health authorities to establish ''regional'' ethics committees for the same purpose, i.e. to oversee and deal with ethical problems of health care, public health and biomedical research at the territory of their respective regions. Regulation of the MH on ethics committees is under preparation (to be issued under the new law). It is supposed that it will require the registration of ethics committees, and thereby also their fulfilling of certain criteria (e.g. detailed requirements concerning statutes, membership, education and training of committee members, etc.).

The approximate number of ethics committees in the whole country is between 40 and 50, established mostly at major hospitals and at the medical research institutes that provide also highly specialised inpatient care. Ethics committees occasionally (so far quite rarely) take on the consultation of ethically difficult cases, or, even more seldom, review and provide advice on local/regional health policies. The same applies with regard to (''regional'') ethics committees established by the regional health authorities in the eight regions of the Slovak Republic. These ECs are supposed to review and give advice on ethical issues connected with outpatient care and biomedical research.

The Central Ethics Committee has been much involved in the preparatory work on the pending regulation. It has also been very supportive in the development or re-activation of ethics committees throughout the country. Ethics support in clinical practice is felt to be a necessary pre-requisite for the development and reform of Slovakia's health care system, which is still struggling with the consequences of the profound transformation undertaken during recent years.

Future perspective

HECs (or similar bodies) should be clearly regulated by law. On top of this, there should be more detailed precepts on practicalities of their establishment and operation – these could be at a ministerial decree level issued under specific legislation's provision, or at the level of guidelines issued by the MH or a similar state authority.

There should be a system of HECs, defined in the law, so their responsibility and competencies are clearly defined and visible both for the health care professionals and for the general public. Misuses of HECs' ''power'' should be considered in advance (considering the particular national 'cultural aspects') – and prevented as much as possible. The important cultural and religious realities should be borne in mind and thoroughly and wisely considered and dealt with.

Furthermore, there should be a system of education (basic – introductory, and continuous) for members of HECs, required by law, or by a ministerial regulation (e.g. at/within registration or accreditation awarding and its renewal). Reasons for this are basically the growing interest and need for clinical ethical support (Glasa, 1993, 1995, 2000a, b, 2004; Glasa et al., 1996, 1999, 2000; Slovak Ministry of Health, 1994).

United Kingdom

Development and present situation

Clinical ethics committees (CECs) are a recent development in the UK. A survey of all National Health Service Trusts carried out in 2000 found that of the 400 Trusts then in existence only 20 had a CEC (Slowther et al., 2001). This number has increased to 78 in 2005 (Slowther et al., 2004). The development of CECs in the UK has been a bottom up rather than a top down process, with the impetus for establishing a committee arising from the experience of health care professionals facing ethical difficulties in their daily practice. Thus, unlike research ethics committees, which are closely regulated in the UK, there is no formal regulation of clinical ethics committees in either the public or private health care sector.

Regulation

Ethics support for health care professionals in the UK is obtained from a variety of bodies including CECs, professional organisation ethics committees, the ethics section of the British Medical Association and regulatory bodies such as the Human Fertilisation and Embryology Authority. However, there is no overarching regulatory framework for ethics support in health care, and in particular there is no requirement for health care institutions such as hospitals to have a formal

mechanism for addressing the ethical issues that arise in clinical practice. Standard setting and regulation of health care institutions is the responsibility of the Health Care Commission. Standards include specific requirements relating to broad ethical principles, for example that organisations have systems in place so that patients and their relatives are treated with dignity and respect (Department of Health, 2004), but the mechanism for meeting these requirements is not articulated.

The royal College of Physicians in the UK recently established a working party to look at ethics support and clinical ethics committees in the UK. Its report, 'Ethics in practice: Background and recommendations for enhanced support' (Royal College of Physicians, 2005), was generally supportive of the development of clinical ethics in the UK and recommended that: *'Health care institutions should review their existing arrangements for providing advice and education, and implementing guidelines on the recognition and handling of ethical uncertainties and dilemmas in clinical practice*'.

The Report also made specific recommendations regarding CECs including the need for an agreed statement of core competencies for an effective CEC, and the provision of education and training for members to meet them. The UK Clinical Ethics Network, a national network of CECs, has established a sub-committee to look at developing a set of core competencies, and recommendations for training of CEC members. The Network is an independent organisation and has no regulatory authority. However, it is to be hoped that the recommendations of the RCP Report and the work of the Network will encourage the Department of Health to consider a more explicit requirement for health care institutions to have a mechanism for addressing ethical issues arising in clinical practice.

Future perspective

In the UK context, where there is a nationally regulated, publicly funded health service, regulation of clinical ethics committees would best sit within the overall regulatory and monitoring framework of health care provision rather than within a legislative framework. A legal requirement for health care institutions to have a clinical ethics committee would still necessitate the establishment of a regulatory and monitoring structure to ensure that the law has a meaningful impact on patient care.

A separate regulatory framework for CECs, such as the existing framework for research ethics committees in the UK, would set clinical ethics support apart from the day-to-day provision of patient care. Inclusion of clinical ethics support in the regulatory standards and monitoring processes that govern delivery of health care (overseen by the Health Care Commission in the UK) would emphasise the integral role of ethics in all clinical and organisational decision-making. Within the general regulatory framework, specific criteria could then be set regarding clinical ethics committees to address competency, training and evaluation of the support provided.

Discussion

Regulation of HECs: descriptive aspects

Historic background

Seven of the eight countries in this study had installed HECs in at least a few healthcare institutions by February 2007. At the beginning, most ethics committees were mixed committees, fulfilling both HEC- and REC-related tasks (Lebeer and Moulin, 2000, 2001). In some countries, review of research protocols became their prevailing activity, and HECs were founded separately to deal with issues of clinical ethics. With regard to the purpose of HECs there have been differences between Western and Eastern European countries. In Eastern Europe, conflict resolution, management of moral crisis, and assistance in moral quandaries have prevailed. In Western Europe, HECs have rather been conceived of as facilitators of ethical reflection. Beyleveld's and others' critique of the temporary use of HECs for the sake of crisis management in the UK (Beyleveld et al., 2002) can be interpreted as an indication that this has been perceived as a deviation from an accepted standard.

In the transitional countries of Central and Eastern Europe, ethics committees were set up during and after fundamental societal and political changes. After the fall of communism in 1989 and 1990, health care systems of former totalitarian states had to be transformed and assimilated to the emerging democratic societies. Founding HECs under these circumstances has rather been a top down process, as the example of Croatia shows. Moreover, regulation of these committees has been both central and strict. Laws were authorised on a national level, and complemented by ministerial

decrees and guidelines of national ethics committees.

In Western Europe, the development has been almost reverse. Numerous HECs were rather local initiatives at the beginning, answering to a perceived need to discuss moral problems in patient care. In this bottom up approach, regulation has mostly remained weak and decentralised. It seems that in these countries, it is feared that too much regulation might diminish the HECs' contribution to the development of biomedical citizenship and democratic structures in healthcare (see Lebeer, 2003). However, the lack of a well-regulated super regional structure could as well be seen as a disadvantage if compared to RECs.

Types of regulation

To analyse regulation of HECs, the following two dichotomies will be distinguished: central or local regulation, and strict or weak regulation. Central regulation refers to the national and supranational (e.g. European) levels, whereas 'local' regulation implies anything below. In central regulation, authority can rest either with the legislator, a government agency (e.g. a ministry), a national bioethics commission or European res. global organisations. Local regulation, instead, emanates from local administrative bodies, health care trusts or health care institutions.

Under a strict type of regulation, compliance of ethics committees with pre-defined moral and procedural standards and rules may be required. HECs may as well be equipped with the authority to require obedience of healthcare providers to their guidelines. Weak regulation, instead, leaves more room to the committees for independent reflection. It refrains from interfering with the committees' autonomy. Put positively, the core of weak regulation is to facilitate or contribute to moral deliberation within HECs and health care organisations.

Our hypothesis is that strict and weak types of regulation correspond with diverging ideas about the purpose of HECs and with different underlying concepts of medical ethics. Ascribing ethics committees the authority to solve conflicts and to supervise morality may require a more rigorous way of control of the committees themselves as well as their addressees (strict regulation). If the ethics committee is predominantly conceived of as a facilitator of reflection, more latitude may be appropriate (weak regulation). Considering these distinctions, the following overview of types of regulation can be given (Figure 1).

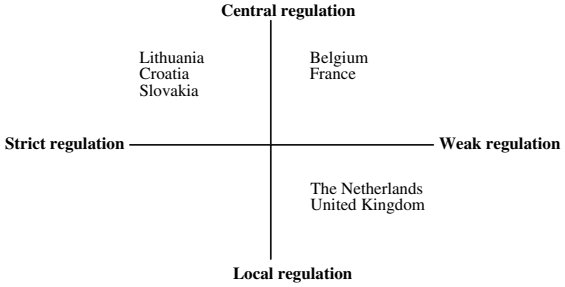

Figure 1. Types of regulation.

Regulation of HECs in Croatia, Lithuania and Slovakia has a tendency to be strict and central at the same time. Belgium and France have implemented central regulation as well. In terms of bindingness, however, it appears to be weaker and more facilitating than in the Eastern European countries. Committees in the Netherlands and the United Kingdom are almost self-regulated.

In Croatia, Lithuania and Slovakia, national ethics committees in combination with legal norms and provisions regulate the installation and a number of procedural aspects concerning HECs. In Lithuania, HECs were conceived following the idea of deliberative bodies when they were set up. However, in reality, these committees have been criticised for having become sentinels. According to evaluative research, these tensions can be traced back to different ideas about medical ethics held by healthcare institutions, committees and medical ethicists (see the country report from Lithuania, and Gefenas, 2001).

In Western Europe, the purpose of HECs is somewhat more clearly the facilitation of moral deliberation rather than managing conflicts or supervising a substantial moral position. Accordingly, latitude as to the organisational forms of clinical ethics is broader even in those countries in which HECs are regulated by national laws. National legislation in France refers to clinical ethics in general, not to ethics committees specifically, and does not mention ethics consultation. However, as HECs have already been installed in a number of French hospitals, the respective legal norms can be interpreted so as to connect the committees to local ethics networks, and to link these networks to a regional ethics centre (*Espace Éthique*). The French National Consultative Bioethics Committee has supported the aim of these legal prescripts (CCNE, 2004).

Belgian legislation has required local ethics committees for hospitals since 1994. Originally, no difference had been made between RECs and

HECs. In fact, the regulation of clinical ethics has primarily been left to the local administration of hospitals. The Belgian country report demonstrates the importance of a careful separation between HECs and RECs. At the same time, it shows the significance of balance between the two types of committees as far as regulation is concerned.

In the Netherlands and the UK, the development of HECs has been a bottom up process. As a consequence, regulation of HECs still widely rests with healthcare institutions, (umbrella) organisations of hospitals or (in the UK) healthcare trusts. In both countries a close connection between HECs and daily healthcare provision is aimed at. Similar to the Dutch Association of Bioethicists (NVB) and the Centre for Ethical and Philosophical Aspects of Care, the UK Clinical Ethics Network and the Royal College of Physicians have recently set up working groups to explore ways to improve the contribution of clinical ethics support services to moral deliberation on the ward (Royal College of Physicians, 2005).

Regulation of HECs: normative aspects

The normative question as to how HECs should be regulated will be discussed in three steps. First, arguments in favour and against central and local, strict and weak regulation are analysed. Second, it will be explored whether the weight of these arguments changes when specific circumstances in particular countries are taken into consideration. Third, suggestions will be made as to the regulation of HECs in Europe. In anticipation of further European unification it will be considered what type of regulation would be preferable, and what should be regulated to let HECs develop to live up to their proposed purposes.

Central or local regulation

In the light of the country reports it is assumed that the following four factors can be influenced by the scope of regulation: (1) the relevance and appreciation of HECs; (2) mutual comparability and consistency of the work of HECs; (3) avoidance of redundancy by co-ordination of the committees' work on guidelines and ethical case deliberation; (4) connection and adjustment of HECs to daily healthcare practice. The question is if these factors are better served by central or by local regulation and, if there are differences, for which one of them central regulation is to be preferred and for which one local regulation would fit better.

The formal authority of HECs to enface their addressees' compliance to guidelines and judgements is limited compared to the authority of RECs. Therefore, it is essential for HECs to be relevant and appreciated as advisory bodies. According to the Belgian contribution, the relevance of HECs can be increased and maintained by distinguishing clearly between research ethics and clinical ethics. Furthermore, the development of education programmes for committee members as well as a good structural integration of HECs into the procedures of healthcare institutions are expected to improve the committees' relevance for institutional healthcare delivery. The better their quality, the more relevant they can be.

It can be assumed that central regulation can improve and strengthen a committee's relevance on a higher organisational level. It should not be concluded, however, that central regulation is the only way to achieve this goal. Rather, it can be a supportive means, granting both non-regulatory co-ordination and local regulatory instruments a more significant impact.

Second, regulation may improve the comparability of different committees, and the consistency of their advisory work within a larger context, for example a region or a country. As to the procedures, composition, requirements for membership, methods of fulfilling basic tasks as well as evaluation of the committees' work, comparability can for instance be improved by shared standards. In a similar way, the development of guidelines about substantial moral questions could be co-ordinated.

Third, the pragmatic consideration that networking capability of HECs is improved can be another argument in favour of central regulation. With a well-developed structure of central regulation of HECs, the already existing hospital policies could not only be co-ordinated in a better way, but also used as a source for policy development in other hospitals, by national ethics commissions or by the legislator. As with the other two factors, regulation on the central level is a complement, and could be implemented following considerations of subsidiarity: if either local regulation or non-regulatory structures appear to be insufficient, additional support can be given effectively by a central regulatory authority.

According to the principle of subsidiarity, over-centralisation should be avoided. For HECs, as a consequence of over-centralisation, space for reflection and the connection to daily work would easily be jeopardised. An advantage of *local* regulation, therefore, lies in the fourth factor,

namely that it can better adjust and connect HECs to daily healthcare delivery. The British country report points out that the location of regulation in nationwide structures may enlarge the distance between HECs and healthcare delivery. Such a development might be avoided by linking HEC regulation to an intermediate level, e.g. to networks of hospital sponsors or healthcare trusts.

In summary, regulation can be a reasonable means to increase the quality and status of HECs if carefully applied. Central regulation can improve the relevance and appreciation of HECs, and broaden their comparability and consistency on a larger scale. Furthermore, there are pragmatic advantages, for example a better networking capacity. Avoidance of alienation from daily healthcare delivery, particularly from the institution where the HEC is located, would render small-scale regulation preferable instead. Central regulation in connection with local networks seem to be a stronger alternative than either to limit regulation to the local sphere or to leave all the co-ordination to non-regulatory networks. A good connection to daily healthcare delivery remains an important task under all circumstances, and can be guaranteed by other means, for example by a structured interaction between the committee and moral deliberation on the ward (Steinkamp and Gordijn, 2001).

Strict or weak regulation

The question if regulation of HECs should rather be strict or weak is related to the question of the committees' accountability. Strict regulation subjects HECs to rules with a strong binding force. Furthermore, it entitles the committees to control and monitor their addressees. Weak regulation of HECs, instead, can be interpreted both in a negative and in a positive sense. Negatively it means less interference with the autonomy of the committees and their target groups; positively it means the facilitation of independent reflection.

To what extent a HEC can be held accountable for its advice depends on the purpose, tasks and responsibilities ascribed to it (Ashcroft, 2005; Reeves and Brody, 1992). Comparing the countries participating in this study, three ideas in terms of the purpose of HECs can be identified. According to the first idea, a HEC is an interdisciplinary panel to facilitate and practise moral deliberation and reflection in institutional healthcare delivery. According to the second idea, the committees' purpose is to directly intervene and give advice in medical decision-making. Following the third idea, a HEC is conceived of as a group of moral experts supervising the adherence of healthcare providers and institutions to a fixed set of moral norms.

As far as the orientation towards a projected purpose of HECs is concerned, a preference in clinical ethics can be identified in favour of the first idea, namely that HECs should be panels to practice and facilitate reflection (Wilson Ross et al., 1993; van der Kloot-Meijburg and Ter Meulen, 2001). Next to granting space for these activities, a facilitative HEC would aim to support and facilitate the responsibility of healthcare providers as well. Furthermore, a facilitative HEC would best fit the general goal of biomedical citizenship and democratisation in the health care sector, which has been defined by Lebeer as a leading idea of clinical ethics in Europe (Lebeer, 2003). A HEC conceived of as a surveillance panel, instead, would rather limit the autonomy of its target groups than be supportive in guiding reflection about moral questions in healthcare delivery (Gefenas, 2001).

Remarkably, in Western European countries ideas about purpose, tasks and responsibilities of HECs have first emerged without there being any regulation at all. In Eastern European countries, instead, a relatively strict form of regulation has been in place from the beginning. In view of these differences, a well-considered middle position, pointed out in the recent UNESCO Guide No. 2, 'Bioethics Committees at Work' (UNESO, 2005), might be suggested as an orientation mark. The report argues that freedom and independence yield accountability in the first place. To ensure accountability on a long-term basis, however, a certain degree of regulation is necessary. If the rules and regulations become too strict, and if they grant insufficient latitude, accountability can in turn be undermined. Applied to the situation of HECs, it can be concluded that regulation should be as strict as necessary to ensure accountability, and as weak as possible to refrain from undermining it.

As to the specific forms of regulatory instruments to safeguard accountability, Fry-Revere has suggested to consider five levels: professional self-regulation, licensure and professional discipline, government contracting, judicial remedies, and government commissions (Fry-Revere, 1992). For the development of such specific forms in the context of the European Union, further research would be recommendable.

Do the arguments shift depending on country specific conditions?

The general pre-supposition has been that the main purpose of HECs lies in facilitating ethical

reflection and deliberation. Assuming that the purpose of regulation is to support HECs to live up to this standard, central and weak regulation appears to be preferable. The question rises, however, whether or not the validity of this conclusion is context-independent. The more specific question may be asked if HECs in transitional countries should be regulated in the same way as in established democratic societies. Are there relevant differences, which justify or necessitate variations of the concept of regulation?

Two differences will briefly be considered. First, due to social and political conditions in the healthcare institutions of a particular country, HECs may temporarily be assigned a purpose other than (the facilitation of) ethical reflection. Second, during the implementation of a HEC, preliminary arrangements may have to be made so as to enable the committee to gradually grow into the role defined for it.

As to the first point, the purpose of ethical reflection generally applies to HECs under all societal circumstances, in established democracies as well as in transitional countries. Even if the purpose appears to be different temporarily, it remains valid as an aim to strive for. In situations of transition or transitional crisis, however, it may become necessary to let a modified purpose prevail, for example if an independent advisory body is needed for conflict resolution or to monitor the adherence within a healthcare institution to basic principles of ethics. In such a case, a stricter form of regulation may temporarily be necessary.

Second, HECs were assigned a supervisory rather than a reflective function mostly early in the process of political reform in transitional countries. When in such a situation, HECs are being implemented into still predominantly authoritarian structures, stricter regulation may be justified because otherwise, setting up a HEC may prove impossible at all. If this is the case, regulation should be transformed at a later stadium of development. Perpetuating strict regulation in a situation where it is not necessary, may limit the space for reflection as well as the accountability and relevance of HECs in the long run.

Hence, the arguments in favour of central and weak regulation may temporarily take on a different weight. There are circumstances when regulation needs to be adjusted. However, this does not change the general preference for central and weak regulation. Therefore, changes in the direction of stricter regulation should be rendered reversible.

Do the arguments shift in view of the European unification?

Finally, the question rises if there are specific ways of regulation of HECs, which are desirable in view of the goals and the process of European unification. In general, two types of regulation of ethical questions in Europe have been established so far. First, several bioethicists and bioethics organisations have aimed to determine a substantial 'European' morality. For example, in the *EC Convention on Human Rights and Biomedicine* (Council of Europe, 1997), basic principles were agreed upon to guide decision-making concerning controversial moral issues of recent medical technologies. Another example is the *Barcelona Declaration*, a consensus document promoting a set of ideas, which can form the basis for a different set of moral principles, presumed to be specifically European (The Barcelona Declaration, 1998; Rendtorff and Kemp, 2000a, b).

Similar to Beauchamp and Childress (2001), who have summarised a set of principles of biomedical ethics including respect for autonomy, non-maleficence, beneficence and justice, the *Barcelona Declaration* defines four ideas: autonomy, dignity, integrity and vulnerability. These ideas were agreed upon because, first, they are supposed to fit better the situation of people in need. Second, other than Beauchamp's and Childress' principles with roots in the US-American language of rights and the tradition of utilitarianism, the ideas in the *Barcelona Declaration* are thought to better connect to the European traditions of charity and solidarity in healthcare. Primarily this applies to the concept of autonomy, which in the *Barcelona Declaration* is a collective term with a number of different meanings, and to the idea of vulnerability, which is based upon the philosophy of the 'other' by Emanuel Levinas (1981).

A second type of European bioethics regulation is procedural. Following the Declaration of Helsinki and other international guidelines, numerous procedures have been implemented to protect human subjects in medical research. For example, the EU Clinical Trials Directive 2001/20/EC makes prescriptions as to the design of medical research involving human research subjects (European Parliament, 2001). Next to presenting the respective norms, the document prescribes steps on how to implement these norms in the EU member states.

For research ethics, numerous procedures have already been elaborated, whereas clinical ethics is lagging behind in this. Copying the regulatory structure of RECs, however, seems neither desirable nor feasible for HECs because of a major difference between healthcare and medical research (Miller and Brody, 2003). In regular healthcare delivery, all decisions and actions are required to be directed towards the patient's good, while respecting his or her autonomy. In medical research, however, the benefit of research subjects is one aspect of a different range of valuable aims to consider. For example, there is a consensus that insignificant risks for participants of research are considered acceptable for the sake of scientific progress. Hence, in contrast to clinical ethics, the field of research ethics is structurally determined by a specific tension of interest. Therefore, a stricter form of regulation might be advisable for RECs, whereas it could be counterproductive for HECs. The latitude, which appears to be a pre-requisite of HECs' accountability, would fall short of the stricter requirements for the review of research.

A further specificity of HECs is that appropriate latitude in regulation can be derived from the substantial ideas about the ethics of patient care as phrased in the Barcelona declaration. Therefore, regulation of HECs cannot only be procedural. Rather, the first mentioned, substantial way of regulating bioethics forms an essential source for the regulation as well. Up until now, this source has not yet been utilised sufficiently. Whereas it has been said that facilitating reflection is a main purpose of HECs, a second purpose can now be added, namely the advocacy for patients in the situation of vulnerability. If vulnerability is to be considered a basic moral principle, which expresses the obligations of healthcare providers to patients in a way specific to European thinking, it could become a reference point for the regulation of HECs.

Conclusion

Contributions about the situation in eight European countries have shown that regulation of HECs is generally less developed than regulation of RECs. In Eastern Europe, regulation of HECs is mostly centrally organised and rather strict. In Western Europe, regulatory structures are weaker when compared both to Eastern European countries and to the international regulation of RECs. Whereas in Belgium and France, there is some regulation on the national level, the United Kingdom and The Netherlands have opted for non-regulatory forms of co-operation between HECs. Assuming that the facilitation of ethical reflection and the development of biomedical citizenship are general purposes of HECs (Lebeer and Moulin, 2000, 2001; Lebeer, 2003), it has been argued that central and weak regulation is the most appropriate.

Aims of central and cautious regulation would be to facilitate the committees' relevance, their accountability, and structured ethical deliberation. As HECs are not disciplinary panels, a societal and political climate affirmative to ethical reflection is essential. Under conditions adversarial to ethical reflection, a stricter form of regulation may temporarily become justified. Careful implementation of central and weak forms of regulation, however, will remain the main aim, especially within the process of European unification. A temporary tightening of regulation, which may at times be a means of choice, should therefore be revoked as soon as space for ethical reflection becomes available again.

Notes

1. In the USA these committees are also referred to as institutional review boards (IRBs).
2. In the UK, HECs have been referred to as clinical ethics committees (CECs).

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