Medical ethics in the European Community

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Author's abstract

Increasing European co-operation must take place in many areas, including medical ethics. Against the background of common cultural norms and pluralistic variation within political traditions, religion and lifestyles, Europe will have to converge towards unity within the field of medical ethics. This article examines how such convergence might develop with respect to four major areas: European research ethics committees, democratic health systems, the human genome project and rules for stopping futile treatments.

Unity and pluralism

From the iron grips of churches, kings and dictators Europe has, fortunately, moved steadily towards more personal freedom for its citizens. Although there have been many setbacks, each century has seen an increase in personal freedom.

Freedom, defined as the sum of personal options, means the appearance of multiple life-styles and sub-cultures – in other words pluralism, as the complementary concept to the forceful unification throughout centuries, when fear was the driving force behind the apparent unity.

This much-wanted historical trend has made discussion of both national ethics and European ethics difficult. What is the core behind all the legitimate diversities? And who is going to encircle such a core, if it exists, and to express 'the voice of the people'? The difficulties can lead to conceptual apathy, thus letting important ethical dilemmas in medicine lie untouched; or they can lead politicians to reach for a revival of the forceful unification, which today is that of legal prohibition.

It is obvious that both apathy and prohibition are unsatisfactory reactions in a modern society. Do more balanced alternatives exist? I believe that they do, both when considering the inter-personal level, and the person-state-level, discussed below. This is because there is a common cultural core in Europe,

young and feeble in some areas, old and consolidated in others: the fundamental human rights and their political projection, the democratic system. The third level discussed below, the existential/religious, still creates difficulties however, for a national, or a European, ethical consensus.

Because scientific innovations appear at a high rate in medicine, societies have to counteract tendencies both to apathy and to legal prohibition as the only public reactions. The last decades have shown that democratic bodies such as parliaments can deal with medical-ethical problems, although often in an inappropriate way because they are not used to dealing with the concepts relevant to medical ethics.

The three levels

In the preceding section it was stated that three levels of interactions would be analysed. The first is the *inter-personal level*. In medical ethics this is exemplified by the patient-doctor relationship and the patient-researcher relationship. The inter-personal level deals with the individually named patient, in a concrete situation, with a named doctor or researcher as partner. Its most personal components are those usually confined to the non-professional private sphere: for example, politeness, respect, symmetry in dialogue, and information. But it also comprises the projected elements of national laws, for example: health legislation relating to the duties of health personnel, and criminal law relating to the citizen's protection against forceful intrusion by other citizens, including health personnel.

The second level of medical ethics is the *person-state-level*. This comprises the laws that set standards for the medical aspects of a health system serving citizens as a whole. Examples are the legal definition of death, access to major organ transplantations, access to non-selective and selective abortion, distribution of scarce health resources, and human experimentation.

The third level is the *existential/religious level* of medical ethics, comprising the application of medical methods (or even the deliberate non-application), and involving man in a deeper existential

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context. Examples are: research on fertilised human eggs; the right to die without further medical intervention; in some countries the right to die by the aid of a medical intervention; and, for members of certain religious communities, the mere existence of laws permitting free and selective abortion.

The intra- and international variation of norms and legislations on these three levels is substantial, even in Europe. The greatest variation is in the third level. Different religious beliefs, Catholic, Islamic, Jewish, Lutheran, to say nothing of the strong anti-belief movements (sometimes reacting with a vigour similar to that of fundamentalistic religions), are least influenced by the converging political forces between European countries.

Public reactions to ethical dilemmas in medicine

Probably all ethical debates and the resulting norm-setting or controlling systems start with real things happening. There are several examples of such a sequence: fundamental human rights were identified as a reaction to severe suppression; the concept of equity was created as a reaction to slavery and other examples of racism; and freedom for women was fostered after innumerable examples of male sexism. Today the explosion of interest in medical ethics is the result of developments in medicine; for example new methods for sustaining fundamental bodily functions, of lungs, kidneys, and the gastrointestinal tract. Again, technological innovations have led to the need for redefining the beginning and the end of human life, for looking into the womb, directly or indirectly and so on. The ethical problems created by new medical techniques have appeared at a rate that has provoked society to a number of almost automatic responses. One response is *denial* of a personal co-responsibility for the individual citizen. This attitude reflects an escapist tendency, leaving the debate and possible solutions to the experts. This is a dangerous 'solution' in a democratic society.

The opposite response is *prohibition*, ahead of sufficient public debate. This is often suggested by citizens and politicians as a kind of reflex reaction.

A variant of *denial* is the acceptance of an ethical dilemma in medicine, and at the same time *exporting the problem*. This has, for instance, been the case in Denmark until recently with regard to organ transplantation. Major organ transplantations which require the legal acceptance of brain death were, for a long time, not accessible in Denmark, because brain death was considered ethically suspect. For some years Danish patients needing heart, lung or liver transplantations were sent to British, Dutch or German hospitals and were granted public money in order to pay for these operations. To claim that it would be cruel to ask Danish parents to donate organs from their brain-dead young daughter, and, at the same time, to exclude British, Dutch or

German parents from such consideration is a typical example of an 'escapist export' of an ethical problem. Fortunately this export has now stopped because of new law legitimising brain death.

The fourth type of public reaction, *the acceptance of a public debate and of citizens' co-responsibility*, is fortunately becoming more common. Such debate takes time; and time can be made a general political excuse for not making decisions.

Major areas of European medical ethics

I will now discuss four major areas of European medical ethics which will need to be a focus for debate over the next decade.

1) European research ethics committees

Despite a general European consensus on the importance of research ethics, and despite the general acceptance of the Second Helsinki Declaration on the ethics of medical research, and the demand of the declaration, that 'the experimental protocol should be transmitted to a specially appointed independent committee for consideration, comment and guidance', committee systems of Europe differ very considerably. Some countries have a nationwide system built up in accordance with fixed rules for membership, functions etc. Some countries have created a legal base for such committees, others have left it to individual institutions to establish local committees. Accordingly, the range of variation is formidable.

The *number of committees* in each country varies from less than ten, as in Norway and Denmark, to several hundreds in countries without a co-ordinated national system.

The *membership* varies from an overwhelming number of scientists with one, or a few, lay members, to parity between lay and scientific members (even to a slight preponderance of lay members, as is the case in the Danish law of October 1, 1992).

Some committees are only *institutional*, others cover all biomedical research, within medicine, odontology and pharmacy, of an area, being by constitution *regional*. The first type can leave projects from general practice of medicine and dentistry uncovered, the latter comprises *all* biomedical research, whether in practice, industry, research institutions or hospitals.

Some national systems are *single-tiered*, others are *double-tiered*. In the first case national co-ordination of decisional levels and norms is difficult, often exemplified in the way that multi-centre trials are dealt with. In a single-tiered system appeal mechanisms are often not formalised, and hearings of the national system for political reasons are difficult and often yield multi-tongued answers. Research projects in Third World countries, supported by

European governments or granting bodies, are also difficult to bring into a single-tiered system, in order to ensure the necessary research-ethical standard of such projects.

In some countries non-scientific committee members must be '*lay specialists*', for example lawyers, theologians, philosophers; in others such members must be *true lay members*, ie truly representative of a democratic system.

THE NECESSARY CO-ORDINATION OF EUROPEAN ETHICS COMMITTEE SYSTEMS

The co-ordination, and even harmonisation, of the European research-ethical committees, is an urgent task. The great variation in committee membership and functions emphasises the difficulties of such, much needed, co-ordination. It is not primarily a question of linking existing systems together, but of creating national systems in a way that makes a European system possible. In the EC guidelines on European pharmacological research (1), an 'ethics committee' is defined as follows: 'An independent body, constituted by medical professionals and non-medical members, whose responsibility is to verify that the safety, integrity and human rights of the subjects participating in a particular trial are protected, thereby providing public reassurance.'

'Ethics committees should be constituted and operated so that the suitability of the investigators, facilities, protocols, the eligibility of trial subject groups, and the adequacy of confidentiality safeguards may be objectively and impartially reviewed independently of the investigator, sponsor, and relevant authorities.'

'The legal status, constitution, and regulatory requirements pertaining to ethics committees, review boards, or similar institutions may differ among countries.'

'A list of the members, and their positions, of the ethics committee and a description of its working procedures including response times should be publicly available.'

As will be seen the guidelines do not specify the kind of national system needed for a co-ordinated European system. The necessary next step must be a description of, at least, the minimal requirements for a national committee system. If not, European multi-centre studies will be ethically uneven. Furthermore, unless a co-ordinated system is developed, the present unsatisfactory situation will continue, viz that if a given project is criticised on ethical grounds, even if all that is proposed is some simple changes in design, then the project group and the drug company state that 'they have transferred the study to another European country'. Research ethical problems, like water, seek the path of least resistance.

European harmonisation of medical research ethics and the corresponding control systems will be an important signal to countries under develop-

ment, the former Eastern European nations and those of the Third World, that research ethics is not esoteric, but is an integral part of the democratic concept.

'GOOD CLINICAL RESEARCH'

It is a fundamental paradigm of medical research ethics, that all methodologically defective projects on man are in themselves ethically unacceptable. The reason is obvious: such projects will never give a reliable answer, and thus represent a loss of time and resources, especially for the trial patients. Turning this statement round one can say that a high standard of methodology is a necessary (but not sufficient) condition for ethically acceptable medical research on man. There has been visible progress in this direction in Europe since World War II. But still the new and greater Europe needs to progress further before reaching the necessary standards. Fundamental truisms such as 'everything varies' and 'all judgements rest on comparisons' are still not fully understood by many students in medicine, nursing, odontology and pharmacy. And even those embarking on a postgraduate research project in clinical medicine do not always understand basic scientific methodology, for example: precise definitions of diseases, consecutive sampling, randomisation, blinding techniques, the importance of drop-outs, handling medical statistics, and critical literature analysis. The discipline 'methodology', defined as the art of planning, carrying through and interpreting a research project (and its mirror image the art of critical reading) ought to be a *conditio sine qua non* in European curricula. In this way 'good clinical research' would go hand in hand with 'good ethical practice' and 'good clinical practice' (or, more exactly, 'good clinical-pharmacological practice').

2) Democratic health systems

The most important ethical problem to be faced over the next few years is that of distributional ethics, ie how health resources should be distributed in a fair way to those in need. Two aspects of this central ethical problem will need to be considered. The first is the necessity for a public health system which gives all citizens access to health care, not unlimited access, but access representing a fair share of the total national health resources.

Systems which are based mainly or completely on private insurance schemes leave those most in need either with nothing or to charity. Such systems can never achieve the degree of fairness which is necessary for them to be ethically legitimate in a democratic society.

The second aspect of distributional ethics derives from the fact that even countries with a democratic health system face scarcity. The limited resources need to be distributed fairly. Health systems have

never had the ability to cover all need, if all possibilities were exploited, but only recently has this fact become apparent to the public and to the health professions. The continuous flow of new therapeutic possibilities, for example major organ transplantation, intra-temporal computer-assisted devices for the totally deaf and joint alloplasties, has made the economic-ethical dilemma visible to all. Handling the distribution-ethical problem is one of the greatest challenges for the future. It will require us to step back from our own interests in order to help those citizens who are in greater need than ourselves.

PATIENTS' RIGHTS AND DUTIES

Although the patient-doctor relationship has come a long way from the extreme paternalism which once characterised it, many patients are still not accorded their full rights to respect, information and self-determination. This is not only because of doctors' and nurses' attitudes, but is also due to a lack of knowledge and abilities on the part of the health care professionals. To inform patients on technical matters, for instance, presupposes the mastering of a non-professional language, which is precise and does not 'infantilise' the patient.

Increasing respect for patients' rights has to take place on several levels. This issue needs to be tackled early in the training of health profession students both directly in the systematic part of their learning, and indirectly through the implicit and explicit attitudes of their teachers. Fighting prejudices, such as paternalistic attitudes, must also take place early in professional development, at best *before* any prejudices are laid down. Further, the postgraduate climate in hospitals and other institutions needs to include an overall acceptance of patients' rights. And finally, administrative instructions from health departments and health legislation must directly address this aim. It will not be sufficient for there to be debate; or for a few pioneers to set new standards: administration directives with legal backing will be necessary in order to change behaviour in all parts of a health system.

Having reached a general acceptance of patients' rights one can add the complementary demand: that of patients' duties towards the health system. For instance, patients should respect health personnel's right to have personal beliefs, should treat such personnel decently as the fellow citizens they are, and should comply with agreements (or in case of *force majeure* should inform) etc. This complementarity, yet asymmetry in the patient/health-professional relationship, needs to be acknowledged more openly in the future.

3) The ethics of the human genome project

Europe is strongly involved in the ongoing endeavours to map the complete human genome. This

enterprise has both fascinated and scared the public. The fears have centred around the hypothetical grouping of mankind into alpha-, beta- etc types, and the application of such knowledge to, for example the selection of personnel for polluting and dangerous industries (ie selecting those most resistant to industrial diseases), or to the exclusion of those considered 'bad risks' from insurance schemes. Some of the fears of this kind might be turned to promises. Why not welcome the possibility that a baker's apprentice could, if he wished, be tested for genes leading to flour allergy? As for the fascination, it is possible that the unearthing of the formidable genetic variation which exists amongst a population will help to emphasise the necessity of not confusing equity and dignity with an individual's genes and capabilities. In this way the genome project may help to foster an attitude which emphasises the fundamental equality of human beings and not the opposite.

4) When to stop treatment?

Although the ability to preserve life has been a central aim for health care now, when we have access to highly effective life-sustaining techniques, we see the opposite side of the coin: the sustaining of life beyond what seems of value. The appearance of 'The right to die' movement and the introduction of legislation concerning brain death are signs of a new duality in dealing with life-sustaining methods: at the same time they are both a blessing and a curse.

At present, national policies concerning the proper use of life-sustaining techniques vary widely. In some countries there is no guidance; in others there is discussion about whether living wills should be given legal backing. In Holland voluntary euthanasia is openly (although still illegally) practised. Closely co-operating nations need to pool their efforts in clarifying the necessary basic concepts, and in performing the necessary research on diagnostic safety in different terminal states, with the common aim of ensuring that citizens are, on the one hand confident that they will not be treated absurdly without consideration of their personal wishes and quality of life and, on the other hand that they can rely on hospitals not to function as a state sorting-mechanism of unrightful lives.

The necessary debate

Information on, and public discussions of, ethical aspects of health services and health sciences are characterised by their discontinuous, almost stochastic nature. In this way medical ethics shares the fate of existential and religious topics in the public media. Where one would very much wish an ongoing debate, describing the many ethical dilemmas in medicine with all their pros and cons, one gets instead long periods of silence and then

sudden explosions of media interest when experts are expected to give a comprehensive account in two and a half minutes during the seven am news. These 'explosions' can be caused by a report from the US that a family has planned a new pregnancy in order to save their older daughter through a compatible bone-marrow transplantation, or by a son's mercy killing of his senile demented mother. The common characteristic of such journalistic stories is their sudden impact, arousing a lot of emotions and indignation, which disappear as quickly as they arose, in accordance with the natural law of timely symmetry of such journalism. Retention is not intended and is not achieved.

The fault, however, lies not only with the media. The media produce only what attracts readers', listeners' and viewers' attention. Improvement must, therefore, start with us, the citizens, whose genuine interest in, and responsibility for, medical ethics is what is needed to create an ongoing public debate with credible information and nuanced discussions. What is wanted in a modest first stage is just a fraction of the information and journalistic resources which are spent on, for example, sports reporting, to be given to medical ethics.

The obligations of Western Europe

It is particularly important at a stage when the technical-economic systems of North America, Western Europe and Japan have shown their superiority over the fallen East-European empire and its many satellites that the new world is not guided by only one concept: market forces. It is important that non-materialistic values are given high priority, and consequently, that the highly industrialised First World countries realise that economic superiority is not automatically accompanied by cultural superiority. Indeed, the correlation between economic and cultural superiority, if it exists at all, seems to be negative, except in so far that part of fundamental human rights are integrated within the democratic political systems.

This situation creates a double obligation for the European and North American nations. They have to make the democratic principles visible and operational for the former dictatorships and to do this without implying a new, ideological hegemony. Instead, only the principles themselves, with the different technical options should be exported, not the easy 'just do as we do' concept. The second obligation requires at least as much tact as the first one. It comprises ethics and morals as such, and is an important subgroup of medical ethics. Research ethics, the patient-doctor relationship, and ethical issues surrounding large organ transplantation have been analysed in depth. These areas of medical ethics would form a useful basis for direct teaching. But when it comes to fundamental norms, and good

citizenship, many of the populations of former dictatorships probably have more to teach us, the economically and politically privileged, than we have to teach them. At the same time, to acknowledge their values and hopes, and to teach and instruct within areas where they express a need for such help, demands much more from us than a flat market-philosophy.

Public pluralism and intellectual ethics

It is probable that the greatest challenge in medical ethics (and in ethics as a whole) during the next decade will be to change pluralism so that, instead of being a supermarket of incoherent options, it becomes a number of coherent ethical options, chosen according to an individual citizen's own overall preference. Seen in this perspective professional ethics, such as medical ethics, will be provinces of the more general ethical landscape, even if their concepts and analyses can sometimes act as catalysts for more global ethical considerations. Lying behind the seemingly pure intellectual analyses of ethical dilemmas in medicine, as when life begins, or life ends, are fundamental ethical questions reaching far beyond medicine and its contractual and legal solutions at levels one and two.

A necessary larger perspective will, for instance, mean acknowledging the fundamental difference between understanding connections stepwise and piecemeal (to know some of the twigs, but not the tree) and understanding full connections in a long leap (to see the tree, but not to know all the twigs).

It will further mean acknowledging the fundamental difference between the concept of reward or *quid pro quo* closely related to merits, and the concept of benefit unrelated to merits, ie possessing the nature of a gift. In accordance with the latter concept individual human beings are judged not by their merits, but are allocated an identical and unalienable value.

The acknowledgements mentioned would force man to act on two different levels: 1) That of day-to-day necessity, where the stepwise understanding and the correlation between reward and merits rule, and 2) that of an intellect-independent total pattern, where the value of individuals is independent of talents and merits. On the first level one operates with degrees of perfection, on the other with degrees of imperfection, where a general forgiveness is the principal answer to imperfection.

This complicated dualism can be illustrated through an analogy with the nature of music. It is impossible to grasp the total message of emotions and insight that a given piece of music holds through a stepwise acquisition of individual bars' tonal geometry and the individual instruments' functioning. It will need a formidable cultural revolution of our European societies in order to face these existential questions and to take a stand other than the usual attitude of playing the winner.

Religions and churches can play an important role, if their languages and rites converge towards a meeting point for the present secularised society. Further, innovative art might, once more in the history of man, become a necessary eye-opener.

In achieving these developments within Europe, medical ethics might serve both as a part of the message and as one of the messengers.

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