

Guide No.1

Establishing Bioethics Committees



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Bioethics
Committees



UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION
DIVISION OF ETHICS OF SCIENCE AND TECHNOLOGY

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FOREWORD

This Guide is intended to provide precisely what its title denotes: guidance. It is designed neither to dictate ethical principles for inclusion in health policy nor to advocate the development of specific approaches for any Member State of UNESCO, but to offer a number of suggestions after having reviewed the efforts of many Member States that have already established Bioethics Committees at the national, regional, or local levels. The need to reflect on the moral dimension of advances in science and technology, as well as the desire to enhance the public's health has, in many areas of the world, led to the establishment of various forms of Bioethics Committees, four of which are described and discussed in this Guide.

These committees have received various titles: (1) 'ethics committee', 'ethics or bioethics commission', and 'council on bioethics' at the national level; (2) 'health-professional association bioethics committees' at the national and regional levels; (3) 'health care/hospital ethics committees', usually established at the local level; and (4) 'research ethics committees', established at different levels in various Member States.

The Guide has been prepared not only for the use of ministers, but also for their policy advisers at the national, regional and local levels, leaders and members of professional and scientific research associations, and chairpersons and members of various forms of bioethics committees. Each of them, of course, is at liberty to affirm its purposes, articulate its functions and determine its routine working procedures.

To be sure, the suggestions in this Guide could, in time, be incorporated into agreements and policies about how, for example, to control the use or misuse of newly acquired biological and medical knowledge and biotechnologies. But at the present time we need to develop a critical frame of mind and a system of values that prepare us to judge each new biological, molecular and genetic discovery or biotechnology as it evolves and insinuates itself into the awesome and broad domains of the life sciences and health sciences.

Bioethics committees are an ideal platform from which to implement the various standard-setting instruments that have been adopted by UNESCO, particularly the Universal Declaration on the Human Genome and Human Rights (1997) and the International Declaration on Human Genetic Data (2003). UNESCO, as a leading international agency in the area of bioethics, assists its Member States in establishing and developing infrastructures for bioethics, such as ethics teaching programmes, guidelines, regulations, legislation and bioethics committees.

UNESCO's Division of Ethics of Science and Technology has over the years acquired considerable expertise in supporting Member States in addressing ethical queries and quandaries in relation to advances within the broad range of biological sciences and biotechnology. This Guide will be the first in a series aimed at providing practical assistance to Member States that are considering the establishment of and support for bioethics committees. We are grateful to Emeritus Professor,

Stuart F. Spicker, founder and former editor-in-chief of the journal, *Hospital Ethics Committee Forum*, for his support and expertise in developing this Guide.

The hope is that new advances in the life sciences and biotechnology will allow States, perhaps with the involvement and cooperation of present and newly-formed national, regional and local bioethics committees, to channel such knowledge to benefit not only individuals – patients and persons who consent to participate in human research, including healthy persons – but entire societies and even the global community. Establishing bioethics committees may be a first step for States to create platforms and bodies for ethical debate, analysis and policy development.

Continuous reflection on the bioethical issues raised by advances along the spectrum of the biological sciences and various biotechnologies will give us the best chance to shape the future for the benefit of citizens in all Member States.

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INTRODUCTION

It is a commonplace that persons play various roles throughout their lives. Shakespeare in *As You Like It* tells us:

All the world's a stage,
And all the men and women merely players:
They have their exits and their entrances;
And one man in his time plays many parts...

In the bioethical context it is likely that each of us will, at different times, play one or two roles: we may fall ill or be injured and become a hospital patient; or we may become involved in biomedical, behavioural, or epidemiological research, and become an active participant in a research trial or investigation.

During the past forty years, a number of States have witnessed a dramatic change in the attitudes and behaviour of their people – those who have become patients as well as those who have agreed to participate in clinical trials. This change is reflected in the active role that today's patients and research participants have adopted in contrast to the passive role that had dominated for generations.

As this change was taking place, formal moves were made to protect the rights and welfare of patients and research participants. A doctrine of informed consent had already been established and implemented in a number of States. This doctrine was particularly emphasized immediately after the Second World War in the work of the Nuremberg Military Tribunals – particularly the Doctors' Trial – and the establishment and dissemination of the Nuremberg Code (1947). This Code embodied civilized society's response to the barbarities and atrocious "experiments" on unconsenting prisoners and detainees perpetrated by the Nazis in the name of medical science, echoed in the United Nations General Assembly's Universal Declaration of Human Rights (1948).

Democracies are based on the principle of rule with the consent of the governed, and the doctrine of informed consent represented an effort to extend this principle to medicine and the life sciences. Among other things, the doctrine requires disclosure of the nature of experiments and the potential benefits and risks they entail, seeking truly informed consent of those persons recruited to participate in the research enterprise. The Nuremberg Code – though one tends to overlook the fact that it addresses the role of persons as patients – has become especially relevant to the second role persons may play in the health care context, namely, agreeing to participate in clinical research trials, most of which are conducted by physician-scientist investigators.

Codes and declarations, however, by themselves are mere words on paper. No matter how desirable or heartfelt, they are not self-enforcing. To save them from becoming mere rhetorical gambits, they require advocates among those who formulate, implement and monitor public

policies. Consider, for example, the role of France's *Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé* (CCNE) and the United States President's Council on Bioethics – both of which, among a growing number of States that have established policy-making and/or advisory bioethics committees (PMAs) at the national level – serve as platforms for providing guidance and advice to policy makers and governments in their States at the national level (see Appendix 1). In the end governments, and those who influence governments, grant or deny the breath of life to bioethics committees. Here it is also important to point out that some States have elected to establish bioethics committees under statutes, thereby codifying them within the government and granting them virtual permanence (see, for example, 'The Act on the Danish Council of Ethics', 'Statutes of the Ethics Committee of the Gambia Government', and 'Statutes of the National Bioethics Committee of the Republic of Uzbekistan' – Appendix 2).

UNESCO principally addresses governments, ministries and experts – all of whom advise Member States – as well as individual policy makers. Thus, there is a significant science policy dimension that UNESCO is obliged continuously to consider and address not only to assist the governments of its Member States to develop and implement science policies, but in particular to address the ethical dimensions of such policies.

To articulate this mandate in detail, four key goals and four forms of bioethics committees established at three levels of government are discussed in this Guide. The goals are (a) to improve the public benefits of science and technology through a morally sensitive implementation of science policies at national level; (b) to improve patient-centred care in all health care institutions; (c) to protect those who participate in biological/biomedical, behavioural and epidemiological research trials; and (d) to facilitate the acquisition and use of biological, behavioural and epidemiological knowledge.

Part I

THE CHALLENGES AND TASKS OF ESTABLISHING BIOETHICS COMMITTEES

Bioethics, as a social movement, had its inception in industrialized countries during the mid-twentieth century and supplemented the professional ethics of physicians and nurses with clinical or applied ethics by addressing practical issues.

At this practical level, it was obvious that given the advances made by the life and the health sciences, as well as by innovative biotechnologies, there would be a growing need to make difficult moral choices. Health care institutions (mostly at the local level), as well as government and policy agencies (at the national level), soon recognized the importance of developing more formal mechanisms to address and work to resolve ethically charged or value-laden problems in the rapidly shifting dynamics of everyday health care and health policy. At the very least, many leaders of the scientific community thought that the establishment of various forms of bioethics committees would be a significant first step toward initiating discussions and debates on a plethora of contemporary bioethical issues.

A bioethics committee is a committee that systematically and continually addresses the ethical dimensions of (a) the health sciences, (b) the life sciences and (c) innovative health policies. A bioethics committee is typically composed of a range of experts, is usually multi-disciplinary and its members employ a variety of approaches to work toward the resolution of bioethical issues and problems, especially moral or bioethical dilemmas. Moreover, the members of these committees not only become more sensitive to ethical dilemmas but also, in time, develop the knowledge and skills required to deal more effectively with them, frequently finding ways to resolve what may at first appear to be intractable dilemmas.

The term 'dilemma' is a technical one. A bioethical dilemma is a form of argument in which two premises lead to a conclusion that usually reflects unpleasant alternatives – an apparently unacceptable, perhaps unethical, choice. A person or a committee may be caught, it is said, on the horns of a dilemma. Therefore, the conclusion's unpleasant alternatives require the committee's thought, discussion, deliberation and, finally, action. A committee often finds a way to avoid the horns of a dilemma; it resolves it and then makes a recommendation or suggestion leading to a particular action that is morally acceptable, thereby avoiding the extreme, unpleasant alternatives that it originally confronted. A patient, for example, whose case may have been brought before a committee, may have been told that he or she may choose either a longer life with chronic pain or accept a shorter life free of pain. How should he or she decide? How can health professionals and the patient making the choice know what the patient ought to decide? Should a committee be consulted to suggest a resolution of this

patient's dilemma, one that is no longer simply a choice between a longer life with chronic pain or a shorter, pain-free life?

To assist not only today's patients but also participants in human research to become involved in critical decisions that eventually emerge from formulating and analysing their bioethical dilemmas, health professionals turned to documents and doctrines that addressed, albeit briefly, the dignity of all persons, particularly the vulnerable, e.g. persons with limited mental capacity for health care decision-making. The most important of these doctrines – addressing the dignity and autonomy of all persons – is directed to obtaining the informed consent of persons.

1. HUMAN DIGNITY AND THE DOCTRINE OF INFORMED CONSENT

On 10 December 1948, three years after the end of the Second World War, the United Nations General Assembly adopted a Universal Declaration of Human Rights. The Declaration affirms 'the dignity and worth of the human person...for all peoples and all nations'. Article 27 states: 'Everyone has the right freely...to share in scientific advancement and its benefits', which implies that not only physicians but all health professionals and scientists are obligated to make scientific and biotechnological advances available to all the people of the world. The Declaration, then, bears on the ethical responsibilities and conduct of scientists (experts in the life sciences), physicians, as well as other health care professionals.

In many States, in order for a scientist and/or a physician-researcher to initiate a relationship with a potential research participant, who may be infirm or healthy, it is imperative that the principal researcher, or his or her representatives on the research team, seek to realize the ideal of fully informed consent from the potential participant.

The criteria for fully informed, voluntary consent for treating patients or having them and others participate in research trials are as follows:

- 1.a.** The physician researcher or investigator must sufficiently inform the patient or participant in research by providing a basic understanding of the risks and benefits of participation;
- 1.b.** the patient or participant in research must adequately understand and have sufficient time to reflect on his or her clinical condition, the objective of the research protocol – sometimes the various treatment alternatives, if any – and the 'more than minimal risk of harm' of the treatment or research interventions, as well, perhaps, as the 'minimal risks';

REQUIREMENTS FOR INFORMED CONSENT

The individual

- 1a.** is adequately informed;
- 1b.** adequately understands the treatment or the procedures of the clinical investigation;
- 2.** voluntarily participates and is not coerced;
- 3.** has adequate mental capacity; and
- 4.** has reached the age of legal competence.

In recent years, and in a number of States, criteria have been established to enable physicians and/or researchers to decide if partially informed consent from patients and potential research participants is warranted. Some researchers have undertaken investigations that can be conducted, for example, only in the emergency rooms of hospitals, and thus one or more of the four factors for obtaining informed consent may be present only to a modest degree. Clearly, in the emergency context adequate time is not available for the physician or researcher to discuss the details of the treatment or research protocol with an unconscious or incapacitated individual, who is not at that time mentally capable, may even be under age and therefore would not satisfy the criterion of legal competence.

2. THE NEW APPLIED ETHICS OF THE HEALTH PROFESSIONS

In recent decades, philosophical reflection has often focused on everyday practices, especially health care settings and institutions, and everyday practical or applied bioethics has itself become an institution, or at least has been institutionalized, in a number of States in the developed world.

Many philosophers joined medical school faculties, became members of hospital staff and served as consultants to other health care institutions as well as government agencies at the national, regional and local levels. Many remain on university faculties, engaging part-time in applied bioethics, e.g. when called upon by local hospitals to participate as members of, or consultants to, their health care/hospital ethics committees (HECs) or to serve as committee members on research ethics committees (RECs) at the local, regional and national levels.

Bioethicists also serve on governments' PMA's at the national level. Such experts, educated in the humanities (e.g. philosophy, theology, health law), have also captured the interest of health-policy makers, government legislators and politicians, not only at the national level but at the regional and local levels as well. At the same time, many policy makers have also come to appreciate the salience of bioethical concerns and have invested considerable time and effort in becoming ethically informed, focusing on existing literature in bioethics (see Part VI: Recommended Reading). As a result of this confluence, philosophers/bioethicists and policy makers often find that they share common interests and a common discourse.

Moreover, these influential government leaders, who often have the task of creating and implementing regulations that affect health professionals and basic or 'bench' scientists, have discovered that they can and have benefited from the participation and advice, often through formal testimony, of these experts, particularly those educated in bioethics and health law.

The bioethics movement – essentially, the willingness of philosophers/bioethicists and policy makers to address moral quandaries in various health care and health policy settings – has crossed national and cultural boundaries and captured the interest of many States. Given these boundary crossings, it is reasonable to expect confrontations: the prevalent values in States in the developed world are often in sharp contrast with the values prevalent in the developing world. Recently, some have warned that with the trans-cultural expansion of bioethics, there is the danger that a new, intellectual imperialism will emerge, driven by the expertise and greater resources

of the developed world, but none the less potentially problematic. Others fear that the alternative is an arid ethical relativism. All seem agreed, however, that the globalization that ties the world together in so many ways has not ignored health, where local concerns now frequently have significant transnational implications.

In the end, virtually everyone agrees that health care – only one dimension of societies, to be sure – is becoming a cosmopolitan, global enterprise embraced not only by developed but also by developing States. We can surely expect that what constitutes bioethics today will itself undergo radical transformation; it has already incorporated the bioethical issues ingredient in environmental and space ethics.

3. WHAT ARE BIOETHICS COMMITTEES?

As defined above, a ‘bioethics committee’ is a committee that systematically and continually addresses the ethical dimensions of (a) the health sciences, (b) the life sciences and (c) innovative health policies. The term ‘bioethics committee’ simply signals that a group – a chairperson and the members – will meet to address issues that are not simply factual, but are profoundly normative. That is, they do not convene to determine only what is or is not the case regarding some realm of interest. The concern of the committee goes beyond the factual level of empirical data. It is established to answer not only the question, ‘How should I decide and act?’ but the broader question, ‘How should we decide and act?’ This will move us from ethics – a traditional branch of philosophy – to politics: ‘How ought a government to act?’

Bioethics committees, therefore, formulate their questions in normative terms, that is, as a group they reflect and debate carefully about certain individual or societal values, and this requires examining not only one’s own conduct but also the conduct of others.

Members of bioethics committees usually turn to basic literature published under the rubric ‘bioethics’; this body of books and articles may well take the reader to theological as well as philosophical writings. On the other hand, most people tend to trust their experience, having lived within their own particular settings and cultures, with their long-standing values, norms and habits of behaviour – those we generally accept as well as those we reject. In nearly all societies, murder and theft, for example, are considered not only unacceptable but also unethical. Long-standing values such as usually preferring life and health to infirmity and premature death, constitute the foundation for further ethical as well as legal and even economic discussions and deliberations.

Although bioethics committees have been established to advise the medical community and health professionals on how they ought to act with respect to specific, though sometimes intractable, moral controversies, these bioethics committees are more frequently expected to advise policy makers, politicians and law makers, and not only members of the health professions and experts in the life sciences. These committee members focus their efforts on the principles,

norms and values that emerge in the health care context, where not only behaviour but health professionals' conduct (and sometimes patients' conduct) requires continuous scrutiny and even formal oversight. Bioethicists, experts in ethics and knowledgeable about health care and policy, play an important role; in recent years they have turned more to the problems of everyday life and applied bioethics has emerged as a prominent field of study, often in non-academic health settings.

Bioethicists do not purport to provide the single, correct ethical answer to every moral conundrum, for there are no such ready-made answers; bioethical quandaries are not like some problems in mathematics that can submit to only one solution. Still, bioethicists can help policy makers; bioethics committees analyse these problems in a sophisticated way that makes their work far more useful than it might otherwise be.

4. REASONS FOR ESTABLISHING BIOETHICS COMMITTEES

As a new adage has it: 'None of us is as smart as all of us'. This sentence functions like a modern camera, almost automatically pointing the lens to and changing the focus from the individual to the group, perhaps only a dyad – two subjects – but usually more than two participants working together with a shared purpose as well as specific goals.

This adage suggests that the constraints we each experience as individuals – we view the world only through our own perspective and are limited by the reach of our resources – may often be overcome when we join with others to work together. Committees provide a venue for working together and the members of a bioethics committee – which can be composed of a scientist, a physician, a nurse, an attorney specializing in health law, an administrator, a social or a behavioural scientist, a bioethicist and others – convene and interact, each member drawing on the strengths and compensating for the weaknesses of his or her colleagues. It is not an ideal situation, for we can all recall occasions when committees acted wrongly or foolishly. But perfect alternatives are not to be had and the advantages of committees seem obvious.

Furthermore, arrogance is very likely to raise its ugly head when individuals strike out on their own. When successful, they tend to believe their accomplishments were achieved in a social vacuum, devoid of the efforts of others; rarely is this the case, however.

Warning us about arrogance, we may recall Thomas Hobbes' reflections in *Leviathan*, published in 1651: '... such is the nature of men that howsoever they may acknowledge many others to be more witty or more eloquent or more learned, yet they will hardly believe there be many so wise as themselves; for they see their own wit at hand and other men's at a distance'.

Taking Hobbes' reflections seriously compels us, particularly in today's biotechnological and scientific context where health professionals encounter suffering and dying patients, to appreciate the fact that individuals more and more tend to work together – convene as a group of specialists, conduct grand rounds with their colleagues as well as groups of residents,

even publish the results of their research as co-authors. As we have observed, it is also not unusual for scientists and health professionals to serve on various formal committees: in their own institutions, in their local communities and as expert consultants at the regional and national levels. These activities point to the fairly recent practice of convening in groups; when formalized they become committees, commissions and councils.

A theologian, the late Richard A. McCormick, delineated eight variables or background conditions that serve to support and to promote interest in establishing bioethics committees:

1. *The complexity of problems.* Researchers and health professionals desire to make ethically acceptable decisions, but the bioethical dilemmas and problems themselves may have become indistinct, complicated and hard to understand; the results of proposed solutions may not only be difficult to realize but may also easily lead to disagreements. By probing their expertise, members of a committee may be able to grasp the problems and formulate the dilemmas.

2. *The range of options.* This range frequently exceeds the perspective of a single researcher and health professional. Committees, however, offer multiple perspectives and may be better able to appreciate the options.

3. *Protection of research and health care institutions.* In an increasingly open and critical society, institutions are concerned for their public image. They are concerned about their integrity and reliability. In some countries it creates anxiety to minimize the risk of lawsuits. Committees demonstrate that scientists and health professionals seek guidance from peers, groups and committees in order to share responsibility.

4. *Nature of judgements in clinical decisions.* Researchers and health professionals do not always have the competencies, other than expertise in research and the delivery of health care, to make sound bioethical decisions that include all the components of a problem or of a patient's case. Bioethics committees, being multidisciplinary, offer a better opportunity to provide sound guidance, even if they cannot always recommend ideal decisions or resolve all bioethical dilemmas.

5. *The emergence and prominence of patient autonomy.* Conflicts between the key values of patients, research subjects and researchers often require mediation, which a bioethics committee can offer, while respecting each patient's dignity and autonomy.

6. *The emergence of economic considerations.* Given today's limited research and health care resources and the growing claims upon them, decisions must continuously be made concerning the fair and equitable distribution not only of research, hospital and pharmaceutical expenditures, but the ever-increasing costs for the time and expertise of scientists and health professionals, whose self-interest is today more easily and more frequently exposed to the economic interests of their employers.

7. *Religious convictions of some groups.* Research and health care institutions need a platform for discussing their bioethical and religious standards with respect to scientific and

medical practices; there is often theological dissent on a number of bioethical issues in such institutions. Today, religious policies, which may be formulated at the institution's administrative level, range far beyond scientific and medical expertise.

8. *Individual decisions, as affected by the plurality of publics.* Scientific decision-making is no longer simply a one-on-one affair; researchers and health care personnel must be responsive to a variety of publics. When there are bioethical conflicts, their resolution may not be achieved simply by appealing to scientific and medical judgements alone. Policy decisions will have to be taken that extend far beyond a single researcher or physician's expertise.

McCormick is surely on the mark when he underscores these variables. Bioethics committees possess advantages that individual decision-makers simply do not have, especially given the uncertainty that is inherent in scientific and medical practice. In short, uncertainty has created what McCormick calls a 'climate' for establishing bioethics committees.

These eight background conditions serve to indicate the significant challenges and tasks of bioethics committees wherever they are established, whether at the national, regional, or local levels of government.

In addition, there are at least five reasons for establishing bioethics committees:

The principal objectives of bioethics committees in all States are to (a) provide expertise and represent different viewpoints concerning ethical issues raised in biology, medicine and the life sciences; (b) enhance the public's benefits; (c) improve patient-centred care; (d) protect patients and healthy participants who become involved in physiological, biological, behavioural, or epidemiological research trials; and (e) facilitate the acquisition and use of new knowledge directed to improving health and the delivery of health care.

If this set of five objectives is to be realized, it will in part be due to the fact that different types of bioethics committees (perhaps two or even three working together on specific issues) have focused on one or more of these goals.

5. POSSIBLE MISUNDERSTANDING OF THE PURPOSES AND FUNCTIONS OF BIOETHICS COMMITTEES

Virtually all scientists and health professionals have had the advantage of extensive university and post-university education, following which they are licensed by governments and various public authorities to be free to do research and to practise their professions – professions that require contact with the general public, individual patients and both infirm and healthy participants in clinical research trials.

Yet, such authority warrants various forms of protection for those who interact with scientists and health professionals – protection provided by law, which is nothing less than a system of social control. In the science and health care context, law is reflected in various statutes, judicial decisions and, particularly, government regulations. Freedom of research, as well as the value of scientific and professional expertise need therefore to be balanced with protection

of human rights and the common good. Bioethics committees are essentially the platforms to balance the good of science, human rights and the public's interest.

States, having established various forms of bioethics committees, require them to define their objectives and goals and to work to resolve bioethical dilemmas that emerge in the various research and health care settings. Researchers and health professionals may easily misunderstand the purposes and the functions of bioethics committees, viewing them as simply the precursors to further control of their practices, i.e. external controls by non-scientists or non-health professionals. It is not surprising to learn that a number of researchers and health professionals, particularly those who have not served on bioethics committees, may be sceptical of these committees' activities and resist them, perhaps because they mistrust the power and influence that they presume committees may exert on policy makers. They may also fear that public distrust of science and technology may unnecessarily hamper the freedom to conduct research through the regulations of bioethics committees.

Anxiety concerning the presumed power of bioethics committees, as well as governments' laws and regulations, are not the only causes of misunderstanding about these committees' purposes and functions. Sometimes the expressed goals of bioethics committees are unclear. The committee may be perceived as threatening, making dogmatic choices to foist decisions on patients and potential participants in research trials, thus undermining the authority of scientists and health professionals and how they construe honest disagreements with their patients and with those who plan to become involved in biological and biomedical research.

Another difficulty that affects committee members concerns responsibility. If the committee deliberates on some issue and makes recommendations to policy makers, scientists or professionals, will these serve to diffuse responsibility to the point where members feel no individual responsibility?

Fortunately, policy makers, researchers and health professionals have come to appreciate the fact that bioethics committees are a far better mechanism for effecting what usually turns out to be modest controls and easily followed regulations of their practices than are courts of law and other quasi-legal mechanisms. Of all the mechanisms that exist in modern States for discussion and analysis of difficult moral issues in relation to rapid advances in science and technology, bioethics committees are the best platforms to explore these issues. They are democratic mechanisms, involving various viewpoints and different disciplines, in order to reconcile freedom of research and scientific and professional expertise with concerns for human rights and the common good.

Part II

ESTABLISHING BIOETHICS COMMITTEES AT DIFFERENT LEVELS OF GOVERNMENT

Member States of UNESCO have the option of establishing bioethics committees at the national, regional and/or local levels. This has the advantage, in time, of encouraging the creation of a network among bioethics committees to serve not only the needs of all the people but also smaller populations in regions and even local communities. Furthermore, bioethics committees established at the national level have the option, even if they decide to limit their goals, to select among a variety of functions, including those that are usually the concern of committees organized at regional and local levels. At the same time, the establishment of bioethics committees does need not originate at the national level.

BIOETHICS COMMITTEES AT DIFFERENT LEVELS OF GOVERNMENT

1. National
2. Regional
3. Local

1. NATIONAL LEVEL

In federal systems such as Australia, Austria, Canada, Germany, Malaysia, Switzerland, the United States of America and Venezuela, both national and regional governments possess authority and autonomy in their respective spheres. The regional entities, e.g. provinces or states, exhibit significant self-rule and have power beyond what the national authority delegates to them, though they are inherently vulnerable and subordinate, as are local committees.

In unitary systems – for example, Denmark, France and the Philippines – only the national government possesses authority and autonomy; regional governments are subordinate to the authority of the national government that determines their powers, functions and very existence. Whether a government is federal or unitary has a bearing on the actual establishment of bioethics committees. At the national level, various types of committees can be distinguished, depending on how the committee is established:

Type 1: Committee that is established by a governmental body, in most cases either parliament or the relevant ministry (of health, science, law). In some cases, committees are established by the president or the chancellor of the State. Committees of this type are usually authoritative since they result from a political decision to have a national committee in the country. An example is the Danish Council of Ethics (see Appendix 2).

Type 2: Committee established by a non-governmental body, such as a professional organization (e.g. academy of medicine, academy of sciences), a policy-advisory body (e.g. health council,

medical research council), or an NGO (e.g. the National Bioethics Committee of Uzbekistan that has been created as an advisory body with the Avicenna Foundation – see Appendix 2). Committees may also result from joint action of several bodies. An example is the Ethics Committee of the Gambia Government, established by the Medical Research Council and the Department for Health (see Appendix 2).

Type 3: Committee created by the National Commission for UNESCO. Examples are presented in Appendix 1 (e.g. in Ecuador and Egypt).

In this typology, all committees are operating at the national level. However, the impact and role of the committee may vary according to the type of organization that has established it and the policy framework within which the committee is operating. Usually, Type 1 committees have most impact and have the strongest status in the political system of the country. Bioethics committees established at the national level may have further characteristics. They may be independent (e.g. France, the United Kingdom) or integrated within the government (e.g. Japan, New Zealand). Independent committees are said to have the advantage of existing in a non-partisan environment; integrated committees are said to have the advantage of ensuring political accountability. The committees may be advisory (e.g. the United Kingdom, the United States) or policy making (e.g. France). They may be permanent (e.g. France, Germany), or ad hoc (e.g. the United States).

In France, for example, the *Comité Consultatif National d’Ethique* (CCNE) was established by a decree signed by the President in 1983 and enacted into law on 29 July 1994. It has frequently influenced legislation. In other States, bioethics committees may reflect different fields of competence, though they may be situated at the same level. In the Japanese Government, for example, a subcommittee at the national level would likely be convened on an ad hoc basis to produce a report on a specific bioethical issue.

Permanent committees are said to have the advantage of stability and continuity; they address a variety of issues over the long term, but their membership changes little, ensuring a more or less constant point of view. Precedents are apt to be a major concern and the product is usually quite legalistic. On the other hand, ad hoc committees are temporary bodies constituted of experts to address particular issues. As they have brief lives, they are much less encumbered by consistency of precedent and continuity

2. REGIONAL LEVEL

Regional bioethics committees will more likely be established in States with federal rather than unitary governments, since the former are more likely to permit or even assist their establishment. For example, in the United States, for many years the federal government had only authorized the establishment of RECs (see Part II, section 4) or institutional review boards – IRBs, the vast majority of which are located in research institutions, e.g. university

medical schools, colleges and hospitals. Most of their members are trained in one of the life sciences and employed within these institutions.

Not many years ago, however, RECs were also authorized and established regionally, outside these home institutions – a policy some have challenged, arguing that their accountability remains in question. These regional research-review committees are known by various names: non-institutional, non-local, geographic, professional, external, independent, contract, for-profit and commercial IRBs. They also review scientists' research protocols that involve the participation of human beings, but many of the protocols they review will, if approved, be conducted at more than one geographic site; these are noted as multi-centre clinical trials.

3. LOCAL LEVEL

The establishment of local bioethics committees is most likely to occur in community and religion-affiliated health care institutions whose principal goal is to improve patient-centred care or in research institutions that are in need of ethical review of research protocols. These committees are likely to be HECs (see Part III, section 3).

In a number of States, bioethics committees have generally been established at the local level to review bioethical issues raised by the use of human participants in biomedical, behavioural and epidemiological research; the researchers are, in general, formally appointed to university faculties that include schools of medicine, nursing and the allied health professions. These committees are likely to be RECs (see Part III, section 4).

Part III

DIFFERENT FORMS OF BIOETHICS COMMITTEES AT DIFFERENT LEVELS OF GOVERNMENT

Bioethics committees are of different forms and function at different levels of government. Cooperation among committees is not uncommon, though many committees choose to operate on their own. Outsiders viewing these arrangements may register confusion and bemoan the absence of uniformity; but committees, knowing what works for them, care little about organizational charts. In short, each of the four forms of committees, having established its own purposes, functions, working procedures and operations, may conclude it is of no benefit to combine with any other form. In practice and in many States, committees do combine various forms.

FOUR FORMS OF BIOETHICS COMMITTEES

1. Policy-Making and/or Advisory Committees (PMAs)
2. Health-Professional Association Committees (HPA)
3. Health care/Hospital Ethics Committees (HECs)
4. Research Ethics Committees (RECs)

To assist the reader further to appreciate the structure of the remaining sections of this Guide, the following table clearly shows that in order to establish bioethics committees a primary decision needs to be made concerning (a) the level of government and (b) the specific form(s) of the committee.

LEVELS OF GOVERNMENT AT WHICH FOUR FORMS OF BIOETHICS COMMITTEES ARE LIKELY TO BE ESTABLISHED

FORMS	NATIONAL	REGIONAL	LOCAL
1. PMA	+	+	-
2. HPA	+	+	+/-
3. HEC	-	-	+
4. REC	+/-	+	+

KEY: + = HIGHLY LIKELY +/- = LIKELY - = HIGHLY UNLIKELY

Prior to the actual establishment of a bioethics committee, at its initial meetings the chairperson and members will commit to a principal goal that will henceforth serve to drive its activities in carrying out the functions it has determined are focal, at least for the initial year or longer. The principal goal will usually depend on which form of committee has been established.

GOALS OF THE DIFFERENT KINDS OF BIOETHICS COMMITTEES

1. PMA: Establish sound science and health policies for Member States' citizens
2. HPA: Establish sound professional practices for patient care (physicians' associations, nurses' associations)
3. HEC: Improve patient-centred care (hospitals, out-patient clinics, long-term care institutions, hospices)
4. REC: Protect human research participants while acquiring generalizable biological, biomedical, behavioural and epidemiological knowledge (pharmaceuticals, vaccines, devices)

1. POLICY-MAKING AND/OR ADVISORY BIOETHICS COMMITTEES/COMMISSIONS/COUNCILS (PMAs) AT THE NATIONAL LEVEL

BACKGROUND

It is a common but mistaken assumption that policy-making issues can be sharply separated from bioethical issues during committees' deliberations. This assumption ignores a simple fact: the more one delves into health-policy problems that emerge in the health care context, particularly at the national level, the more one discovers a bioethical component that should also be addressed. Of course, health-policy analysts may not immediately grasp this; they are not usually educated in the analysis of moral reasoning and mistakenly believe that their own methods – usually involving statistical competence – are value neutral. But in research ethics, for example, estimating the risk of harm to research subjects, compared with estimating potential benefits that usually accrue to others, is clearly not ethically neutral and value free – patient-subjects' health and lives may well be in the balance. Bioethics matters in the everyday, real world.

It is therefore not unusual for ethical issues to be overlooked. This, in part, accounts for the present establishment of only a few statutory and therefore permanent PMAs at the national level and the need for the periodic re-establishment of many PMAs at the national level (see Appendices 1 and 2). The head of State may well have sole authority to determine if a PMA is to be established at all and whether it would be politically advantageous. In the context of formulating collective and enlightened science policy at the national level relevant to the public good, applied ethics, as has already been mentioned, is a sound working approach

when formulating and working to resolve bioethical issues that arise in discussions, deliberations and even negotiations concerning future policies. Indeed, some professional philosophers who do not focus on bioethical matters and theories have come to appreciate the fact that traditional and contemporary ethical theories may well be enriched by an exploration of bioethical issues pertinent to institutions, not merely individuals.

States that have established bioethics committees at different levels may also support the adoption of a broader mandate – especially at the national level – and thus be willing to carry out a number of functions and address numerous bioethical issues that, in time, may lead to special reports on particular bioethical problems and issues, and even influence the formation and adoption of new health policy and legislation.

PURPOSES

1. To advise governments, parliaments and other governmental bodies on bioethical problems and issues raised by progress in health care, biology, the biomedical sciences and biotechnology.
2. To publish recommendations on bioethical issues and thereby influence policy-making and increase public awareness and participation. When government advisers need to respond to advances in the basic and behavioural sciences as well as biotechnology, such recommendations may eventually serve to influence the formation of new legislation and contribute to public awareness and debate.
3. To provide a forum for discussions at the national level of a plethora of bioethical problems, issues and particular cases that have received public attention through extensive media coverage, e.g. press conferences, publications, television and the Internet.

FUNCTIONS

1. Members of PMAs may be persons of distinction, but few are experts in all the areas of their committee's purview – and fewer still are learned in bioethical inquiry. One of the members' main tasks, then, becomes self-education. Much of this proceeds informally – members learn from each other, talk with knowledgeable outsiders and canvass existing literature. Some self-education, however, is formal, as seminars may be convened, materials distributed, or outside speakers invited. Geographical proximity is an advantage in the process, for face-to-face communication has unique advantages in forging relationships. In the age of the Internet and e-mail, however, this is less important than it was in the past.
2. An important function of bioethics committees is to undertake fundamental inquiries into the human and moral significance of developments in the biological and behavioural sciences and biotechnology, and to become familiar with the regulations regarding the protection of adults and children who participate in clinical trials.

3. The committee must also appreciate the consequences of regulating, limiting or restricting (e.g. by establishing a temporary moratorium) biological and behavioural research involving human participants.
4. The committee should offer a platform to deliberate the appropriate uses of biological and biomedical technologies.
5. The committee is also the proper place to reflect on the moral and cultural implications of innovative biological technologies in order to determine whether they require the formulation and promulgation of new rules and regulations at the national level.
6. The committee should explore specific bioethical policy questions related to these developments.
7. A further task is to facilitate a greater understanding of bioethical problems and dilemmas not only by members of the various health professions and the scientific community, but also by media professionals and the lay public.
8. The committee should study broader bioethical problems and issues not necessarily tied to specific technologies.
9. Finally, the committee should explore possibilities for productive collaboration among Member States on particular bioethical problems, dilemmas and cases.

COMMITTEE SIZE

PMA's may be composed of as many as 40 members (e.g. France's *Comité Consultatif National d'Ethique*), or as few as 18 members (e.g. the United States President's Council on Bioethics). As with most committees, commissions and councils at the national level, a delicate balance must be struck: neither too few nor too many members. Small size tends to encourage efficiency and consensus building, though at the price of uniformity; large size more easily accommodates representativeness and diversity, though at the price of efficiency and internal cohesion.

RECRUITING CHAIRPERSONS AND MEMBERS

If, at the national level, a PMA is purely advisory to the head of government, the head of government will have absolute authority over the appointment and removal of the PMA's chairperson and the members. As its subject matter is highly technical, however, this authority will nearly always be exercised after consultation with advisers who may be officials, experts, or even trusted friends.

If the PMA is a policy-making body, the head of government will have the authority to appoint the chairperson and the members, but the legislature will likely be called upon to confirm these appointments. This sharing of authority often means that a State's legislature plays a significant role in influencing the head of government's choices, supporting some candidates and vetoing others.

Whether advisory, policy-making, or both, the PMA, at the national level, presents two key recruitment issues. One is the role of the chairperson, however limited, in determining

the membership. Key government officials, e.g. ministers of health or members of their staff, may take the initiative to nominate a highly respected and knowledgeable person to serve as chairperson, as well as to suggest the names of potential members to serve on a bioethics committee at the national level. In unitary States, as was mentioned, this may be the only viable option, as regional and local governments do not usually have the authority to establish such a committee.

The chairperson may have discussed the organization of the committee with domestic governmental policy advisers who tend to serve the interests of the bureaucracy and who may well have been involved in his or her appointment as chairperson. Indeed, these advisers may have suggested that certain persons serve as committee members, perhaps representing specific disciplines. With regard to bioethics committees, it is important that a number of members selected have been educated in a health profession and have had scientific training as well.

Chairpersons tend to favour maximizing their influence over the selection of members, arguing that this is necessary to ensure efficient operation of the committee. The chairperson may agree to serve in this capacity only if he or she is given the authority to select the committee's members on the basis of a number of criteria and procedures. The chairperson may take the initiative personally to contact a number of qualified persons and invite them to serve as members of the committee; this itself is a formidable task and requires significant time. The chairperson may also accept nominations by or without invitation; in short, the chairperson may decide to cast a wide net to locate renowned and qualified candidates to serve on a newly established PMA at the national level.

It is not unusual for a chairperson to insist that he or she should be free to influence the committee's agenda, including the items to be covered and the order in which they will be addressed. Critics, however, regard granting the chairperson influence over the committee's membership and agenda as a serious flaw. In their eyes, it virtually guarantees dominance of the chairperson, thus destroying much of the rationale for creating the committee.

Regardless of who selects the committee members, the question is which criteria should be employed. One obvious criterion is expertise; the subject matter is usually too complicated for amateurs, it is said, and so only those certified as knowledgeable should be selected. But knowledgeable in what? In one of the basic or life sciences? Clinical medicine? Bioethics? Policy-making? Each speciality tends to regard itself as most important and tends to derogate the proper role of the other specialities.

A second criterion is representativeness. Democracies, for example, do not follow the principle of rule by an élite, even an expert élite; all stakeholders should be in a position to exert some influence. Only with this approach can the system guard against control by self-serving guilds. All relevant segments of the population, according to this view, are entitled to a place on the committee. Opponents, however, see the focus on representativeness as a rejection of merit and an invitation to political deal-making.

Another criterion is experience. The committees have very practical tasks to accomplish and there is no substitute for experience. A most important criterion embraces character: integrity, collegiality, industriousness and other traits may be indispensable, for members must work together and the committee not collapse amidst bickering and betrayals.

When establishing and organizing bioethics committees, whether as policy makers or advisory bodies to government leaders, it is important to appoint professional bioethicists (philosophers and/or theologians). In addition, it would be both beneficial and prudent to invite professionals who have extensive experience in a few areas, e.g. a scientist who has held a post as a health-policy maker; perhaps he or she has been a member of a State's government – a member of parliament, a minister of health, or a member of an advisory board at the highest level of government.

Furthermore, these advisory or policy-making committees should be councils on bioethics, not of bioethicists; they should, in short, be heterogeneous.

Finally, the committee must seek credibility from the outset; it should not be viewed as 'of one mind', or the tool of government, or a contesting interest. In short, the committee should be free of the obligation to seek consensus among its members. This can be made transparent when the committee publishes its reports; which should include dissenting views.

FUNDING

Whether PMA committees are advisory, policy-making, or both, permanent, ad hoc, or some combination, may well determine the committees' principal sources of funding.

In some States, PMA committees have been incorporated into the government and are financed by States' taxpayers; in other States, funds are acquired from a variety of sources, e.g. an organization that has one or more representatives on the PMA may agree only to support its own members, and this will often suffice if all represented organizations and interest groups continue to support their own representatives on the PMA. This is generally very bad practice, however, for the representatives will normally care only for the interests that support them.

2. BIOETHICAL DILEMMAS: CASES FOR PMAs

CASE 1

The Goal: A State intends to increase significantly the supply of viable human organs for transplant to satisfy an ever-increasing demand by desperately ill people – not only citizens but also newly arrived residents – who are awaiting viable non-cadaveric organs that would likely prolong their lives; without transplant surgery they are destined to die prematurely.

The Case: A State X follows an organ donor policy that requires donors to formally register their willingness to be organ donors. As a result, there are insufficient organs available for donation. In

response, it has been proposed that the State adopt a presumed consent policy, according to which the deceased will have his or her organs made available for donation unless he or she expressly 'opted out' through a formal declaration.

The Dilemma

Premise 1-A If the present policy prevails, i.e. citizens are not presumed to be organ donors upon their death, but must take formal steps to 'opt in' – provide their informed consent – such that prior to their death they have documented their consent to be donors in order to save the lives of others, then the present shortage of viable organs will not only continue but will be exacerbated and many desperately ill people will die prematurely; and

Premise 1-B If the present policy is replaced by a policy of presumed consent, then those opposed will suffer a dignitary harm as well as be required to take inconvenient steps to register their decision to 'opt out' as organ donors.

Premise 2 Either a State's citizens are not presumed to be organ donors upon their death, the 'opt in' policy, or they are presumed to have consented to be organ donors, the 'opt out' policy.

Conclusion Either a State's shortage of viable, non-cadaveric organs continues, due to maintaining its 'opt in' policy – where it is expected that the informed consent of an adequate number of potential donors will not be obtained – and potential recipients who could have benefited from transplant surgery die prematurely, or the State adopts an 'opt out' policy but, in doing so, its citizens suffer a dignitary harm since they are automatically organ donors and are required to take specific steps to register their unwillingness to become donors.

Furthermore, by choosing the 'opt out' policy States reject the important social value of solidarity, notwithstanding the fact that a policy of presumed consent, where it has been instituted, has had a positive and sizeable effect on the rate of organ 'donation'.

Given this initial dilemma, and following the committee's deliberations, which policy should the PMA recommend? Are there ethically acceptable alternatives?

CASE 2

The Goal: Severe diarrhoeal illnesses continue to remain one of the most important causes of global childhood morbidity and mortality in developing States, where preventive measures are largely hindered by economic and social factors, e.g. unsanitary living conditions, unsafe drinking water and so forth. Government leaders of developing States that have recently experienced an epidemic of rotavirus diarrhoeal illnesses in infants and young children have agreed that the dramatic increase in morbidity and premature death in their States is not only unacceptable but now clearly requires political, economic and health-policy action, since it is imperative to control the spread of these infections that result in severe diarrhoea, dehydration, chronic morbidity and premature death (current figures approach the 1 million mark every year and this may rise to 5 million by 2025 in developing countries).

Rotaviral diarrhoea is, simply stated, a prolific killer of infants and young children in the developing world, though this is not the case in developed States, where severe dehydration is treatable, though not without serious consequences in a number of cases. In any case, a web of political, economic, social-sanitation, health-policy and medical problems confront developing States; these must be addressed immediately.

The Case: Not much is understood regarding the pathogenic mechanisms of these illnesses, but biomedical scientists and physicians do know that they are the result of 'ingenious mechanisms' that affect the intestine's immune system, producing pathogenic infections.

So far, drugs have not been effective in preventing or assuaging chronic diarrhoeal disorders. However, many parents may insist that physicians administer them (inappropriately) to their children. A few pharmaceutical firms prior to 1998 had invested in research and development with the hope of discovering a truly safe, effective and profitable rotavirus vaccine that would not produce significant 'side effects' that turn out to have health consequences far worse than the diarrhoeal illnesses the vaccines aim to prevent, including adverse reactions in many who participated in the experimental vaccine's clinical trials. It goes without saying that pharmaceutical firms expect to make a significant profit – as do their shareholders – when they discover an efficacious and safe drug, vaccine or device.

In a number of developed States a rotavirus vaccine was widely administered to young children; at first it seemed to prevent severe diarrhoea. But those who early on advocated universal vaccination soon discovered that the vaccine was not very effective when given to infants; universal immunization for diarrhoeal diseases was therefore no longer recommended by public health agencies as the way to control the spread of these infections and illnesses, and the number of deaths among infants and young children. The medical community was clearly disappointed, despite continuing interest in the original vaccine. After the vaccine was withdrawn by the manufacturer in late 1999 (perhaps because it was not profitable, rather than unsafe), it acquired a 'tarnished profile'. Those who argued for its reinstatement did so because it was no longer available in developing States, where it had been quite effective, given that no safe, alternative treatment was available other than major public health interventions to provide safe drinking water, sanitation and uncontaminated food.

It should be noted that there are a number of organized anti-vaccine groups who view the failure of the initial rotavirus vaccine as yet another example of how vaccines actually injure children; e.g. following the administration of this vaccine some children, even those in developed States, suffered intussusception – severe intestinal obstruction due to the assimilation of some ingested material, usually unsafe water, contaminated food, or 'foreign objects'.

Complicating the situation, evidence from testing so-called 'next generation' rotavirus vaccines indicates that infants and children in developing States have suffered the burden of illness and its consequences ever since the first vaccine was withdrawn in late 1999. Indeed, the vaccine

advocates are vociferous, claiming that in developing States rotavirus kills in excess of one thousand children per day, a risk far greater than the lower incidence and ‘minimum risk’ of acquiring intussusception (one case per 2,500 children immunized, though some say one case in 4,500).

The conclusion following the second set of vaccine trials is that the vaccines (or even the original rotavirus vaccine) should be made readily available and affordable to children in developing States, since it is well known that there is a significant delay before children in developing States receive vaccines produced in developed States as socio-economic inequalities continue to prevail.

Finally, it is argued, in developing States the benefits of the original vaccine to decrease deaths from rotavirus far exceed the risk of harm due to intussusception.

The Dilemma

Premise 1-A If the original rotaviral diarrhoeal vaccine developed in Northern States is safe and efficacious, but remains unavailable for infants and young children in developing States, then developed States are conducting themselves unjustly – depriving these infants and children of a life-saving vaccine, though the children in Northern States continue to have adequate treatment without vaccinations, notwithstanding the fact that there are some cases of intussusception; and

Premise 1-B If the original rotavirus vaccine developed in Northern States becomes available once again (in spite of its tarnished image) and is administered to prevent severe diarrhoea in infants and young children in these States, then there is an unethical double standard with respect to the prevention and treatment of rotaviral diarrhoea among the world’s children.

Premise 2 Either the rotavirus vaccine withdrawn in 1999 remains unavailable to children in Southern States, or it is reintroduced in these States.

Conclusion Either Northern, developed States continue to treat infants and young children in Southern, developing States unjustly, or they apply a double standard – since children with similar infections are successfully treated in Northern States without recourse to a rotavirus vaccine.

Does international justice require that the same ethical standards (concerning the prevention of rotaviral diarrhoea in infants and young children) be adopted in all States?

What should a PMA recommend to government leaders?

2. HEALTH-PROFESSIONAL ASSOCIATION (HPA) BIOETHICS COMMITTEES

BACKGROUND

From the fifth to the fourth century B.C. – the origin of the Hippocratic tradition in Western medicine – physicians were considered responsible for their patients’ health. Over the past century, however, when medical knowledge has grown exponentially, physicians and patients increasingly have come to believe that they both share this responsibility. Furthermore, in the past, physicians’ judgements were sacrosanct and determinative of the diagnoses and prescribed treatments, however inadequate and mistaken these diagnoses and inefficacious treatments may have been by present-day standards.

The Hippocratic Oath – clearly aspirational, whether or not it actually served as a guide for physicians in antiquity – as well as similar Codes in Ayurvedic, Chinese and Arabic medicine, not only mention physicians’ duties to their patients, but also their duties to the other members of their guild, what we today call the medical and nursing professions.

Contemporary HPAs are the voices of independent groups of health professionals – physicians, nurses, allied health professionals and other groups – and are organized to unite them. They have been organized to advance the interests of their members and, secondarily, the interests of the patients they serve. In pursuing these goals, HPAs have participated in the formulation of legislation that links the rules and regulations of a particular health profession to the rules and regulations of the government; in time, these regulations may have to be revised and updated. HPAs also focus on the individual health practitioner and are not solely limited to informing, educating and influencing policy-makers at the national level.

By the end of the twentieth century, health care professionals who had already practised for years found themselves engulfed in a new health care ethos. They had no choice but to accept cultural and ethnic diversity – not simply transnational engagement, but quite real and serious conflicts of values. Many health professionals had been committed to a schema of universal values or had taken the notion for granted. Now, compelled to recognize a diversity of values, they embraced some and rejected or revised others. Nevertheless, the search for a universal bioethics continues. Indeed, this was precisely the mandate given to UNESCO by the General Conference in 2003: to draft a declaration on universal norms on bioethics.

The best approach, then, for many States’ patients and physicians is to come to appreciate that they, as well as other health professionals, share in these dyadic relationships; they are both responsible for the patient’s health. Thus, most agree on the need to establish a mutually respectful relationship between each health professional and his or her patient. Thus HPAs not only advise and assist their health-professional members, who are frequently faced with patients’ complaints about procedures as well as alleged violations of patients’ rights, but also take concrete steps to organize meetings and seminars on such issues in order to restate and address patients’ rights as well as their responsibilities.

PURPOSES

HPAs, as voluntary health-professional organizations, usually represent the majority of a Member State or region’s professionals and seek to achieve their particular goals. It is not unusual for an HPA to craft its own Code of Ethical Conduct, usually a brief document (well publicized and disseminated among its members), that echoes the language of similar codes while reflecting the organization’s unique features. In addition, HPAs have other purposes: to develop guidelines for its members to conduct ethically responsible research practices, to promote its members’ education and to endeavour to protect the public against misconduct by its members.

FUNCTIONS

1. HPAs perform a variety of functions: they seek to bolster the income, authority and status of their members; they try to improve the welfare of the patients whom they serve; and they work to influence public policy to further these goals. Sometimes these functions reinforce each other; sometimes they conflict. When they conflict, it is the interest of the HPA membership that nearly always prevails. The determination of this interest is normally in the hands of the HPA's leadership. They know and care more about the organization and its issues than anyone else. Their task is not only to try to wrest the best arrangement for their members from the larger society; it is also to educate the members as to what this best arrangement is, so that they are not unrealistically bold or unnecessarily timid.

HPAs usually take it upon themselves, through the internal creation of subcommittees, to promote the self-education of their members by publishing papers and reports, using the Internet, email and so forth.

2. Since the chairperson and members are usually experts in clinical medicine, it is not necessary for an HPA to establish special educational sessions to enable its members to remain up to date in their clinical specialities. However, the mandate of an organization whose objective is to enhance the status and authority of its professionals needs to familiarize itself with national and perhaps regional politics. It is not unusual, for example, to observe that a health-professional association finds itself unprepared when legislation is passed (at the national and/or regional levels) that directly affects the responsibilities, income and workload of its health-professional members. If leaders representing a given health profession are not routinely present at pertinent legislative hearings, members will feel ignored and betrayed.

3. HPAs usually perform a variety of functions: advocate the promotion of health, and accident and disease prevention; establish policies that may evolve into national or regional legislation (e.g. prepare papers and briefs on bioethical issues and thereby influence government committees considering health policy proposals); and carry out strategies to facilitate changes among its members. In addition, HPAs frequently provide guidance to their members to help them influence and adapt to major changes in the delivery of health care. A growing number of HPAs has established committees to address bioethical issues; they may be called 'ethics committees', 'committees on ethics', 'bioethics committees', and so forth.

4. HPAs decide for themselves how they will be governed and administered. To realize their purposes and carry out their functions, HPAs require adequate professional staff; the professional staff usually organize educational activities, conduct short courses, convene conferences, provide a list of members prepared to travel and lecture before selected audiences, and publish

documents and papers as well as establish websites accessible on the Internet to disseminate their policies. HPAs, once they have established a 'track record', may seek to collaborate with other States' HPAs, perhaps to co-sponsor programmes on topics in professional ethics. As a committee of health professionals the HPA may also seek to collaborate with the PMA of that State's national level of government.

COMMITTEE SIZE

The number of HPA committee members may be as high as 40 or 50. The need to form subcommittees is virtually built into the HPA if it is a large body. But large committees, though more representative of the membership, are unwieldy and internal politics can more easily serve to undermine an HPA committee's objectives, not to mention its meetings.

The criteria for selecting an HPA committee's members are not unlike other committees: expertise, experience, political contacts, relevant skills and collegiality. Much of the work takes place away from public view (e.g. political networking), or is very far from glamorous (e.g. maintaining membership lists). For these reasons, leaders often find that they must call time and again on a small number of faithful members.

Chairpersons may frequently call upon subcommittees with particular expertise to undertake various internal tasks (e.g. to track and document for audit the HPA committee's income and expenditures). In addition, the chairperson of an HPA committee expects the members to assist in disseminating the accomplishments of the profession and influence legislation at the national level of government, sometimes to support, sometimes to inhibit, their codification into law.

RECRUITING CHAIRPERSONS AND MEMBERS

It is not uncommon for HPA committees to be organized by a few health professionals who have recently confronted a serious ethical problem in their health care settings. Perhaps, for example, they had been cooperating in a major health policy project but found that policy makers cared only for high profile, technologically advanced projects. The policy makers are sincere – the leader witnessed the death of a loved one owing to lack of the technology – but the professionals are convinced that the policy is unwise and unethical because its benefits affect very few persons. To prevent a repetition, the professionals may work through their HPA committees to influence the views of future policy makers as well as future members of the HPA.

FUNDING

HPAs almost always establish annual dues to be paid by their members; this is usually the HPA's largest income source. HPAs also frequently receive external funding from governmental, non-profit and private sources. It is not unusual for many health professionals, who could afford to join and pay the HPA's annual dues, to elect, for a variety of reasons, not to join the HPA of their clinical speciality.

BIOETHICAL DILEMMAS: A CASE FOR HPA COMMITTEES

The Goal: At the national level, the bioethics committee of a State's medical association (HPA) is considering the promulgation of a new policy intended both to respect AIDS patients' right to confidentiality – given the long-standing, privileged physician-patient relationship – and to protect the public's health, when there is widespread, if exaggerated, fear of contagion. Its present policy is to reveal the names of all hospital patients who are HIV positive or have contracted AIDS.

The Case: The Executive Board of the State's medical association has received numerous complaints from its physician members that they are being contacted by third parties to reveal to the State's health authorities the names and other confidential, privileged, medical information of those patients who have been diagnosed as either HIV sero-converted – HIV positive – or have contracted AIDS.

The Executive Board of the HPA has contacted the HPA's bioethics committee. It is the Board's position that physicians put the interest of their patients first. But does this policy entail protecting patients who may be exposed to the disease or fail to protect those who may contract the disease? Will physicians remain their patients' advocates or violate their privileged physician-patient relationship by revealing the identity and medical records of their HIV positive and AIDS patients to the State's health authority?

The Dilemma

Premise 1-A If the bioethics committee of the HPA continues to follow its present policy, to reveal the names of all hospital patients who are either HIV positive or have contracted AIDS, then it will not only alienate a majority of its physician members, who affirm the long-standing ethical precept, i.e. the privileged physician-patient relationship – but intentionally violate their patients' confidentiality (though the present policy would satisfy the State's health authority); and

Premise 1-B If the bioethics committee sustains the long-standing bioethical policy that physicians defend their privileged physician-patient relationship and not reveal the confidentiality of patients' diagnoses – particularly those who are either HIV positive or have AIDS – then the public health authority will quite likely become the Medical Association's adversary.

Premise 2 Either the State's Medical Association maintains its present policy and requires its members to reveal the names and medical records to the State's health authority of all patients who are diagnosed as HIV positive or have AIDS, or it changes its present policy and urges its physician members not to reveal to the State's health authority – on the basis of the privileged physician-patient relationship – their patients' confidential health status and medical records.

Conclusion Either the State's medical association's bioethics committee will alienate and undermine its members for failing to defend the privileged physician-patient relationship regarding HIV positive and AIDS patients, thus abandoning their role as patients' advocates

and, furthermore, discouraging HIV positive and AIDS patients from seeking medical care that will only increase contagion, or the Association will not only risk reprisal from the State's health authority but also compromise their patients' expectation of ethical, medical practice by disclosing what their patients presumed was strictly confidential.

Which policy should the HPA's bioethics committee recommend? Are there morally acceptable alternatives? Can the bioethics committee suggest a policy that would avoid the extreme, perhaps unacceptable, alternatives?

3. HEALTH CARE/HOSPITAL ETHICS COMMITTEES (HECs)

Background

HECs have been established to assist health care providers and patients to find their way out of the maze created by modern, technological medicine; they are chiefly designed to ensure good health care decision-making practices and to assist patients, but without interfering in the patient-physician relationship. To accomplish this and other goals, they have to undertake self-education, become involved in their health care institution's guidelines and policy development and, most important, address individual patients' cases that involve a bioethical and not just a medical review of the patient's problems.

There is a growing interest among Member States to establish HECs at the local level – mostly in hospitals, long-term care institutions, hospices and, in a few cases, home-health care agencies.

HECs usually reflect multidisciplinary membership and are not only designed to assist patients' interests but the interests of medical staff – this is essential if they are to improve patient-centred care throughout the health care institution. Today's health professionals prefer advice (not necessarily recommendations or decisions) from their peers, especially in ethically problematic cases.

When a health care institution establishes an HEC, it is usually free from bureaucratic regulation, but this freedom entails accountability, and accountability is usually ensured by rules and regulations. Before the HEC is formed, it must consider how it can best serve patients, its institution and the local community. An HEC usually determines what bioethical and health law issues it will address and it needs to establish ongoing mechanisms and step-like procedures to do so. Furthermore, it tends to focus its energies on patients' problems and cases that arise in the daily work of the health care institution in which it functions. After all, an HEC is principally charged with reviewing patients' cases and broader bioethical and health law issues to improve patient-centred care in health care institutions; though HECs have other principal functions – to be discussed below.

It is important, however, to note that HECs do not, strictly speaking, control their own agendas: in some health care institutions, any health professional, any patient, any patient's relative, or any

employee may contact the chairperson or any member of the HEC and initiate a discussion of his or her bioethical issue. This policy is usually included in the institution's pamphlet that is given to patients and family members when patients are admitted.

Purposes

1. To protect competent patients' decisions – e.g. to accept or reject medical treatment – and to ensure the well-being of patients, mentally competent or incompetent (the latter usually requiring the participation and assistance of a legally-appointed health care proxy).
2. To guard from legal liability health care institutions and those who practise in them. This purpose signals a danger, however: legally protecting the health care institution, its physicians and staff could easily become the primary purpose of HECs. The HEC's chairperson must remain alert to the danger that the HEC may, in time, worry more about protecting the interests of its constituents and the institution than the in-patients: independent bodies, like HECs, may become dominated by the same interests they are supposed to regulate.

Functions

The establishment of HECs has tended to exacerbate the problem of inadequate clinical bioethics and health law education among the health professionals who serve on the committees – disciplines most relevant to the concerns and problems that will be raised during HEC meetings. Rarely do health care institutions have mechanisms in place to provide bioethics and health law education to their HEC members. It is important, therefore, for the chairperson (and perhaps a subcommittee) of a newly established HEC to create mechanisms for enhancing the self-education of the members. Indeed, some HEC chairpersons periodically invite members from the local community with relevant expertise to participate in and even lead these educational sessions.

It should come as no surprise, given the numerous and varied demands on an HEC, to find that many members at first feel daunted by their complex tasks, especially since HECs have generally arisen as the result of a local or grass-roots process virtually devoid of national or regional regulations. Since most of the members of an HEC are health professionals who have volunteered for the task, high quality and practical self-education programmes must be made available to them at no cost and as conveniently as possible.

Generally, HECs have remained true to their initial purpose: the improvement of patient-centred care. An expanded mandate is clearly more difficult to carry out, partly because the time its members can devote to it is limited and partly because its powerful competitors within the hospital view it as a potential threat. An HEC's membership is multidisciplinary, unlike strictly medical committees in hospitals. In many health care institutions, the HEC is the only institutional locus where scientists (e.g. geneticists) physicians, nurses, hospital administrators (or their representatives, e.g. risk managers), health lawyers, bioethicists, social workers, social

scientists and clergy can convene to address the bioethical issues reflected in patients' cases brought before them. This task may eventually, but not necessarily, lead the HEC to provide not simply guidance but recommendations for ethical action by the administration. In short, the HEC may well have a significant and measurable impact on patient care, the education of the institution's staff and the creation of new health policies. HECs, however, are not authorized to practise medicine; this is, as it always has been, the responsibility of individual physicians.

HECs are often called upon to address issues relating to end-of-life decision-making and to consider the bioethical dimension and consequences of health care payment models. Such discussions now include increasingly complex economic issues within a State's health care system, i.e. a full template that brings together bioethics with economics, as well as health law.

An institution's HEC is usually accessed by health professionals who request that the committee address a particular bioethical and/or health law question that concerns their patients. These questions may vary widely, dealing with bioethical aspects at the 'edges of life' – the treatment of anencephalic infants as well as very elderly, terminal patients' requests for assistance in dying. Hospital policy proposals may also be considered; for example, the ethical implications of the hospital's new acquisitions and mergers, or novel financial arrangements.

In practice HECs have the following functions:

1. Bioethics education through:
 - (a) programmes to educate its members and
 - (b) programmes to educate nominees and volunteers who will eventually serve on the HEC;
2. bioethical case review and analysis by the entire HEC regarding:
 - (a) active cases (patients),
 - (b) retrospective cases (discharged or deceased patients) and
 - (c) hypothetical cases (usually those described in the bioethics literature);
3. bioethical case consultation by:
 - (a) a bioethics consultant (e.g. physician, nurse, patients' rights advocate, bioethicist/philosopher),
 - (b) an advisory/ombudsman team (two or more HEC members) and
 - (c) an HEC subcommittee (three or more HEC members);
4. development of institutional guidelines and policies, and analysis of the bioethical aspects of the health care institution's policies concerning the rights and welfare of patients, e.g. rationing beds in the intensive care unit or establishing criteria for Do-Not-Resuscitate (DNR) or Do-Not-Intubate (DNI) orders;
5. search for an equitable distribution of health care resources that attends to both secular and religious factors influencing the distribution and provision of health care resources;

6. initiation of community projects: establishing HEC networks in the same city or region, e.g. creating a bioethics forum in the local community or resolving problems for emergency medical services; and
7. delivery of recommendations to their institutions that patients be educated about advance directives (a living will, a durable power of attorney for health care decisions, the appointment of a health care proxy or agent to support a patient's interests). If an HEC is well established, its functions may evolve into a wider range of activities. These future functions may include:
 8. identification of conflicting interests, rights, duties, and provision of assistance in the process of reconciling competing institutional goals, e.g. the distribution and utilization of scarce or limited health care resources;
 9. resolution of disputes among staff members and between staff, patients and patients' families, e.g. regarding treatment and non-treatment decisions;
 10. provision of support to health care institutions and policies that contain a bioethical component (possibly working with the RECs in the same institution);
 11. conducting bioethics-related research within the institution;
 12. introduction of bioethics into the pre-hospital arena, e.g. in the emergency medicine department or out-patient clinics;
 13. serving as a forum for bioethical discussions, e.g. during the transition to alternate health care financing and payment procedures;
 14. participation in the local, regional or national legislature's public hearings on issues relevant to the public's health; and
 15. aid the drafting of uniform policies, e.g. policies concerning the bioethical aspects of organ and/or xenotransplantation.

COMMITTEE SIZE

There is no perfect size for an HEC, but it should generally be representative of the hospital or health care institution's community. Most HECs, in addition to the chairperson, are composed of fifteen to twenty-five members. If fewer members serve, they may not be truly representative of their constituencies, though they will probably be more efficient. Some HECs always convene their full membership; others may constitute subcommittees to review a particular patient's case.

RECRUITING THE CHAIRPERSON AND MEMBERS

Once the chairperson is selected and appointed, he or she should encourage, through productive conversation, cooperation among the committee members. Deliberation and debate are absolutely essential; indeed, they are themselves creative activities.

1. The chairperson should facilitate but not dominate the conversation;

2. the chairperson should encourage the members to raise questions and express doubts that may not be well articulated in bioethical reading materials and case records alone. Thus, each HEC should seek to cultivate cordial deliberation – bioethics as conversation.

3. the chairperson need not seek consensus, since consensus often reflects compromise that pleases no one very much; it may be profitable to have competing views and losers may win in the future.

Committee members may have been invited to serve (usually by the chairperson, by a hospital administrator, or by the chief of the medical staff) and often have a personal interest in bioethical, not only health law, or other legal issues.

It is not unusual for hospital staff who have close affiliations with religious institutions in the community to volunteer to serve on an HEC. The formal education of the members and their specialities are not likely to be the most significant criteria for HEC membership. One may ask: What is the temperament, attitude, character and capacity for critical thinking of a prospective member? How well can a member tolerate the ambiguity that emerges during discussions of patients' bioethical issues and continue to contribute to conversations regarding these ethically grey areas?

There is no standard membership for an HEC, though most include

- a bioethicist,
- physicians,
- nurses,
- a risk manager,
- a health lawyer (perhaps an attorney not employed by the institution),
- a social worker (perhaps a behavioural or social scientist),
- members of the clergy (in European countries, usually the institution's Pastoral Care Office) and
- patients' representatives from the local community.

HECs usually convene monthly though subcommittees may meet more frequently, particularly the small advisory or ombudsman subcommittee whose two or three members may rotate with other HEC members every few months. Meetings may be called when hospital staff contact the committee regarding an ethical problem involving a patient and/or his or her family.

FUNDING

Although it is not too difficult to establish an HEC, it is at times quite difficult to supplement the institution's initial support. Members are investing their time but are most often not paid for these contributions. However, from their point of view, the members are simply serving the institution as part of their weekly or monthly self-imposed duty. There will be no need to pay extra for the time invested in the HEC but it should be regarded as part of the normal work in the institution.

Direct expenses for HECs are normally very modest, often including little more than a spare room for meetings. Large health care institutions that offer HECs a substantial work agenda may require a secretary and the bioethicist may at times serve as co-chair. Logistical issues – chiefly arranging meetings for very busy people – may present serious practical problems, however. Some supplemental funds for the HEC should be available (e.g. for ethics training of the members). The chairperson must frequently initiate a proactive process that in time should have a positive effect on the institution's administration – especially when the Administration of the health care institution begins to appreciate the significant and positive influence that the HEC's deliberations have had on in-patient care.

BIOETHICAL DILEMMAS: A CASE FOR HECs

The Goal: An elderly patient, depressed by a range of medical problems and a burdensome life, seeks relief from her chronic hernial pain through risky surgery. She wants her autonomous decision – to risk dying during or soon after surgery – respected.

The Case: Ms XX, a 65-year-old woman, has for years suffered from emphysema and related cardiac problems due to years of cigarette smoking. Having retired from her life as a bank employee, she is now virtually confined to her bed; though she periodically gets out of bed unassisted she returns to bed after an hour or so; she is typically exhausted by eating, toileting and other activities of daily living. Ms XX tells whomever she meets that she is tired of living and believes that she is a burden to her loving sister and brother-in-law who live nearby, although her physician and a visiting nurse do not believe that her close relatives resent the demands Ms XX places on them. From her physician's perspective, as well as the judgement of visiting nurses, the patient's sister and husband do not resent providing her with daily care.

Her medical prognosis is unclear, however; she may, under her present circumstances and limitations, live for several years, but like so many others in similar circumstances, she repeatedly says: 'I want to die'.

During a surgical examination – when her hernial pain was severe – a surgeon told her that her hernia could be corrected surgically, but that it was not likely she would survive the surgery. He based his prognosis on her chronic emphysema and present coronary status as well as other findings. Ms XX declared: 'I want the surgery, and that's that'; continuing to explicate one resolution of her bioethical dilemma: 'If I die, then my problems are over. If I make it, then at least I'll be pain free'.

When her examination was completed, and concluding that no surgeon would operate on her, she asked her internist to admit her to hospital. She decided there and then on a strategy: she announced she would refuse all liquids including artificial infusion of any hydration, however administered, unless the surgery was performed. She understood that refusing liquids would cause her death, but repeatedly declared that her present life was not worth

living. Once in hospital she would, she concluded, be pain free because the nurses, she presumed, would provide the appropriate pain medications. She read that patients who refuse all hydration die within one week, anyway.

What should the HEC recommend?

Two Bioethical Dilemmas

1. The surgeon's dilemma

Premise 1-A If the surgeon performs hernial surgery on Ms XX, then she is quite likely to die on the operating table. This will conflict with the surgeon's duty to do no harm (*primum non nocere*), but may also expose him to a lawsuit, e.g. the patient's relatives – her sister and brother-in-law – may well sue him for 'malpractice'; and

Premise 1-B If the surgeon refuses to perform hernial surgery on Ms XX, then she will not only continue to suffer chronic pain for an indefinite period, perhaps years, but also lose control over her life, resent not only her internist and surgeon but also her sister and brother-in-law for concurring with the two physicians.

Premise 2 Either the hernial surgery is performed, or it is not.

Conclusion Either Ms XX dies, leading to a potential lawsuit naming the surgeon, or she continues to experience chronic pain, perhaps for years, and continues to resent her sister and brother-in-law who concurred with her physicians.

2. The relatives' dilemma

Premise 1-A If Ms XX undergoes hernial surgery and dies in the operating room, then they will feel extremely guilty for having concurred with, and not strongly objected to, the physicians' judgement and actions; and

Premise 1-B If the surgeon refuses to perform hernial surgery on Ms XX, then Ms XX will blame her sister and brother-in-law for meddling in what she considers her autonomous choice to undergo the surgery.

Premise 2 Either the hernial surgery is performed, or it is not.

Conclusion Either the immediate relatives will experience long-term guilt, or the patient may never forgive them for denying her her autonomous choice – to undergo the hernial surgery, whatever her risk of dying.

Assuming either the family members or the surgeon – a member of the hospital's medical staff – contacts the HEC, how might the committee assist them? Some will say that if Ms XX refuses all forms of hydration in hospital she is committing suicide – an act in conflict with hospital policy. If the internist decides to support Ms XX's autonomous choice, some may say he participated in 'physician-assisted suicide', or 'physician-assisted dying'. If her internist accepted Ms XX's plan and cooperated with her in executing it, some would say he inappropriately admitted her to hospital. If the surgeon had arranged for Ms XX's hernial surgery when, some time before, she

had made her preference quite clear to him, as well as to her internist – that surgery was the option she alone decided to take – some might say the surgeon had very poor clinical as well as ethical judgement.

4. RESEARCH ETHICS COMMITTEES (RECs)

BACKGROUND

(i) The Use of Animals in Biological, Biomedical and Behavioural Research

The use of animals in research has been and continues to be morally controversial. The bioethical controversies are principally based on the pain and suffering as well as the premature death of animals, especially primates.

As is the case with most ethical controversies, there are extreme views and a middle ground. With respect to the use of animals in research that poses significant risks of harm or premature death, there are two extreme views: (a) governments should entirely forbid the use of animals in research, since the welfare (some claim even the 'rights') of animals is a fundamental value; humans do not have unconditional dominion over other animals; and (b) governments should not impose any regulations on researchers with respect to the use of animals in clinical trials, since the interests of human beings always have priority over the welfare of animals. The middle ground (c) permits principal investigators to use animals in research subject to regulations designed to achieve an optimal balance between safeguarding animals from pain and death and ensuring the utility of research. The middle ground – presuming arguments for using animals are convincing, i.e. the gains to human beings are judged sufficient to justify the burdens imposed on animals – has been summarized as the 'Three Rs': Replacement, Reduction and Refinement.

In preparing to conduct research on animals, principal investigators should whenever possible (a-1) replace animals with non-animal research methods – mathematical models, computer simulation, in vitro biological systems – and (a-2) substitute a less sentient species than vertebrates whenever possible; (b) develop research and statistical models that reduce the number of animals used in each research protocol; and (c) refine experimental techniques to minimize the pain, distress, discomfort and suffering of animals in research to ensure they do not exceed the levels animals normally experience in their daily lives.

In the end, each State remains at liberty to establish policies to regulate the use of animals in biological/life sciences, biomedical and behavioural research.

(ii) The Imperative to Protect Human Participants Involved in Biological, Biomedical and Behavioural Research

The involvement and participation of human beings in physiological and behavioural clinical trials is an essential means of gaining scientific information and contributing to scientific and medical

progress. A clinical trial prospectively assigns human beings to undergo intervention, or be members of comparison groups where clinical investigators study the cause-and-effect relationship between a physiological intervention and a health outcome.

Until relatively recently, though the regulation of clinical research with human participants had its origins in a few States in the mid 1960s, researchers were subject to few controls and regulations except with respect to the use of non-human animals. Extensive controls over human research, it was believed, were unwise because they would stifle creativity and hinder innovation – unnecessary because researchers could be trusted as heirs to a long tradition that put patient-subjects' interests first. Reinforcing this belief was the practice of auto-experimentation, in which researchers used themselves as research subjects. What could more clearly demonstrate a researcher's care and integrity than his or her own assumption of risk of harm? Today, of course, researchers submit to innumerable regulations and auto-experimentation is virtually a thing of the past. Also, today's discourse does not focus on whether the researcher ought to be trusted, but rather on what risks of harm the research participants may assume.

Moreover, researchers allow research subjects to be subject to chance in a way that clinicians who attend to individual patients do not. Risks to human subjects involve chance, owing to the contemporary reliance on probabilistic thinking and the fact that risk of a possible harm is not known with certainty; indeed, chance in research cannot be eliminated. As the poet Stéphane Mallarmé remarked: 'Toute pensée émet un coup de dés'. [All thinking involves a throw of the dice.] In a probabilistic sense, researchers understand that some of their research participants may suffer harm, although they cannot identify specific individuals. In short, before persons agree to participate in clinical research, they are entitled to know that they may be placing themselves in harm's way.

Of course, researchers are expected to protect, not exploit, their patients, clients and all research participants. This moral mandate should be deeply rooted in the researchers' professional identity. Surely, this internal safeguard against abuse is central. In its absence, all other efforts are doomed. Yet, though necessary, this internal safeguard is not sufficient. It must be supplemented by external safeguards, both formal (statutes and government regulations) and informal (pressure from peers and patients). For outrageous exploitation of the vulnerable is not unknown and researchers are not immune to the flaws that afflict the rest of humanity though they are charged with protecting research participants, especially the vulnerable: indigents, dependents on government assistance, the unemployed, some ethnic and racial minority groups, homeless persons, refugees, patients in emergency rooms, residents in long-term care institutions and, particularly, patients with incurable diseases.

One partial solution to these bioethical worries, particularly those generated by pharmaceutical firms who sponsor clinical trials, is the proposal that uniform and universal worldwide standards be established for all human participants in biomedical and behavioural clinical research trials. Indeed,

a major policy shift has recently been proposed in a few Member States: that the purpose, the goals, the anticipated length of all research trials as well as their anticipated outcomes, not simply those that produce positive results, be registered in a publicly available database. They are to be made accessible to the public in order to increase transparency and do away with so-called 'selective reporting' and 'publication bias' that tend to hide negative, or inconclusive, harmful effects from physicians', patients' and regulators' scrutiny.

There are also potential economic consequences: not registering all significant drug studies may lead to even more expensive pharmaceuticals, vaccines and devices. While some have proposed legislation to ensure the transparency of all future, significant drug studies involving human participants, others have urged journal editors to refuse to publish the results of any clinical trial that was not registered when the study commenced.

Opponents of government regulation – particularly the sponsors of research in the life sciences – have expressed reservations about divulging proprietary information that emerges during a drug trial's early phases. This, too, has economic consequences. It is quite likely that clinical trials will, in the future, receive closer scrutiny as an additional measure to protect the public's health.

(iii) Fundamental Dilemmas in Research Ethics

In order further to illustrate the dilemma argument, two extreme choices are inferred from two quite unlikely scenarios: (a) the State permits all biological, biomedical and behavioural research and members of the population to be recruited to participate in research trials without any government regulation and, therefore, without accountability; or (b) the State does not permit any biomedical and behavioural research and therefore its people are not permitted to participate in any investigations, whether conducted by principal researchers from an external or a host State, or both.

The first dilemma

Premise 1-A If researchers are compelled to cease totally or not even permitted to initiate physiological, biomedical or behavioural research proposals involving human participants – who usually experience only 'minimal risk of harm' – and must abandon the quest for 'generalizable knowledge', then the acquisition of generalizable knowledge will be stifled and clinical progress will be undermined; and

Premise 1-B If researchers are permitted to engage in any physiological, biomedical, or behavioural research and are rewarded for dedicating themselves to continuing their quest for new 'generalizable knowledge', then some will be placed at risk of harm – sometimes 'more than minimal risk' – including the possibility of serious, permanent injury or even death.

Premise 2 Either researchers are prohibited from conducting research trials or they are permitted to conduct them free of regulation.

Conclusion Either the fruits of clinical research will be denied to society or participants will be subjected to unreasonable risk of harm – perhaps ‘more than minimal risk’ – including the possibility of serious, permanent injury, or even death.

The resolution of this dilemma is, of course, the adoption of regulations to govern research with human participants – regulations and rules researchers must respect and follow.

The second dilemma

Premise 1-A If researchers are compelled to cease totally or not even to initiate physiological, biomedical, or behavioural research proposals involving human subjects and thus must abandon the quest for ‘generalizable knowledge’, then there will be a significant public outcry (the public’s response to unethical action); the public will anticipate that no further advances in the biomedical sciences will take place, thus inhibiting the very possibility of discovering new cures for diseases like Alzheimer’s, Parkinson’s, other diseases of the brain and the central nervous system and diabetes mellitus, and even serving as a barrier to advances in what has recently been dubbed ‘regenerative medicine’.

Premise 1-B If researchers are permitted and encouraged to dedicate themselves zealously to continuing their quest for new ‘generalizable knowledge’, which requires them to conduct physiological, biomedical, or behavioural research involving human participants in scientific investigations or trials, then society will soon become denigrated and humanity dehumanized. In this case, however, it is not caused by government action but by individuals’ choice for newly-available biotechnologies: e.g. electing to produce carefully engineered embryos for various purposes; allowing potential parents to have their physicians ‘screen out’ certain genetic traits from their embryos while selecting others to ensure the so-called ‘perfect baby’; seeking general ‘enhancement’ of traits in the newly-born such as height, weight, intelligence, memory – in short, seeking the ‘perfect, ageless body’.

Premise 2 Either researchers are prohibited from conducting research trials or they are encouraged and given funding to do so.

Conclusion Either clinical procedures will neither be introduced nor eventually prescribed to improve the health of future patients, or society will soon become denigrated and humanity dehumanized. Only a few have asked the ethical question: How equitable or ethical will these ‘advances’ or enhancements be for those members of society who will not be able to afford these interventions?

Finally, notwithstanding its promises of benefits for future patients, biological, biomedical and behavioural research may also harm those patients and healthy persons who actually participate in the research. In the end, each State, especially developing States where the establishment of RECs is urgently needed, must decide to what extent it will condone and support clinical and scientific investigations involving the participation of its people.

(iv) Bioethics and Transnational Research: External and Host States

It has now become common practice for researchers from Northern States to sponsor and conduct biomedical research in Southern States, soliciting and recruiting people to participate in biomedical and behavioural research, the objective being the acquisition of generalizable knowledge leading to the production of new, safe and efficacious pharmaceuticals, vaccines and devices. The practice has grown mainly because it is much less costly than conducting the trials in developed States.

This transnational, externally-sponsored research has recently become more visible owing to various demands for new drugs, especially to prevent the spread of HIV and its transmission from mother to child, as well as to assuage fully-expressed AIDS.

As transnational research becomes even more common, two ethical issues have generated considerable controversy. One relates to informed consent. As potential participants live in countries with high rates of illiteracy and without prior practices that involve individual persons in decision-making, they may not always be capable of providing informed consent.

A second issue is whether the drugs made possible by the trials will be made available to patients in developing States at a reasonable cost. Pharmaceutical firms are actuated by the profit motive; they are not public charities. Yet developing States will resent assuming risks of harm only to be denied the benefits flowing from the risks taken by their people.

It has been noticed that research proposals using participants from the developing world often focus on clinical problems that are quite trivial in the developing world context, e.g. testing new drugs for migraine. Given this type of situation, a new requirement should be imposed on external researchers: if they recruit research subjects from developing States, then the principal focus of their research should (perhaps must) be directed to diseases, illnesses and common complaints that are prevalent in developing States.

These issues not only raise bioethical questions that bioethicists may debate; they have also become potent political and health-policy issues that threaten the continuation of transnational research. Yet since researchers from external, developed States need to obtain participants for their research and developing host States need the researchers to devise improved treatments for their people, arrangements can directly be made to permit the research to proceed. Fortunately, interdependence breeds compromise.

A number of new drugs are currently being tested at a number of sites in a variety of States, but not without public opposition to some of these clinical trials. Researchers from developed States must therefore continuously face a variety of socio-political problems, especially since opposition to biological, biomedical and behavioural research conducted in developing States is no longer uncommon. Opposition by governments and civil society may become especially pronounced if, for instance, it were uncovered that uninfected people were being recruited along with infected people to participate in a research trial, notwithstanding that

in randomized clinical trials the researchers do not know in advance who will receive the new, experimental drug and who will receive either a placebo or a standard, but not very effective, active substance already marketed and available on prescription.

Furthermore, people in developing States are not only questioning the traditional morality of their own cultures but also the traditional moralities of other cultures, particularly in more developed States. From the perspective of developing States, developed States no longer have the privileged position. Moral experience is indeed quite rich, and this alone warrants careful assessments even of what constitutes a bioethical problem or dilemma.

It is little wonder, then, that people now ask whether it is ethical to recruit human beings to participate in clinical research trials for a potentially life-saving treatment when the healthy participants in the trial may contract the disease itself. And once people become involved and participate, what after-trial care will be provided? These additional bioethical issues are likely to become increasingly contentious as developing Member States become favourite sites for pharmaceutical firms and governments of external, developed Member States.

It is argued that Southern States should permit their citizens to participate in clinical research and take risks by participating in trials conducted by external researchers from Northern States only if it had previously been jointly agreed that, once efficacious and safe drugs are discovered, newly-discovered drugs and vaccines would be provided at reasonable cost to the host State's population and that the material benefits would not be meagre; that this population, too, will receive the new drugs whether they prevent, slow the progress of, or cure the disease or diseases under investigation.

There is, of course, another side to this debate: developing Member States that allow and support clinical investigations also benefit, at least in principle, from the laboratories, equipment and training that typically accompany a trial; officials representing developing States who impose overly stringent demands on researchers from developed States, such as the provision of long-term and inexpensive drug supplies, risk not receiving new, safe and efficacious pharmaceuticals and vaccines – partly because these have yet to be discovered.

Thus, various transnational agreements must be made in advance of the clinical research trials, and compromises and trade-offs must be built into these agreements between the researchers from developed States and the leaders, scientists and health professionals in the developing States where the research will be conducted.

When confronting these ethical conflicts, it is important to note that there are two distinct phases: (a) the review and approval of each protocol by an REC in the external researcher's country, followed by (b) a similar review of the bioethical and scientific designs of the same proposed trial by experts in the host country where the trial will take place. For this two-phase process to be successful, the research protocol should be jointly approved by the external and the host States.

It would be prudent for the host State to establish RECs whose members are well educated in the biomedical and behavioural sciences as well as bioethics and health law. Thus a new policy could be formed: investigators from external States may not conduct clinical trials in host States unless the host countries have established RECs similar to those that exist in developed States. To say the least, the present model is clearly one-sided; the only reasonable way to 'level the playing field', so to speak, is for host States that do not have RECs to establish them, especially since transnational research trials are increasing.

Finally, there are at least two additional ethical obligations that affect clinical researchers of both sponsoring and host States:

1. The external agency sponsoring physiological, biomedical, or behavioural research in a host State must agree to follow the ethical standards and regulations of the sponsoring State's agencies. Some States have adopted rules and regulations, if not legislation, to require its researchers conducting investigations with human participants in host States to apply the same ethical standards in host States as they are required to do when conducting biomedical research in their own country. These standards should be, many have argued, as precise and exacting as those established in the researchers' own States.

2. Once the scientific and ethical review phases of research protocols have been completed in a researcher's State, the appropriate authorities in the host State – perhaps following a review by a national, regional or local REC – must agree that the protocols from the sponsoring, external State meet their own State's ethical standards.

Purposes

1. To assist (a) chairpersons and members of RECs as well as (b) life sciences' researchers and biomedical, behavioural and epidemiological researchers, (c) media professionals and (d) the lay public to understand and appreciate the policies and bioethical concepts that underlie the guidelines and regulations, if any, governing research involving animals and the participation of human beings.

2. To underscore the problems and issues of which those involved in scientific investigations should be cognizant.

3. To take into consideration the design not only of the scientific but also of the bioethical and regulatory dimensions of all research proposals involving human participants.

RECs have been established in States' research centres at the national level as well as in regional and local medical institutions, universities and private and independent research organizations. If funds are made available by government and private sources (e.g. pharmaceutical firms) to be distributed among researchers at several levels, some system of competition among researchers will in all likelihood be created. This will compel each researcher to formulate proposals that must be submitted to both a scientific and a bioethics review committee.

In order to conduct research directed to developing new pharmaceuticals, vaccines and devices, competent researchers must be available and willing to participate, usually without additional compensation, in the review of scientists' proposals and protocols prepared by their peers. Such a system of review is fraught with danger, however. Will investigators seeking approval of their grant proposals from their peers on the REC become REC members themselves at a later date, thus creating potential opportunities for a conflict of interest? 'You approve me and I'll approve you'. Even if reviewers are unacquainted with applicants, might they have less exacting standards in order to make the acceptance of their own research proposals more likely? Do researchers have conflicts of interest that include not only commercial and financial interests, but also career advancement, honoraria, reputation, consultant's fees, royalties, profits, stock-options, and gifts from pharmaceutical firms, as well as more subtle, though less worrisome, interests: the satisfaction resulting from scientific curiosity and altruism?

Will bioethical oversight, a principal task of RECs, be pushed aside by technical, scientific discussions at the REC's meetings? Will the workload of the REC overwhelm its members so they fail to scrutinize each proposal with care – fail to attend to the safety, welfare and rights of those persons who eventually become involved and participate in scientific, biomedical and behavioural research?

Functions

To carry out their functions, RECs are expected to determine the acceptability of the research proposals they review in terms of applicable law and regulations, standards of professional conduct and practice, and local community values. With its broad committee membership, RECs require the participation of informed and concerned health professionals as well as non-scientists, e.g. bioethicists, health lawyers, clergy and laypersons from the local community.

1. It is not unusual for members of RECs to combine research and therapy. The distinction between the two concepts is critical and is captured by paraphrasing the philosopher, Stephen Toulmin: My physician is principally concerned with my liver; a researcher is principally concerned with the liver. This distinction will be reinforced if RECs are not combined with HECs into a single bioethics committee with the same members, particularly since their purposes are incompatible: HECs are primarily concerned with bioethical issues that arise from patients' cases and hospitals' policies; RECs are chiefly concerned with the scientific and ethical designs of the protocols they review prior to approving (perhaps requesting revisions and resubmission) or disapproving them.

Moreover, RECs do not deal with patients or their families, not even when, as sometimes happens, a physician contacts an REC seeking a one-time use of an 'experimental' or not-yet-approved-for-use drug to treat a desperately ill patient when no other pharmaceutical substance is available.

Nevertheless, each committee – HEC or REC – should seek to encourage diversity with respect to the constituency of its members; this can also serve to keep them more objective. Perhaps most importantly, maintaining separate purposes and functions of an REC and an HEC, especially in the same institution, serves to avoid unnecessary intra-institutional tensions and conflicts. This should not entirely preclude some overlapping membership and cooperation between the REC and the HEC, but attempts to combine the two committees have generally failed.

Finally, an organizational decision to maintain separate committees might well produce the advantage of enhancing intra-institutional communication, understanding and cooperation, and reduce, if not eliminate, negative critique, unrealistic recommendations and the unreflective establishment of the health care institution's policies, not to mention setting limits to the overwhelming workload that a combined committee necessitates.

2. Each REC, though principally concerned with the safety and efficacy of proposed research, including the review of bioethical issues, can benefit from the perspectives of outside consultants.

3. Each REC, assisted by an outsider, should scrutinize the recruitment, solicitation and enrolment of research participants, especially the recruitment of vulnerable persons – particularly those whose decision-making capacity is or may become compromised during the investigation.

4. Each REC must itself be attentive to its own potential conflict of interests, e.g. conflicts between the principal investigator, his or her institution and the research participants. To help avoid these conflicts, the additional perspective of an external consultant may prove invaluable.

5. Most of the scientist-members of an REC are themselves well educated in the biotechnological and life sciences; many carry out bench research in laboratories and many others conduct clinical trials at locations where the participants convene periodically to receive controlled dosages of various pharmaceutical substances and vaccines, or to have various devices implanted such as electrodes, pacemakers, artificial joints and other bodily parts.

6. With respect to self-education in research ethics, very few States have formally established educational programmes for RECs' chairpersons and members, even at the local level. There are essentially two dimensions to curricula that, if studied, would provide adequate education in research ethics to RECs' chairpersons and members: (a) the study of criteria for providing sound clinical practice involving the ethical conduct of scientists as well as clinicians and (b) the study of the salient concepts and topics located in the documents of various agencies whose mandate is to regulate the activities of scientists who recruit participants for surveys and clinical investigations that may require the participants to accept various risks of harm or even risk of premature death.

Given the importance of protecting human participants in research trials, self-education at monthly meetings by RECs is by itself simply inadequate. RECs' members, while likely to have earned degrees in the behavioural or life sciences and in medicine, have had little exposure to topics pertinent to the goal of achieving good clinical practices or analytic

discussions of important concepts that are written into a government's rules and regulations, which clinical researchers must implement.

Clearly the time has come to establish RECs in various States and at various governmental levels – national and regional as well as local. Furthermore, significant educational programmes would need to be prepared and made available to RECs' chairpersons and members. These programme sessions would convene on a regular basis in addition to the RECs' actual, formal work of reviewing clinicians' and scientists' research proposals for their bioethical as well as their scientific merits.

Unfortunately, however, in a number of States the education and training of non-scientists for this task is inadequate and this inadequacy may minimize their influence. Health professionals, for example, may stress the complexity of an issue and suggest that non-scientists would do well simply to listen quietly to the discussion. For the REC to function satisfactorily, however, it is essential that non-scientists be well prepared and ready to contribute. Otherwise, their presence will merely camouflage the dominance of the bench scientists and health professionals.

Finally, if policy issues regarding research with human participants are far-reaching and must be resolved with the participation of the non-scientist members of the RECs, the complex nature of the issues and policies may make the efforts of the RECs at best inefficient and at worst self-defeating. After all, the non-scientist members should also fully participate in the review of scientific protocols, including technical matters, degree of risk of harm to participants, likely benefits to future patients, the scientific and bioethical design of the research protocols, competence of the principal researchers, safety precautions to be taken during the investigations, and so forth. In short, the more capable and competent the RECs' non-scientist member and visiting consultants, the less likely the principal researchers and scientist-members of the RECs will be to consider the non-scientist members meddling outsiders.

Committee Size

As is the case with HECs, the size of RECs varies widely, depending on its functions. Including the chairperson, RECs usually comprise ten to twenty members; in a number of States the average number is nine. Again, there is no perfect size for an REC, any more than there is a perfect size for an HEC. To assist in determining an appropriate size for an REC, it is helpful to take time, as the committee is being formed, to work to determine as accurately as possible the number and type of functions the committee intends to carry out, at least during its first year. Most of an REC's members are educated in the life sciences; a few are social and behavioural scientists – a cultural anthropologist, a psychologist, a medical sociologist. The principal function of an REC, as has been noted, is to review the scientific and ethical designs of protocols submitted by scientists who plan to investigate the efficacy and safety of new substances that, in time, may become marketable pharmaceuticals, as well as vaccines and devices. To determine the membership of an REC, then, it is important for the chairperson to be able reasonably to

estimate the number of scientific protocols and proposals the REC will be expected to receive and review at any given meeting.

In Northern States, the number of REC meetings frequently exceeds one per month; in Southern States the RECs convene as few as three, but in a few cases more than four times a year. In developed States, RECs have complained that they are overwhelmed with proposals and thus overworked, especially since virtually all RECs located in Western medical centres are composed of volunteers; its members have full-time responsibilities teaching, writing to fund their own research proposals, serving on other committees in their home institutions or in the local community, and, for some, serving on ad hoc RECs at the national level of government.

Recruiting Chairpersons and Members

An REC's functions require the participation of informed and concerned health professionals as well as non-scientists – e.g. bioethicists, health lawyers, clergy and lay persons from the local community – and, especially important, periodic visits by outside consultants expert in bioethics.

Unlike HECs, there is a greater similarity among RECs with respect to its membership. Most RECs include (a) physicians (usually they have been or are principal researchers; as a group of health professionals they frequently account for more than fifty per cent of an REC's membership), (b) basic scientists (some of whom have an MD degree but did not undertake or complete a medical clerkship or residency), (c) a nurse, (d) a health lawyer, (e) a social or behavioural scientist (medical anthropologist, medical psychologist, medical sociologist), (f) a member of the clergy (in developed States, usually the Pastoral Care Office) and (g) at least one (perhaps more) community representative.

Funding

In numerous developed States, funding biomedical and behavioural research is a significant financial enterprise. Public and private funds for clinical research have increased exponentially and both public and private funds are usually given to the researchers' institutions. Public funds are principally derived from tax revenues and are a major source of support for clinical research institutions; private funds are principally derived from the ever-expanding and extensive pharmaceutical industry as well as from philanthropic foundations and individuals' largesse. In Southern States there is some support for RECs. For example, RECs have been established in Argentina, Brazil, Chile, Columbia, Cuba, Guatemala, Mexico, Panama, Peru and Venezuela.

Thousands of institutionally based RECs, principally in Northern States, have for a number of years received very little financial support from their institutions; the chairperson and members have accepted the extra workload as service to their institutions. Recently, RECs have requested and received annual budgets and more extensive support from the secretariats within their

institutions. A good deal of work is required to prepare, then to review and finally to follow up approved as well as tentatively disapproved protocols, most of which are resubmitted for review.

Surprisingly, in a few States, a number of non-institutional, local, geographic, for-profit, commercial RECs (located in various geographic regions) have been established; they usually require a substantial fee in order to review a single researcher's scientific protocol.

Some have questioned this practice – the main criticism being the absence of accountability on the part of non-institutional RECs. Yet each REC must establish an administrative base, maintain a conference room where the members of the non-institutional REC may convene to conduct its protocol reviews and have other secretarial support to conduct its scientific and bioethical reviews.

Bioethical Dilemmas: A Case for RECs

The Goal: To obtain patients' informed consent to participate in research in a Southern society and transcultural setting without forcing Western interpretations of the notions of informed consent upon a population with different, perhaps even antithetical, values.

The Case: The government of a Southern State has called upon a Northern nation's biomedical researcher and her research team not simply to determine whether a disease X poses a dangerous threat to its people but, if so, to begin research to prevent or to cure disease X. There is, at this time, no safe and effective treatment, no drug or vaccine to give these sick and dying patients. There is, however, evidence to conclude that disease X is transmitted by an indigenous parasite. A large proportion of the population comes in contact with this parasite but attempts to annihilate it have failed. To control the spread of the parasite by chemically spraying the environment (a procedure that also raises environmental ethics dilemmas) would require a far-too-expensive and excessive commitment of the State; adequate funds are unavailable.

Both the external and host researchers agree that the initial investigation will take the form of an invasive, low risk test, in order to make an accurate assessment of the prevalence of disease X. The joint team of researchers plans to establish 'test teams' in a number of the State's public clinics, where it is not unusual for up to 1,000 sick people to appear weekly. It soon becomes obvious that the people in this State do not share the Western team's understanding of disease prevention, causation and treatment, though they understand quite well that Northern doctors can ameliorate the symptoms of, if not cure, some diseases.

The patients arriving at the public clinic anticipate receiving therapy; they do not expect to be asked to participate in research that neither promises them relief of their symptoms, nor an immediate cure of disease X. Will the patients believe they are not in a position to refuse to participate? Will they suspect that future treatment will be conditioned on whether they decide to participate? Are they inevitably coerced or unduly influenced to participate? Will being punctured with a needle be construed as treatment or therapy rather than research that, if successful, is more likely to help others in the future and not the participants?

The Northern principal researcher and her research team fully understand they are required to obtain informed consent of the patients they plan to approach for participation in their clinical research trial. Hence the research team encounters a serious ethical dilemma.

The Dilemma

Premise 1-A If the members of the research team openly seek to obtain the fully informed consent of the patients at the public clinics, they will probably fail to attract the required minimum number of subjects. This will doom the research project and deny the patients (and others) the potential benefit of receiving a drug or vaccine that may either prevent or cure disease X; and

Premise 1-B If the members of the research team do not seek the informed consent of the potential patient-participants, then they will violate the rights and dignity of the potential participants, who will suffer dignitary harm.

Premise 2 Either the research team actively seeks the fully informed consent of the clinic patients being solicited to participate in the research trial or it does not.

Conclusion Either there will be no advance in the biomedical, scientific knowledge required to produce a new pharmaceutical or vaccine to control disease X, or the patients being solicited will suffer a dignitary harm.

What should the two RECs (external and host) recommend to avoid the negative alternatives that are reflected in this dilemma? Can the research team conduct ethically acceptable research without undermining the autonomy and dignity of the potential research participants who are currently patients and not research subjects?

Part IV

PROCEDURES AND OPERATIONS

Once it has been decided to establish a bioethics committee (at any level of government), those responsible for its formation must, early on, consider and agree upon a sequence of steps that will serve to create the committee. These must be clearly formulated and followed in an orderly fashion, leaving some room, perhaps, for minor revisions.

The steps

1. The form of bioethics committee must be determined: (a) PMA, (b) HPA, (c) HEC, (d) REC, or any combination of these forms.
2. Statutes must be developed that reflect approval of the bioethics committee by a legal authority. The statutes must include but may not be limited to the following:
 - (a) the various disciplines that will be represented by the members,
 - (b) the tenure of the chairperson and the members (permanent, renewable, rotating, e.g. 1 or more years), and
 - (c) the number of members required to constitute a quorum for official meetings of the bioethics committee.
3. A chairperson for the bioethics committee must be selected and appointed.
4. The bioethics committee's members must be selected and appointed. The selection process, whatever the steps, must be determined; it may involve bioethicists and philosophers, life scientists, health professionals, behavioural and social scientists, scholars from the humanities, theologians, health-law experts, patient advocates, public officials and laypersons from the local community.
5. The chairperson and the members of the bioethics committee must understand the legal framework within which the committee has been established, since this serves to guarantee the independence of the committee's members (e.g. formal letters from the institution's Administration to the chairperson and members will assure that liability protection has been provided, either separately to each member or collectively to the chairperson and all the committee's members). It should be made clear to all members, which body is responsible for funding the litigation and any other expenses in the case of a lawsuit being filed naming the committee or any of its members, though a lawsuit is extremely unlikely to be filed.
6. The chairperson and the committee, or one of its subcommittees, should prepare and propose an annual budget, then obtain the institution's commitment to provide these funds.
7. The bioethics committee must determine if none, some, or all of its meetings will be open to the public, and who will establish this policy.

8. It must be determined to whom the chairperson of the bioethics committee is responsible and accountable.
9. The Committee's operations and work procedures should be developed and clarified during its initial meetings. This may include preparing formal reports and other documents, including taking and recording the minutes of all discussions and decisions taken at all meetings.
10. A bioethics committee should establish a permanent and well-staffed secretariat to support its administrative requirements and to clarify the committee's relationship, if any, to the Administration. Without a secretariat, the stability of the committee cannot be assured and its effectiveness and permanent existence may be jeopardized. The secretariat should be established and reflected in the institution's organizational chart and the institution's professionals and staff should be notified of its existence and mission. The secretariat should be ready, willing and able to assist in managing the daily affairs of the bioethics committee, especially the documentation of its

HOW TO ESTABLISH A BIOETHICS COMMITTEE?

Checklist of subsequent steps

1. Determine the level

- a. National
- b. Regional
- c. Local

2. Determine the form of committee, depending on the goal

- a. Policy → PMA
- b. Research → REC
- c. Professional guidelines → HPA
- d. Case consultation → HEC

3. Make statutes

4. Select chairperson

5. Select members

6. Determine the legal framework

7. Determine the budget

8. Decide whether meetings will be open or closed

9. Determine to whom the chairperson is responsible

10. Determine work procedures

- a. Frequency of meetings
- b. Formal reports of the meetings
 - i. Minutes
 - ii. Decisions
- c. Distribution of reports
- d. Provision of documents
- e. Preparation of meetings

11. Establish the secretariat

12. Provide ethics education to members

- a. Determine the need for training of members
- b. Establish a training programme for members

transparent, i.e. that as a matter of committee policy it is prepared to make annual self-evaluations as well as external evaluations of its performance (see Part V).

Take the example of France's *Comité Consultatif National d'Ethique*: To inform and interact with the media and to carry out other functions that involve documentation and the dissemination of information, the *Institut National de la Santé et de la Recherche Médicale* (INSERM/Paris) is involved. This agency has the continuous responsibility to provide technical and administrative support, as well as stability, to the *Comité Consultatif National d'Ethique* by making available for use its *Centre de Documentation et d'Information sur les Problèmes d'Ethique dans le Domaine des Sciences de la Vie et de la Santé*.

11. Instruction should be provided in bioethics and in-service educational programmes organized for the entire bioethics committee (some institutions provide funds to local universities and colleges to offer formal education in bioethics to the committee's present and future members).

Part V

EVALUATING BIOETHICS COMMITTEES

1. SELF-EVALUATION

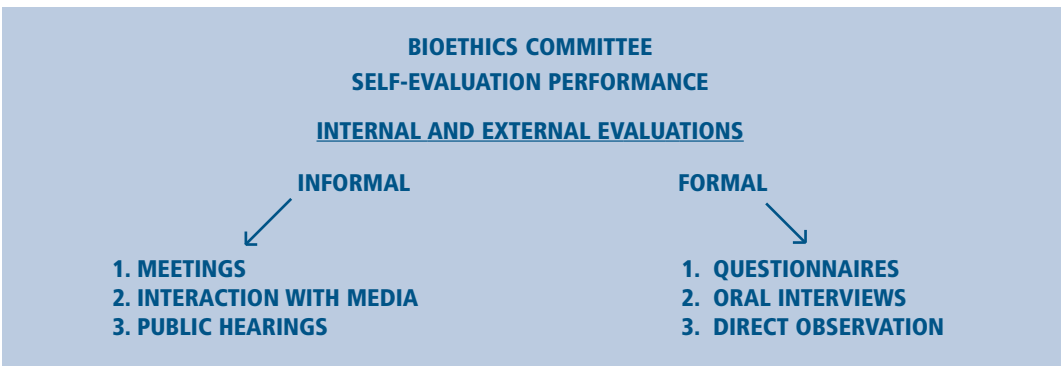
Any programme must confront the question of how successful it truly is. This, in turn, raises the question of who is to make this determination. Self-evaluation is one answer.

It may be either formal or informal. Formal evaluations may take the form of questionnaires, oral interviews and direct observation by outsiders; informal evaluations typically involve members' unstructured discussions. Members must insist on high standards and create peer pressure that pushes all concerned to excel. The very activity of evaluation may be a valuable educational experience as members learn more about themselves, their colleagues and the committee's purposes, functions, procedures and operations. Insiders, moreover, bring with them the advantages of practical experience and their unique perspective.

Yet, by itself, self-evaluation is rarely sufficient. There is the human tendency to judge oneself too kindly or to be swayed by irrelevant factors in the judgement of others. There is also the absence of detachment. In any case, as a committee's work has profound implications for the external world, the external world normally insists on being involved.

2. EXTERNAL EVALUATION

External evaluation may also be of an informal nature. The media may discuss a committee's operations or a public official may focus on it at a public hearing or during an interview. These evaluations may sometimes produce significant effects, perhaps by generating a public demand for a change in policy or personnel.



Most committees' activities are invisible to officials, to the media and to the public, who lack the knowledge or interest to pursue the matter. On the other hand, experts invited especially for this purpose are ready, willing and able to perform serious evaluations. Of course, one must beware: not all those claiming to be experts are actually expert, and bias and personal factors may distort if not poison a report. But a sound external evaluation may be extraordinarily valuable. It should identify strengths that can be maintained, weaknesses that should be corrected, policy considerations that may have been overlooked, and personnel and other sensitive matters that the committee has lacked the fortitude to address. But for the evaluation to matter, the committee and its institutional superiors must take it seriously. Otherwise, its findings and recommendations, no matter how wise, will soon be forgotten.

If committees fail to address evaluation, the danger is that they will become institutionally isolated, lose credibility and forfeit long-term viability. Important persons will be discouraged from serving and recommendations will increasingly be ignored. The greatest hope for success is to invite criticism (through formal and informal, periodic but regular, evaluations) and to remain transparent and open to change.

The second question posed by evaluation is how success is to be defined. The simplest answer is to view success as a function of the goals of the committee. But this may not be easy to measure (e.g. to what extent do HECs improve patient care, or RECc protect participants in research trials?) and emphasis on meeting goals may result in a committee's selecting goals that are easy to meet. Another approach would be to define success in terms of satisfaction: How satisfied are the committee's constituents (and the committee's own members) with the work it performs? Among the problems here, is that satisfaction may result from personal factors (friendship, for example) and different observers may apply different criteria in weighing their level of satisfaction.

As important as it is, then, evaluation is notoriously difficult to carry out. Still, it is essential that bioethics committees understand that evaluation is not a time-wasting intrusion or a threat to their good works, but an opportunity to think deeply and carefully about what they do with an eye to helping them do these things better. If committees fail to address their own evaluation, they risk undermining their own authority and usefulness.

WHEN GOVERNMENT AGENCIES FORMALLY EVALUATE THE EFFECTIVENESS OF A BIOETHICS COMMITTEE'S PERFORMANCE, THE COMMITTEE SHOULD :

1. Invite objective experts
2. Records strengths and weaknesses and be willing to change
3. Publicize policy changes to maintain credibility

Part VI

RECOMMENDED READING

(1) BIOETHICS

General texts

Ahronheim, J.C., Moreno, J., Zuckerman, C. *Ethics in Clinical Practice* (2nd ed.). Aspen Publishers, Frederick, MD, 1999.

Beauchamp, T.L., Childress, J.F. *Principles of Biomedical Ethics* (5th ed.). Oxford University Press, New York, NY, 2001.

Gillon, R. (ed.). *Principles of Health Care Ethics*. John Wiley & Sons, Chichester, 1994.

Gracia, D. *Fundamentos de Bioetica*. Eudema, Madrid, 1989.

ten Have, H. and Gordijn, B. (eds.). *Bioethics in a European Perspective*. Kluwer Academic Publishers, Dordrecht/Boston, MA/London, 2001.

Jonsen, A.R., Siegler, M., Winslade, W.J. *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine* (5th ed.). McGraw-Hill/Appleton & Lange, New York, NY, 2002.

Veatch, R. *Case Studies in Medical Ethics*. Harvard University Press, Cambridge, MA, 1977.

(2) HEALTH CARE/HOSPITAL ETHICS COMMITTEES

Journal

HEC Forum (Hospital Ethics Committee Forum: An Interdisciplinary Journal on Hospitals' Ethical and Legal Issues) was first published bimonthly in 1989 by Pergamon Press in New York; in 1997, it was published quarterly. In 1992, the title was changed to *Healthcare Ethics Committee Forum*, as ethics committees began to proliferate not only among hospitals but also in other health care institutions. It was published by Kluwer Academic Publishers, Dordrecht, the Netherlands, in 1992; Springer became the publisher with the appearance of Volume 17, 2005. Its publication has continued without interruption (see Spicker, S.F. (ed.). *The Healthcare Ethics Committee Experience: Selected Readings from HEC Forum*. Krieger Publishing Co., Malabar, FL, 1998.)

General texts

Brodeur, D. 'Toward a Clear Definition of Ethics Committees'. *Linacre Quarterly*: 233-247, August, 1984.

Brown, B.A., Miles, S., Aroskar, M.A. 'The Prevalence and Design of Ethics Committees in Nursing Homes'. *Journal of the American Geriatric Society*, 35 (11): 1028-1033, 1987.

- Craig, R.P., Middleton, C.L., O'Connell, L.J. *Ethics Committees: A Practical Approach*. The Catholic Health Association of the United States, St. Louis, MO, 1986.
- Cranford, R.E., Doudera, A.E. (eds.). *Institutional Ethics Committees and Health Care Decision Making*. (Published in co-operation with the American Society of Law & Medicine) Health Administration Press, Ann Arbor, MI, 1984.
- Gracia, D. *Procedimientos de Decisión en Ética Clínica*. Eudema, Madrid, 1991.
- Hosford, B. *Bioethics Committees: The Health Care Provider's Guide*. Aspen Press, Rockville, MD, 1986.
- Lo, B. 'Behind Closed Doors: Promises and Pitfalls of Ethics Committees'. *New England Journal of Medicine*, 317 (1): 46-50, 1987.
- McCormick, R.A. 'Ethics Committees: Promise or Peril?' *Law, Medicine and Health Care*, 12 (4): 150-155, 1984.
- Ross, J.W. et al. *Handbook for Hospital Ethics Committees*. American Hospital Publishing, Inc., Chicago, IL, 1986.
- Ross, J.W., Glaser, J.W., Rasinski-Gregory, D., Gibson, J.M., Bayley, C. (eds.). *Health Care Ethics Committees: The Next Generation*. American Hospital Publishing, Inc., Chicago, IL, 1993.

Ethics consultation

- Fletcher, J.C. et al. (eds.). *Ethics Consultation in Health Care*. Health Administration Press, Ann Arbor, MI, 1989.
- La Puma, J., Schiedermayer, D. *Ethics Consultation: A Practical Guide*. Jones and Bartlett Publishers, Boston, MA/London 1994.

Self-evaluation

- Griener, G.G., Storch, J.L. 'Hospital Ethics Committees: Problems in Evaluation'. *HEC Forum*, 4 (1): 5-8, 1992.
- Povar, G. 'Evaluating Ethics Committees: What Do We Mean By Success?'. *Maryland Law Review*, 50 (3): 904-919, 1991.
- Van Allen, E., Moldow, D.G., Cranford, R. 'Evaluating Ethics Committees'. *Hastings Center Report*, 19 (5): 20-24, 1989.
- Youngner, S.J. et al. 'Patients' Attitudes Toward Hospital Ethics Committees'. *Law, Medicine and Health Care*, 12 (1): 21-25, 1984.

(3) RESEARCH ETHICS COMMITTEES

Journal

IRB (Institutional Review Boards: A Review of Human Subjects Research) was first published in March, 1979 by The Hastings Center: Institute of Society, Ethics and the Life Sciences (presently located at 21 Malcolm Gordon Road, Garrison, New York, NY 10524-5555, U.S.A.). Its publication has continued without interruption, though its subtitle was changed to

Ethics & Human Research with the appearance of Vol. 23, No.1, January-February, 2001.

General texts

- Beecher, H.K. 'Ethics and Clinical Research'. *New England Journal of Medicine*, 274 (24): 1354-1360, 1966.
- Bernard, C. *An Introduction to the Study of Experimental Medicine* (trans. Greene, H.C.). Dover Publications, Inc., New York, NY, 1957 [published in 1865].
- Brieger, G.H. 'Human Experimentation: History'. In *Encyclopedia of Bioethics*, Macmillan Publishing Co., New York, NY, 1978.
- Eckstein, S. *Manual for Research Ethics Committees* (6th ed.). Centre of Medical Law and Ethics, King's College, London, 2002.
- Faden, R.R., Beauchamp, T.L. *A History of the Theory of Informed Consent*. Oxford University Press, New York, NY, 1986.
- Freund, P.A. (ed.). *Experimentation with Human Subjects*. George Braziller, Inc., New York, NY, 1969. [Most of the essays in this book were originally published in the Spring, 1969 issue of *Daedalus*, the Journal of the American Academy of Arts and Sciences.]
- Jonas, H. *Technik, Medizin und Ethik: Praxis des Prinzips Verantwortung*. Suhrkamp Verlag, Frankfurt, Germany, 1985; reprinted 1987.
- Katz, J. *Experimentation with Human Beings: The Authority of the Investigator, Subject, Professions, and State in the Human Experimentation Process*. Russell Sage Foundation, New York, NY, 1972.
- Levine, R.J. *Ethics and Regulation of Clinical Research* (2nd ed.). Yale University Press, New Haven, CT, 1988.
- Nuffield Council on Bioethics. *The Ethics of Clinical Research in Developing Countries*. Nuffield Council, London, 1999.
- Orlans, F.B., Beauchamp, T.L., Dresser, R., Morton, D.B., Gluck, J.P (eds.). *The Human Use of Animals: Case Studies in Ethical Choices*. Oxford University Press, New York, NY, 1998.
- Sieber, J.E., "Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards". *Applied Social Research Methods Series*, Vol. 31, Sage Publications, Newbury Park, CA, 1992.

Transnational research ethics

- Angell, M. 'Investigator's Responsibilities for Human Subjects in Developing Countries'. *New England Journal of Medicine*, 342: 967-969, 2000.
- Emanuel, E.J., Wendler, D., Killen, J., Grady, C. 'What Makes Clinical Research in Developing Countries Ethical? – The Benchmarks of Ethical Research'. *Journal of Infectious Diseases*, 189: 930-937, 2004.
- International Ethical Guidelines for Biomedical Research Involving Human Subjects*.

Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), Geneva, 2002.

Macklin, R. 'Justice in International Research'. In *Beyond Consent: Seeking Justice in Research* (Kahn, J.P., Mastroianni, A.C., Sugarman, J. (eds.)). Oxford University Press, New York, NY, pp.131-146, 1998.

Macpherson, C.C. 'Research Ethics Committees: A Regional Approach'. *Theoretical Medicine & Bioethics*, 20 (2): 161-179, 1999.

McMillan, J.R., Conlon, C. 'The Ethics of Research Related to Health Care in Developing Countries'. *Journal of Medical Ethics*, 30: 204-206, 2004.

Rivera, R., Ezurra, E. 'Composition and Operation of Selected Research Ethics Review Committees in Latin America'. *IRB: Ethics & Human Research*, 23 (5): 9-11, September-October, 2001.

Varmus, H., Satcher, D. 'Ethical Complexities of Conducting Research in Developing Countries'. *New England Journal of Medicine*, 337: 1003-1005, 1997.

World Medical Association Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects. [Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964; amended 1975 (Tokyo, Japan); 1983 (Venice, Italy); 1989 (Hong Kong, Peoples Republic of China); 1996 (Somerset West, Republic of South Africa); 2000 (Edinburgh, Scotland).]

Appendix 1

BIOETHICS COMMITTEES AT THE NATIONAL LEVEL OF GOVERNMENT				
Country	Official Name	Date Established	Website	Type ¹
Algeria	Conseil National de l'Ethique des Sciences de la Santé	1990	http://www.sante.dz	1
Argentina	Ethics Committee for Clinical Investigation	1991	http://www.favaloro.edu.ar	2
Australia	Australian Health Ethics Committee	1991	http://www.health.gov.au/nhmrc	1
Austria	Bioethikkommission (Commission on Bioethics)	2001	http://www.bka.gv.at/bioethik	1
Azerbaijan	National Committee on the Bioethics of Scientific Knowledge and Technology	1999		2/1
Belgium	Comité consultatif de Bioéthique de Belgique/Raadgevend Comité voor bio-ethiek van België (Belgian Advisory Committee on Bioethics)	1993	http://www.health.fgov.be/bioeth	1
Bolivia	National Ethics and Bioethics Steering Committee, Bolivian Academy of Medicine	2000		2
Cameroon	Société Camerounaise de Bioéthique (NGO established by law)	1990		2
Côte d'Ivoire	Comité Consultatif National de Bioéthique de la République de Côte d'Ivoire (National Bioethics Advisory Commission of Côte d'Ivoire)	2002		3
Croatia	Nacionalno bioetičko povjerenstvo za medicinu (National Bioethics Committee for Medicine)	2001		1
Cuba	Comité Nacional Cubano de Bioética (Cuban National Bioethics Committee) (Created by President of the Academy of Sciences of Cuba, and President of the UNESCO Cuban National Commission)	1996		3
Cyprus	Cyprus National Bioethics Committee	2002		1
Czech Republic	Centrlni Eticka Komise Pri Ministerstvu Zdravotnictvi Ceske Republiky (Central Ethics Committee of the Ministry of Health of the Czech Republic)	1990		1
	Bioeticka Komise Rada Vldy Ceske Republiky pro Vyzkum a Vvoj (Bioethical Commission Associated to the Research and Development Council of the Government of the Czech Republic)	1997	http://www.vlada.cz/1250/eng/vrk/rady/rvv/rvv.eng.shtml	2

¹See pages 17-18

ESTABLISHING BIOETHICS COMMITTEES

Denmark	Det Etske Rad (Danish Council of Ethics)	1987	http://www.etiskraad.dk	1
Dominican Republic	Comisión Nacional de Bioética (National Bioethics Commission) (National Commission for UNESCO)	1998		3
Ecuador	Comité Nacional de Bioética del Ecuador (Established by UNESCO Quito)	1998		3
Egypt	Egyptian National Committee for Bioethics (National Commission for UNESCO)	1996	http://www.egnatcom.org.eg	3
Estonia	Eesti Bioetika Nounkogu (Estonian Council on Bioethics)	1998		1
Finland	Tutkimuseettinen Neuvottelukunta (National Advisory Board on Research Ethics)	1991	http://www.pro.tsv.fi/tenk	1
	Valtakunnallinen terveydenhuollon eettinen neuvottelukunta (National Advisory Board on Health Care Ethics)	1998	http://www.etene.org	1
France	Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé (National Consultative Ethics Committee for Health and Life Sciences)	1983	http://www.ccne-ethique.fr	1
Gambia	Medical Research Council Ethics Committee of the Gambia Government	1982		1/2
Georgia	National Bioethics Council of Georgia	2000		1
Germany	Der Nationale Ethikrat (German National Ethics Council)	2001	http://www.ethikrat.org	1
Greece	Hellenic National Bioethics Commission	1998	http://www.bioethics.gr	1
Holy See	Pontificio Consiglio per la Pastorale Degli Operatori Sanitari (Pontifical Council for Pastoral Assistance to Health Care Workers)	1985	http://www.vatican.va	1
Hungary	Egészségügyi Tudományos Tanács Tudományos és Kutatásetikai Bizottsága (Scientific and Research Ethics Committee of the Medical Research Council)	1989	http://www.ett.hu	1
Iceland	Visindasidanefnd (National Bioethics Committee of Iceland)	1997 (reformed in 1999)	http://www.visindasidanefnd.is	1
Iran	Committee of Bioethics, National Committee for Ethics in Science and Technology	2004		3
Ireland	Comhairle Bitheiteice na hÉireann (Irish Council for Bioethics)	2002	http://www.bioethics.ie	2
Italy	Comitato Nazionale Italiano di Bioetica (The National Bioethics Committee)	1988	http://www.palazzochigi.it/bioetica	1
Japan	Council for Science and Technology –Bioethics Committee	1997	http://www.mext.go.jp	1
Jordan	National Bioethics Committee	1998		1/2

ESTABLISHING BIOETHICS COMMITTEES

Lebanon	Comité Consultatif National Libanais d'Éthique pour les Science de la Vie et de la Santé	2001		1
Lithuania	Lithuanian Bioethics Committee	1995	http://www.sam.lt/bioetika	1
Luxembourg	Commission consultative national d'Éthique pour les Sciences de la Vie et de la Santé du Grand-Duché de Luxembourg	1988		1
Malta	Ministry for Social Policy, Bioethics Consultative Committee	1989	http://www.health.gov.mt/statutory_bodies/bcc.htm	1
Mexico	Comisión Nacional de Bioética (National Commission of Bioethics)	1992	http://www.bioetica.salud.gob.mx/diplomado_invest.html	1
Netherlands	Standing Committee on Medical Ethics and Health Law. Health Council of the Netherlands	1977 (1983)	http://www.gr.nl	1
New Zealand	National Ethics Committee on Assisted Human Reproduction	1993	http://www.newhealth.govt.nz/necahr	1
	National Health Committee	1992	http://www.nhc.govt.nz	1
	Health Research Council of New Zealand, Ethics Committee	1990	http://www.hrc.govt.nz	1
Norway	Den Nasjonale Forskningsetiske Komite For Medisin (National Committee for Medical Research Ethics)	1990	http://www.etikkom.no	1
	Den nasjonale forskningsetiske komite for naturvitenskap og teknologi (The National Committee for Research Ethics in Science and Technology)	1990	http://www.etikkom.no	1
	The National Committee for Research Ethics in the Social Sciences and the Humanities	1990	http://www.etikkom.no	1
Portugal	Conselho Nacional de Ética para as Ciências da Vida (The National Council of Ethics for the Life Sciences)	1990	http://www.cnecv.gov.pt	1
Russian Federation	Russian National Committee on Bioethics	1992		2
Saudi Arabia	National Committee for Medical and Bioethics, King Abdulaziz City for Science and Technology (KACST)	2001		1
Serbia and Montenegro	National Committee for Bioethics	2003		3
Singapore	Bioethics Advisory Committee	2000	http://www.bioethics-singapore.org	1
Sweden	Statens Medicinsk-etiska Rad (National Council of Medical Ethics)	1985	http://www.smer.se	1
Switzerland	Commission nationale d'éthique pour la médecine humaine (Swiss National Advisory Commission on Bioethics)	2001	http://www.nek-cne.ch	1

ESTABLISHING BIOETHICS COMMITTEES

Syrian Arab Republic	Comité national de bioéthique syrien	2004		1
Thailand	Ministry of Public Health, Ethical Review Committee for Research in Human Subjects	1977	http://www.dms.moph.go.th	1
Tunisia	Comité National d'Ethique Medicale (Committee of Medical Ethics of Tunisia)	1994		1
Turkey	Biyoetik Ihtisas Komisyonu - Milli Komite (UNESCO) (Bioethics Ad Hoc Committee for the Turkish National Commission for UNESCO)	2000	http://www.unesco.org.tr	3
Ukraine	Commission on Bioethics under the Cabinet of Ministers of Ukraine			1
UK	Nuffield Council on Bioethics	1991	http://www.nuffieldbioethics.org	2
USA	President's Council on Bioethics	2001	http://www.bioethics.gov	1
Uzbekistan	National Bioethics Committee of the Republic of Uzbekistan (NGO)	2002		2

Appendix 2

EXAMPLES OF STATUTES OF BIOETHICS COMMITTEES AT THE NATIONAL LEVEL OF GOVERNMENT

1 DENMARK: The Act on the Danish Council of Ethics

2 GAMBIA: Statutes of the Ethics Committee of the Gambia Government

3 UZBEKISTAN: Statutes of the National Bioethics Committee of the Republic of Uzbekistan

The Act on the Danish Council of Ethics

The Danish Council of Ethics was created under Danish Act No. 353 of June 3rd 1987 on the Establishment of an Ethical Council and the Regulation of Certain forms of Biomedical Experiments. The Act has been amended partly by Act No. 315 of May 16th 1990 to amend the Act on the Establishment of an Ethical Council and the Regulation of Certain forms of Biomedical Experiments, and partly by Act No. 503 of June 24th 1992 on a Scientific-Ethical Committee System and the Treatment of Biomedical Research Projects.

The Council was formed by the Minister of the Interior in 1987, but on the creation of the Ministry for Health later in the year the Council passed into the organizational jurisdiction of the Minister of Health. The subsequent amendments to said Act have been incorporated in the wording of the Act as follows.

§ 1.

(1) The Minister of the Interior shall set up a Council of Ethics for the health care services and biomedical research involving human subjects. The Council shall work in cooperation with the health authorities and the scientific ethical committees. The Council shall carry out its work on the assumption that human life begins at the moment of fertilization.

§ 2.

(1) The Council shall consist of 17 members, to be appointed by the Minister of Health according to the following rules: Eight members shall be appointed by the Minister of Health. The appointment shall consider the appointees' publicly substantiated knowledge of the ethical, cultural and social questions of

importance to the work of the Council. Nine members shall be appointed by the committee mentioned in Section 10. Said persons must not be members of parliament, of a municipal council or of a county council. Where the committee cannot agree on an appointment, the majority of the committee shall decide on the appointment.

(2) The appointments made under subsection 1.1 shall ensure equal representation of men and women. As regards the appointments made under subsection 1.2 there may be only one more of one sex than of the other.

(3) The chairman is appointed by the Minister of Health from among the appointees on the recommendation of the committee mentioned in Section 10 of this Act.

(4) The members and the chairman are appointed for a term of 3 years. Reappointment may take place once.

(5) The Council shall lay down its own rules of procedure.

§ 3.

(1) The Council of Ethics shall have a permanent secretariat, the staff of which shall be employed and dismissed by the Minister of Health on the recommendation of the chairman of the Council.

(2) The necessary funds for the work of the Council shall be granted in the annual budgets.

§ 4.

The Council shall submit a recommendation to the Minister of Health concerning the establishment of rules on the protection of fertilized human ova, living embryos and fetuses. The same shall apply to genetic experiments on human gametes used for fertilization. The recommendation shall include a report on the current state of research and an evaluation of probable developments within the next few years. Furthermore, said recommendation shall include an evaluation of any ethical problems potentially resulting from such developments as well as an assessment of the question of legal regulation in the event of violation of the rules to be laid down according to the recommendation.

§ 5.

The Council shall submit a recommendation to the Minister of Health on the possibility of carrying out genetic treatment on human gametes used for fertilization and of fertilized human ova, embryos and fetuses. The recommendation shall include a report on the current state of research and of the individual procedures and probable developments in this field within the next few years. Furthermore, the recommendation shall include an assessment of the ethical and legal problems that may result from such developments, as well as propositions for possible rules governing the right to carry out the treatments in question.

§ 6.

The Council shall submit a recommendation to the Minister of Health on the possibility of using new diagnostic techniques in order to detect congenital defects or diseases in fertilized human ova, embryos and fetuses. The recommendation shall include a report on the current state of research as well as probable developments in this field within the next few years. Furthermore, the recommendation shall include an assessment of any ethical and legal problems potentially resulting from such developments as well as propositions for possible rules governing the right to use the techniques in question.

§ 7.

The Council shall submit a recommendation to the Minister of Health on the establishment of rules for the cryopreservation of human gametes intended for fertilization and of fertilized human ova. The recommendation shall include a report on the current state of the technique and an evaluation of the results thus achieved. Besides this, such recommendation shall include an assessment of any ethical and legal problems potentially resulting from such techniques.

§ 8.

Apart from performing the tasks assigned to the Council in pursuance of § 4-7 of the Act, the Council can:

- 1) Discuss general ethical questions in connection with experiments on human subjects in cooperation with the scientific ethical committees.
- 2) Advise health authorities on the assessment of general ethical questions of major importance to the health care services relating to the use of new methods of treatment, new diagnostic techniques and new medical technology, as well as take up problems within its scope at its own initiative.
- 3) Advise public authorities in connection with the ethical evaluation of questions on registration, disclosure and use of information on hereditary diseases or characteristics of individuals or groups of persons.

§ 9.

(1) The Council shall follow developments in the fields mentioned in § 4-7. The Council shall inform the public on developments and on the work of the Council, and it shall take the initiative in making any ethical problems that may arise subject to public debate. The Council can arrange public enquiries and set up working parties to report on special problems.

(2) The Council can make use of special experts.

(3) The Council shall simultaneously submit an annual report to the Minister of Health and to Parliament.

§ 10.

(1) At the beginning of each parliamentary year and after general elections Parliament shall appoint a committee of nine members (made up in the same proportions as Parliament). An alternate shall be appointed for each member in the same manner.

(2) The committee shall appoint the members mentioned in subsection 1.2. of Section 2.

(3) The committee shall follow the work of the Council of Ethics by means of joint meetings etc. Furthermore, the committee can ask the Council of Ethics to deal with specified subjects within the Council's terms of reference.

§ 13.

The Minister of Health shall introduce the bill mentioned in § 4.1 during the parliamentary year of 1990-91 at the latest.

§ 14.

(1) This Act shall come into force on the day following its publication in the Danish Official Gazette.

(2) The committee mentioned in Section 10 shall be set up for the first time immediately upon the coming into force of this Act.

§ 15.

This Act does not extend to the Faroe Islands or Greenland, but can be extended by Royal Decree to the Faroe Islands and Greenland subject to such adaption as may be required by circumstances peculiar to those parts.

Statutes of the Ethics Committee of the Gambia Government

1. The Ethics Committee of the Gambia Government/MRC is accountable to the Director of the Department of State for Health and to the Director of the MRC Laboratories, The Gambia.

2. The Committee shall consist of 11 members: a Chairman, 4 members to be nominated by each Director (one of each four to be a lay member who is not an employee of the respective institution) and the two Directors. The Director, with the Chairman, will nominate from the members one who will act as Scientific Advisor to the Chairman who will act as his/her deputy.

3. The Chairman and members will be appointed following consultation between the Directors. The Chairman, if at all possible, should be independent of both institutions.

4. Members should serve for an initial period of 2 years which may be renewed for a further 2 year period and exceptionally for longer.
5. The Committee will review research projects to be undertaken under the auspices of the MRC Laboratories, The Gambia, by either members of the unit or attached workers. The Committee will also review ethical aspects of other research work to be carried out in The Gambia if requested to do so by the Director of Medical Services, Department of State for Health, or his deputy.
6. The quorum for a meeting shall be the Chairman, or his deputy, and three members, one of whom must be a lay member, and one a nominee of the Director of the Department of State for Health.
7. A project will be deemed approved when it has received the support of at least 4 members of which one is not an employee of MRC. In the event of more than one member having strong objections or reservations the submission may be resubmitted or rejected.
8. Applicants whose project has been rejected will have the right to appear before the Committee in person to appeal against this decision.
9. Meetings will be held at monthly intervals after a meeting of the MRC Laboratories' Scientific Co-ordinating Committee.
10. The Director of the MRC Laboratories, and the Director of Medical Services shall be members of the Committee ex-officio, but shall not have voting rights on any project considered by the Committee.

The Secretariat will be provided by MRC.

Statutes of the National Bioethics Committee of the Republic of Uzbekistan

Article 1

The National Bioethics Committee of the Republic of Uzbekistan (referred to henceforward as NBC) is created as advisory body within the Ibn Sino (Avicenna) Foundation of Uzbekistan.

The following organizations are founders of NBC:

- Ibn Sino International Foundation of Uzbekistan
- National Commission of Uzbekistan for UNESCO
- Ministry of Health Care of Uzbekistan
- Academy of Science of Uzbekistan
- Ministry of Justice of Uzbekistan
- Ministry of Higher and Secondary Specialized Education of Uzbekistan

- Ministry of Public Education of Uzbekistan
- Imam al-Bukhori International Foundation
- “Oila” Republican Center
- “Mahalla” National Foundation

Article 2

Main objectives of the NBC are:

- Formulation of recommendations on topics which have been submitted to it by various governmental agencies, private institutions and non-governmental organizations.
- Organization of studies related with examination of the principles of ethical norms.
- Realization of research works in medicine, biology and pharmaceutical industry.

The NBC is coordinating the activities of respective governmental agencies and non-governmental organizations in the following field of activities:

- Development of ethical dimension in the behavior of health professionals and researchers as well as in the decision-making and law-making, based on the Universal Declaration on the Human Genome and Human Rights.
- Educational programmes in bioethics at university, secondary school and community level, based on fundamental values, such as respect for others, social responsibility and justice.

Article 3

Functions of the NBC are the following:

- Coordination of cooperation of Uzbekistan’s governmental and non-governmental organizations with the International Bioethics Committee of UNESCO and other National Bioethics Committees.
- Elaboration and practical implementation of new educational standards in the field of medical ethics including the introduction of theoretical bioethics and clinical bioethics, adoption of a bioethical approach in medical faculties and community-based bioethical teaching for the general public.
- Contribution to the implementation of the National Program of Uzbekistan for Personnel Training by creation of teacher training centers and development of new teaching tools and materials.
- Support of scientific studies in the field of aging research (including gerontology), neuroscience research and human genome.

Article 4

Chairperson of the NBC is an elected President of the “Ibn Sino” International Foundation of Uzbekistan. The NBC consists of 20 experts from founder organizations.

Article 5

The NBC organizes its session once a year, during which the report on the activities of the previous year is presented and the draft project of new programmes for the next year is approved. The decisions of the NBC is adopted by consensus. The decisions adopted by the NBC are distributed among respective governmental and non-governmental organizations.

Article 6

The NBC has its own secretariat consisting of three persons: Chairperson, Vice-Chairperson and Executive Secretary. The address of the Secretariat of the NBC is: 51-A, Parkent Street, Tashkent, 700007, Republic of Uzbekistan.

Division of Ethics of Science and Technology of UNESCO

The Division of Ethics of Science and Technology reflects the priority UNESCO gives to ethics of science and technology, with emphasis on bioethics. One objective of the medium-term strategy of the Organization is to “promote principles and ethical norms to guide scientific and technological development and social transformation”.

Activities of the Division include providing support for Member States of UNESCO that are planning to develop activities in the field of ethics of science and technology, such as teaching programmes, national ethics committees, conferences and UNESCO Chairs.

The Division also ensures the executive secretariat for three international ethics bodies, namely the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC).

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