

Assisting Countries in Establishing National Bioethics Committees: UNESCO's Assisting Bioethics Committees Project

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The *Universal Declaration on Bioethics and Human Rights* adopted by UNESCO in 2005 advocates for the establishment of independent, multidisciplinary, and pluralist ethics committees at national, regional, local, or institutional levels. The purpose of these committees is (a) to evaluate the relevant ethical, legal, scientific, and social issues related to research involving human beings; (b) to provide advice on ethical problems in clinical settings; (c) to assess scientific and technological development, formulate recommendations, and contribute to the preparation of guidelines; and (d) to foster debate, education, and public awareness of and engagement in bioethics (Article 19).¹ Already in the very first draft of the *Declaration* the need to promote and establish national bioethics committees was mentioned. Although the text was gradually elaborated, the same basic idea has been preserved throughout the process of drafting, negotiating, and adopting the text.² At the same time, the terminology shifted from bioethics to ethics committees, emphasizing the broad scope of such committees. Reference to ethics committees, especially at a national level, has been specifically motivated by two concerns. The first is that ethics committees will be one of the most important intermediary bodies for the implementation of the normative instruments adopted by the member states. Without the existence of a body of experts in the field of bioethics or ethics of science and technology in general who can advise policymakers, it is not realistic to expect that states will take appropriate measures to give effect to the principles set out in the *Declaration*. For this reason, Article 22 states that states should encourage the establishment of ethics committees. The second concern is related to the need for informed pluralistic, public debate. As a forum for intercultural exchange, a national (bio) ethics committee can provide a platform to engage citizens and society as a whole in dialogue about (bio)ethical issues on a regular basis. In countries with a weak or limited ethics infrastructure, the creation or reinforcement of a national (bio) ethics committee may be an effective way to promote the development of (bio) ethics. However, in the majority of member states, such committees do not exist at the moment. UNESCO has therefore initiated a project to assist member states in regard to bioethics committees (ABC [Assisting Bioethics Committees] project). This paper discusses the opportunities and challenges related to establishing and strengthening such committees within the context of the ABC project. The terminology used will be "bioethics" rather than "ethics" committees, addressing, as formulated in the *Declaration*, "ethical issues related to medicine, life sciences and associated technologies as applied to human beings" (Article 1).³

Aim and Focus of the Project

The ABC project aims at reinforcing the bioethics infrastructure in member states through the establishment of national bioethics committees and, once they are established, through the enhancement of the functioning of these committees. The project is an essential component of UNESCO's capacity building effort in the area of ethics of science and technology.⁴ In many countries, experiences exist with bioethics committees at various levels of government. In most countries, such experiences relate to research ethics committees that deal specifically with reviewing research protocols, either at the level of hospitals and research institutes, or at the regional or national level. The focus of the ABC project is limited. First, the emphasis is on bioethics committees at the national level. Functioning at this level will allow bioethics committees to operate as expert bodies for promotion of policy—advice, guidelines, and legislative action, public debate, and education. Second, the focus is on bioethics committees with a wide mandate covering the area of bioethics as a whole, thus going beyond a specific interest in research ethics, cloning, or reproductive medicine. A national bioethics committee, in the perspective of the project, is different from a more specialized committee such as a research ethics committee because its mandate will not be limited to ethical review of research protocols.

Implementation of the Project

Fact-finding

The first stage of the project is to obtain accurate information concerning the state of the art of (bio) ethics committees in all countries. A “diagnosis” of the ethics infrastructure is necessary, not only to determine whether there are ethics committees at the national level but also to assess the ethics resources that can be mobilized (available ethics expertise, ethics education, ethics advisory bodies at different levels, ethics-related legislation and guidelines, codes of conduct, ethics review mechanisms). For this purpose, UNESCO has launched the Global Ethics Observatory.⁵ The database of ethics institutions currently has information on 105 commissions at the national level in 69 countries. Data are available on country, level of operation (international, national, state/provincial, institutional), type of founding organization, membership, frequency of meetings, secretariat (permanent, temporary, or nonexistent), foundation year, areas of ethics covered (bioethics, or science ethics, animal ethics, etc.), and type of activity (e.g., research protocol review, awareness-raising, policy development and advice, case consultation, public debate, teaching). The majority of committees have multiple activities (see Table 1). The most frequently mentioned activity was policy development and advice (71 committees), followed by awareness-raising (67), organization of conferences and meetings (67), and guidelines development. Two thirds of all committees focusing on policy development and advice also undertake the other three commonly mentioned activities. Research protocol review is indicated as activity of 41 committees. The majority (37) combine this task with guideline development (25), policy development and advice (25), and awareness-raising activities (20), but 4 committees have research protocol review as their only activity.

Table 1. Type of Activities Undertaken by 105 (Bio)ethics Committees at the National Level in the UNESCO Global Ethics Observatory Database

Type of activity	Committees with multiple activities	Committees with only 1 activity
Advocacy	28	
Awareness-raising	67	
Case consultation	25	
Conference and meetings	67	
Database	19	
Documentation center	17	
Guideline development	63	
Policy development and advice	71	
Public debate	53	
Publications	57	
Regulatory activities	29	
Research	31	
Research protocol review	41	4
Teaching	33	

Specific information concerning national bioethics committees is also provided on the World Health Organization (WHO) Web site.⁶ A useful survey has been published by the German National Ethics Council.⁷ The European Union-funded Networking for Ethics on Biomedical Research in Africa (NEBRA) project examined the situation of research ethics committees, for example, in West and Central Africa.⁸ A regular source of information is *Ethically Speaking*, a newsletter of the European Group on Ethics in Science and New Technologies to the European Commission. It provides updates on activities of European as well as non-European national ethics committees.⁹

Another way to obtain information is through meetings of networks. Currently three such international networks exist (leaving aside networks exclusively focused on research ethics). The Global Summit of National Ethics Committees has been convening since 1996 every 2 years (2008 in Paris, 2010 in Singapore). The Conférence européenne des comités nationaux d'éthique (COMETH), set up in 1992 and bringing together committees from member states of the Council of Europe, has had nine meetings (lately in 2007 in Berlin). The Forum of National Ethics Councils (NEC Forum) meets every half year at the initiative of the national committee in the country that has the presidency of the European Union. Recently, this assembly has been expanded into the EC International Dialogue on Bioethics, organized by the European Commission, in order to facilitate dialogue between the 27 members of the NEC Forum and (until now 14) non-European committees (recently convened in conjunction with the 15th meeting of the NEC Forum in Spain in March 2010).

Also, meetings at the regional level provide an occasion to exchange and clarify information concerning ethics committees. For example, UNESCO has organized in collaboration with the WHO Regional Office for the Eastern Mediterranean the First Regional Meeting of National Bioethics Committees on May 5–7, 2007, in Cairo. It brought together experts from 15 countries in the region plus representatives of the Arab League Educational, Cultural and Scientific Organization, the Gulf Cooperation Council, and the Islamic Organization for Medical Sciences.

Practical Information and Guidelines

The many books and guides on ethics committees use to focus on the substance of work of specific types of committees, such as hospital ethics committees or research ethics committees. For example, the *Draft Guide for Research Ethics Committee Members*, currently drafted by the Council of Europe, highlights the key ethical issues that will be faced when research proposals involving human beings are reviewed.¹⁰ Although it presents information concerning the role, composition, and method of working of committees, the *Guide* primarily emphasizes the ethical items to be considered and the operational procedures in the review process.

Since the launch of the ABC project, requests have demonstrated a need for practical and procedural information among policymakers. They were interested in knowing what practical steps to take if they want to establish a bioethics committee at the national level. To facilitate this practical information and to make accessible experiences from all parts of the world, a series of guidebooks have been developed. The first guide explains the various steps to be taken when creating a national bioethics committee, in conjunction with information regarding purposes, functions, membership, legal framework, and funding of the committee.¹¹ The guide presents a checklist for establishing a national bioethics committee. For policymakers the first decision is to determine what type of committee they want to establish. Depending on the goal to be achieved (policy advice, research review, professional guideline development, and case consultation) four types of committee are distinguished: policymaking and/or advisory committee, research ethics committee, health-professional association committee, and healthcare or hospital ethics committee. The second guide explains the appropriate working methods and procedures.¹² Once a committee has been established, it should become operational as an effective and efficient body of experts. Practical guidance is provided regarding general procedures (preparing for meetings, following agendas, recording of deliberations, establishing subcommittees) and specific procedures for each type of committee. The guide also discusses how committees can be evaluated and how they can extend their influence among policymakers, scientists, the public, and the media. The third guide focuses explicitly on education.¹³ When a committee is operational, there will be a need for training and education of committee members. The guide provides information about what committee members need to know and suggests topics for training programs. Examples of training programs in various countries are given, as well as an extensive list of international bioethics journals and international Web sites for (self-) education. New guides are currently being drafted on policymaking as well as public debate.

Technical Support

When a member state is interested in a national bioethics committee, the different modalities of establishment and type of committee can be discussed in detail during site visits with (English-, French-, or Spanish-speaking) experts who have practical experience within national committees of their countries. During preparatory meetings in 2006 in Paris, these experts developed a common methodology and plan of action, so that a coherent framework for the technical consultation could be used. At the request of the country, UNESCO then organizes an exploratory mission with a team of experts who can discuss with

interested stakeholders in the host country the relevant structural and operational issues in order to facilitate the de facto creation of a national bioethics committee. Such missions have been undertaken in 14 countries, all in Africa and Latin America (see Table 2).

Within an intergovernmental organization like UNESCO, explaining the need, providing information, offering expertise, and outlining the possible modalities for policy is as far as one can go in encouraging member states to establish a national bioethics committee. The actual decision is up to them. This implies that the exploratory visit will not necessarily result in the creation of a committee. However, nine countries have now established national bioethics committees as a consequence of the technical mission of UNESCO, and one country (Oman) has established a committee without such a mission, using only the guidebooks. In most countries, policymakers acted swiftly and constituted a national committee not long after the exploratory mission. In other countries, however, the process takes more time. As Table 2 shows, five countries are currently in the process of building momentum for establishing a committee. This is sometimes because of the need to bring together different stakeholders, the difficulties of going beyond the existing structure of research ethics committees, or because of the modalities chosen for the committee. For example, in Mauritius, disputes have emerged about who should take the lead (the University or the Academy of Sciences), but finally a bill has been submitted to Parliament for the creation of a national committee. Although such legal action will produce a strong and independent committee model, it can take a long time before it is politically adopted (as the experiences in Brazil demonstrate¹⁴).

As soon as a national committee has been constituted, the ABC project focuses on its second objective, that is, supporting the committee to become an operational and effective body. A formal agreement is concluded between UNESCO

Table 2. Countries Involved in the ABC Project (2007–2010)

Country	Exploratory technical mission	National Bioethics Committee established	Training workshop on working methods	Training workshop on bioethics
Cape Verde	2008			
Chad	2008			
Colombia	2009	2009	2010	
Côte d’Ivoire	—	2002	2009	2010
El Salvador	2008	2009	2010	
Gabon	2007	2008	2009	2010
Ghana	2007	2009	2009	2010
Guinea	2008	2008	2009	2010
Jamaica	2007	2008	2009	2010
Kenya	—	1983	2009	2010
Madagascar	2007	2007	2010	
Malawi	2007	2010	2010	
Mauritius	2007			
Nigeria	2009			
Oman	—	2010	2010	
Togo	2007	2007	2009	2010
Trinidad and Tobago	2009			

and the recently established committee. It outlines intensive cooperation for the next 3 years, including training courses, provision of documentation, internships for the secretariat, networking and partnerships, and co-organizing public events. Currently (mid-2011), with five committees, an agreement has been signed, and the first training on working methods was provided to these committee in 2009. Interestingly, two already existing committees (in Côte d'Ivoire and Kenya) joined the project because they changed and broadened their mandate, signed the agreement, and organized the first training. Four committees (Colombia, El Salvador, Madagascar, and Malawi) will enter the second stage of the project in 2010, and the Sultanate of Oman requested to join after having recently established a national bioethics committee. Thus, since 2010, national committees in 12 countries are participating in the project. All committees are receiving training courses (in the first stage on working methods, in the second stage on bioethics). A first opportunity to exchange experiences was provided during an EU-funded international conference in Mexico in November 2009.¹⁵

Challenges

What is a national bioethics committee? There is no official definition of a national bioethics committee, at least not in UNESCO. In reality, there is heterogeneity. The same denomination "national bioethics committee" does not guarantee similarity of activities. On the other hand, differences in names may express various roles and structures. A committee or commission (e.g., the French Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé) often indicates that the body plays an official role within a governmental policy structure. A council (e.g., the Danish Council of Ethics) will often focus on deliberation and consultation, whereas an advisory board (e.g., the Finnish National Advisory Board on Health Care Ethics) will deliver recommendations. The committees also have different organizational modalities: they can be connected to the government or to nongovernmental organizations. Examples of the first are committees created by law as separate legal entities (in France and Brazil) and committees created by the president (United States). Committees can also be created and hosted by a ministry (often the Ministry of Health; e.g., Mexico and Gabon) or by an entity within a ministry (e.g., the UNESCO National Commission in the Ministry of Education, like in Guinea). Examples of the second are committees created and hosted by the Academy of Sciences (e.g., Madagascar and Tajikistan), the National Science Foundation (e.g., Sri Lanka), the Medical Association (e.g., Azerbaijan) or a charity (e.g., the Nuffield Council in the United Kingdom). All these modalities have advantages and disadvantages in terms of independency, continuity, credibility, and support.

An operational description of a national bioethics committee should at least include three components: (a) it is a group (chairperson and members) that are meeting regularly, (b) it systematically addresses the ethical dimensions of medicine and the health sciences, the life sciences, and associated technologies, and (c) it focuses on issues that are not simply factual but normative. This description will at least enable the identification of committees that function as such. In some countries, national committees exist on paper, but they never meet as a group. In other cases, they restrict their activities to merely analysis of

scientific and technical issues without really addressing ethical questions. A fourth component is that the committee should operate at the national level and be recognized as a national body. This does not necessarily imply that the committee has been established by a government or is connected to governmental agencies (as the example of the Nuffield Council illustrates).

Different tasks and mandates. Committees can have different objectives, specified in their mandate, for example, to develop and advocate policies, to improve patient care, to implement sound professional practices for patient care, and to protect human research participants. In practice, many committees combine various goals, regardless of their name. For example, the National Ethics Committee in Rwanda is only focused on research protocol review, whereas the National Bioethics Committee in the Democratic Republic of Congo has a range of activities, except protocol review. The first committee is a research ethics committee, the second a policy advisory committee. Because the second has a broad mandate as formulated in Article 19 of the UNESCO *Declaration* it is included in the ABC project; the first one is not. The reason is that a committee with a broad mandate is more likely to contribute to the development of an ethics infrastructure, but the formulation of such a mandate will usually require cooperation between various governmental ministries and agencies, which is not customary in many countries.

Antagonism between national research ethics and bioethics committees. The ambiguity concerning national committees is demonstrated in the dispute about their origin. The Medical Ethics Committee of Slovenia was established in 1965, the Comité Consultatif National d'Ethique in France in 1983. Both claim to be the first national bioethics committee. In fact, the first committee is a research ethics committee, the second one a policy-advisory body. In principle, the characteristics of these committees are different. The *research ethics committee* has a practical focus: it is reviewing research protocols. In its activities it can use international guidelines and directives. It can apply a clear methodology that is outlined in many documents and specified in scholarly literature in the area of research ethics.¹⁶ Its goal is protection of human subjects in research. The work of the committee is often associated with institutional and economic interests. The *bioethics committee* has a wider focus. The goal is developing and drafting guidelines and legislation and stimulating public debate. It cannot draw on many internationally accepted guidelines and documents. It therefore has to use an explorative and analytic approach, because it is often confronted with new ethical issues for which it has to develop national policies. It may be guided by political interests but is, in principle, focused on the common good and the public interest. Because of these differences many countries have established at the national level at least two different committees. In practice, however, the distinction is less clear. On the one hand, committees may combine different tasks. In most countries it is practically not feasible to set up two different committees, because resources and expertise are limited. Even when review committees at local and institutional levels exist, it may be necessary to have a national committee as a board of appeals or to review nationally important or controversial research projects. On the other hand, committees may evolve and expand their mandate. They start as a review committee but become convinced of the need to develop national policies and legislation so that they transform into policy-advisory committees. This has been

the case with the national committees in Gabon and Kenya; they have expanded their mandate and have requested to be included in the ABC project. This development is inherent in the evolution of medical ethics into research ethics and into global bioethics, which has to take into account a wider set of issues than research protocol review: access to healthcare, benefit sharing, biodiversity, cultural traditions, traditional medicine, social responsibility, and health. However, one of the obstacles in some countries is that existing research ethics committees leave no room for the further development of bioethics.

Need for training and support. Experiences in the ABC project show that sustainability is a serious challenge. Once established, committees should become operational.¹⁷ This is a matter not only of personal engagement of chairperson and members but also of material and immaterial resources. There is a need for on-site training programs and involvement of committee members in extensive courses elsewhere. Capacity building of the secretariat needs to be assured by internships and sharing of experiences with more experienced committees. Bioethics documentation is often lacking. Internet resources are often not easily accessible in developing countries. In collaboration with the ABC project, bioethics documentation is provided by the National Reference Center for Bioethics Literature in Georgetown University (United States). But it is clear that more efforts will be required, especially in francophone countries. The ABC project also includes internships for secretariat members as well as partnership with experienced committees.

Networking. Global networking of national ethics committees is growing, as pointed out above. The basic question is what is the purpose of such networking. Until now, the focus seems to have been on international meetings where information is exchanged and contacts are intensified. But the resources spent on meetings of chairpersons do not necessarily result in reinforcement of the operational capacities of the committees at the national level. In our view, the usefulness of convening global meetings should be reassessed. Generally, national committees from developing countries do not attend those meetings, and there is no activity or further exchange between meetings. In particular, recently established national bioethics committees in developing countries could make better use of the available resources in their own country and region. The main challenge for committees in these countries is lack of financial resources and expertise.

Final Considerations

In the current stage of global bioethics, it is inevitable that all countries develop an adequate infrastructure to deal with the ethical dimensions of healthcare, science, and technology. If expertise, ethics education, public debate, and regulatory frameworks are weak or lacking, an operational national bioethics committee can be a driving force for the growth of bioethics in a country. The process of establishing a committee is complicated and primarily a political decision. The proper functioning of a committee, however, is dependent on resources and external support. It is imperative that not only international organizations but also scientific communities, funding agencies, and experienced committees elsewhere address the need for capacity building. This will be a

significant application of the principle of international solidarity and cooperation (as stated in article 13 of the *Universal Declaration on Bioethics and Human Rights*).

Notes

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