

The UNESCO Universal Declaration on Bioethics and Human Rights Perspectives from Kenya and South Africa

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Abstract In October 2005, UNESCO (the United Nations Educational, Scientific and Cultural Organization) adopted the *Universal Declaration on Bioethics and Human Rights*. This was the culmination of nearly 2 years of deliberations and negotiations. As a non-binding instrument, the declaration must be incorporated by UNESCO's member states into their national laws, regulations or policies in order to take effect. Based on documentary evidence and data from interviews, this paper compares the declaration's universal principles with national bioethics guidelines and practice in Kenya and South Africa. It concentrates on areas of particular relevance to developing countries, such as protection of vulnerable persons and social responsibility. The comparison demonstrates the need for universal principles to be contextualised before they can be applied in a meaningful sense at national level. The paper also assesses the 'added value' of the declaration in terms of biomedical research ethics, given that there are already well-established international instruments on bioethics, namely the World Medical Association's *Declaration of Helsinki* and the CIOMS (Council for International Organizations of Medical Sciences) guidelines on biomedical research. It may be that the added value lies as much in the follow-up capacity building activities being initiated by UNESCO as in the document itself.

Keywords Global bioethics · Kenya · National bioethics · South Africa · UNESCO · Universal principles

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Introduction

In October 2005¹, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the *Universal Declaration on Bioethics and Human Rights*. The preamble states: "It is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and the environment" [3]. As the declaration is non-binding, this universal foundation will be implemented at the level of the nation-state. The onus is on UNESCO's member states to incorporate the declaration's provisions into their national laws, regulations or policies. This paper examines the synergies between the declaration and bioethics regulation in two countries, Kenya and South Africa.

Before the UNESCO declaration was adopted, international instruments such as the World Medical Association (WMA) *Declaration of Helsinki* and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* of the Council for International Organizations of Medical Sciences (CIOMS) were already well-established in bioethics [5]. Indeed, the Helsinki declaration and the CIOMS guidelines are noted in the preamble of the UNESCO declaration [3]. These instruments have had a significant influence on the national bioethics policies of developing countries [1], including Kenya and South Africa.

The objectives of this paper are twofold. The first is to assess the translation of universal principles into national practice. The comparison between the UNESCO declaration and Kenyan and South African bioethics forms the basis for this analysis. The second is to locate the "added value" of the declaration, particularly to developing countries, given the pre-existence of international level bioethics documents. Empirically based, the paper draws on documentary evidence and interviews conducted in Kenya and South Africa in 2005 and 2006.

Background

The empirical research for this paper was carried out as part of a larger doctoral project on the global governance of human genomic and biomedical research and in particular the part developing countries play in this. The theoretical framework for this project is provided by international relations, a sub-discipline of political science. While international relations theory is not referred to overtly in this paper's analytical sections, it provides the context for the understanding of universality contained therein. That is, universality is explored pragmatically, with regard to the relationship between broad principles negotiated at international level and their subsequent adaptation to national level policy and practice, rather than philosophically, in terms of universal versus pluralist moral reasoning.

¹ The declaration was adopted in 2005, but the copyright is 2006 in the published version, thus the citation is given as 2006 throughout the text of this paper.

'Bioethics'

What exactly is meant by 'bioethics' is notoriously difficult to determine. This is illustrated by the fact that the UNESCO declaration contains no clarification of the term. While a definition appeared in earlier drafts, the impossibility of reaching a consensus on wording necessitated its being left out of the final version. For the purposes of this paper, bioethics is understood specifically in terms of the regulation of biomedical research. The UNESCO declaration itself has a wider remit, covering medical practice and protection of biodiversity and the environment as well as research ethics [20]. Since the overall doctoral project is concerned chiefly with human subjects research, however, these broader considerations will not be discussed here.

Methodology and Limitations

Much of contemporary international relations theory concerns the roles of both state and non-state actors in global governance mechanisms. Reflecting this, the doctoral fieldwork consisted of 70 semi-structured interviews with a range of persons considered to be stakeholders in genomics and bioethics in France, the United Kingdom, Kenya and South Africa². The sample was chosen to reflect different societal perspectives on genomics and bioethics and thus consisted of those who formulate policy at international and national levels, those who must implement these policies in laboratories and ethics committees, those who claim to represent public concerns and those with commercial interests. The breakdown of sectors was as follows: policy-makers (20), scientists (17), ethicists (18), civil society representatives (12) and businesspersons⁴ (3). These 70 interviews, the data used in this paper draw on only 22 and come mostly from those with members of research ethics committees. Thus they are illustrative rather than representative.

Studying a declaration as it evolves makes for exciting and contemporary research. It also carries limitations, however; in this instance, fieldwork may have been conducted too early to enable an assessment of the social and political impact of the UNESCO declaration in Kenya and South Africa. In the wider context of the doctoral research project, this limitation will be addressed by the inclusion of UNESCO's previous declarations on genomics and genetics, which have had longer

² Thirty interviews took place in Kenya, 34 in South Africa, 3 in the United Kingdom and 3 in France. The 6 non-Africa-based interviews were with people involved in the negotiation of the UNESCO declaration.

³ The term 'ethicist' denotes both members of ethics committees and academic ethicists. While not all those interviewed who sat on ethics committees had been trained in bioethics as a philosophical discipline, all those interviewed who had received such training sat on at least one ethics committee.

⁴ Note that these categorisations are somewhat arbitrary, there being some overlap between sectors. One Kenyan scientist interviewed also acts as an advisor to both the national government and UNESCO, for example.

⁵ Doctoral study began in October 2004, during the drafting period of the UNESCO bioethics declaration.

to become established within national policy frameworks. It is worth noting that the research process became by default an awareness-raising exercise, in that many of the people interviewed were previously unaware of the bioethics declaration, or indeed its predecessors.

Previous Studies

The UNESCO declaration features in several publications. *Developing World Bioethics* devoted a whole issue to the draft text in September 2005. The articles were largely critical, questioning the content of the draft declaration, how it had been put together and whether UNESCO was the right body to be taking on such an endeavour [8]. Professor Henk ten Have, Director of the Division of Ethics of Science and Technology at UNESCO, responded that the journal's contributors were perhaps *not au fait* with how UN agencies work [4]. After the declaration was adopted, Herman Nys wrote an editorial for *the European Journal of Health Law* outlining its basic tenets and comparing it to *the European Convention on Human Rights and Biomedicine*. He emphasised the obligations of states to take on the declaration, despite its being legally non-binding [10]. Professor ten Have has himself written about the declaration, in the wider context of UNESCO's activities in ethics. In his article in the *Kennedy Institute of Ethics Journal* he described how these activities fall into three areas, namely the adoption of normative instruments such as the declaration and their subsequent implementation through national level capacity building and awareness raising [6].

There has been a growing literature in recent years on research ethics in developing countries. A few examples, taken from *British Medical Journal*, the *Bulletin of the World Health Organization* and *PloS Medicine*, will serve to illustrate that contextualisation of international instruments at national level and capacity for ethical review have been among the major concerns raised. Sylvester Chima has suggested that international guidelines need to be interpreted legislatively at local and regional levels and has thus called on the African Union to pass binding directives that are nevertheless adaptable to the laws of each state [3]. Kates et al., in a case study published in January 2007 reviewing the practices of research ethics committees in several African countries, including Kenya and South Africa, highlighted insufficient funding and training as the biggest challenges facing these committees and proposed that workshops be set up on how to apply ethical principles at local levels. They also called for more empirical investigation of ethics in African research [7]. Peter Singer and Solomon Benatar, in a 2001 article on the Helsinki declaration, contended that building capacity in research ethics will have far more impact on ethical standards than revisions of this or any other research ethics code, implying that declarations themselves are of limited use unless the capacity exists to implement them [5, p. 747]. Zulqar Bhutta has also argued that

⁶ The *Universal Declaration on the Human Genome and Human Rights* (1997) and the *International Declaration on Human Genetic Data* (2003).

strengthening local capacity in bioethics is key to promoting ethical health research in developing countries¹].

The UNESCO Declaration

The *Universal Declaration on Bioethics and Human Rights* was adopted by acclamation at the UNESCO General Conference on 19 October 2005. This was the end of a process that began with an invitation by the 2001 General Conference to the UNESCO International Bioethics Committee to report on the possibility of elaborating a universal instrument on bioethics. The Committee recommended that this instrument be declaratory in nature (that is, non-binding) and the drafting process was launched in January 2004 [9]. Thus the actual negotiation period lasted under 2 years. The declaration is aimed primarily at states, but can also be implemented by individuals, groups, communities, institutions and corporations, public and private where appropriate [6]. It covers a wide range of bioethical principles, several of which had already become customary in bioethics and feature in documents such as the Helsinki declaration and the CIOMS guidelines (informed consent, for example). Some of the principles of particular relevance to developing countries will be elaborated further below.

Bioethics in Kenya and South Africa

Kenya and South Africa were chosen as fieldwork destinations because of their significant involvement in genomics and bioethics at local, national, regional and international levels. Both countries have recently adopted national guidelines on bioethics: in Kenya the 2004 National Council for Science and Technology (NCST) *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* (human subjects guidelines) and the 2005 Ministry of Health (MoH) *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines* (vaccines guidelines) and in South Africa the Department of Health (DoH) *Ethics in Health Research: Principles, Structures and Processes*, which were drawn up by members of both the Department and the Interim National Health Research Ethics Committee, appointed under the National Health Act of 2003 [

Both Kenya and South Africa decided that national bioethics guidelines were necessary partly in order to protect poor and marginalised people from being exploited by unscrupulous researchers [3]. Among other texts, the guidelines draw on the Helsinki declaration, the CIOMS guidelines and several documents from the World Health Organization and the United States, but are tailored to their national contexts, with specific provisions addressing the vulnerabilities that may

¹ The guidelines are dated 2004, but the copyright is 2005 in the published version, thus the citation is given as 2005 throughout the text of this paper.

² Note that the *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* (2004) reference the 1993 version of the CIOMS guidelines rather than the more recent 2002 version.

have enabled past abuses [11, 13]. Participants from ethics committees cited a similar assortment of guidelines and regulations—international, regional and national—as influential, including some from Europe, the United Kingdom and Australia.

Synergies between the UNESCO Declaration and Bioethics in Kenya and South Africa

As the UNESCO declaration is non-binding, if its principles are to be applied universally they will necessarily have to be reflected in national level documents and systems. This section compares the main tenets of the declaration that are of special relevance for developing countries with Kenyan and South African bioethics policy and practice. The comparison has two purposes. The first is to illustrate how internationally determined, universal principles might be implemented at national levels in developing countries. The second is to show to what extent these principles were already reflected in national systems, before the adoption of the declaration.

Community Consent—Article 6

The UNESCO declaration states that for a research project on a group or community, agreement from representatives may be sought, in addition to that of the individual participants [20]. Community Advisory Boards facilitate this in some areas of Kenya (interviews, K_06:2005 and K_25:2005) and dialogue with community members through such boards is a requirement for HIV/AIDS vaccines research [11]. The South African guidelines stipulate community involvement and consultation for research involving ‘‘collectivities’’, on issues such as ownership of data and distribution of benefits and harms [13].⁹

Vulnerability—Article 8

This article holds that ‘‘individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected’’ [20, p. 8]. The Kenyan human subjects guidelines give special instructions concerning research with underdeveloped communities, prisoners, married women in rural areas and pregnant or lactating women [9], while the vaccines guidelines state that the vulnerable and poor must be protected from exploitation [11]. The South African guidelines invite ethics committees to be ‘‘especially vigilant when considering research proposals involving vulnerable populations’’ [preamble] and contain detailed provisions for research involving pregnant women, fetuses, prisoners and vulnerable communities [13].

⁹ ‘‘Collectivities are groups distinguished by: common beliefs, values, social structures and other features that identify them as a separate group; customary collective decision-making according to tradition and beliefs; the custom of leaders expressing a collective view; members of the collectivity being aware of common activities and common interests.’’ [28]

Cultural Diversity and Pluralism—Article 9

Under the declaration these should be given "due regard" [Again, the national guidelines contain specific examples of what this might entail. The Kenyan human subjects guidelines, in the context of gaining informed consent from married women in rural communities, remind researchers that each of Kenya's 42 tribes will have "unique sociocultural backgrounds" [11], while the South African guidelines, in a section on indigenous medical systems, call on researchers to respect the cultures and traditional values of all communities. [The Kenyan vaccines guidelines are less detailed and, in a similar vein to the UNESCO declaration, simply require that research teams be sensitive to "sociocultural issues," without specifying what these issues might be [30].

Social Responsibility—Article 14

This article of the UNESCO declaration is considered particularly innovative [14] it is perhaps not surprising, then, that it should prove more specific than any of the national guidelines as to how social responsibility could be implemented. Where the Kenyan and South African guidelines require research to be relevant to study populations and each country in general, by addressing either "health needs" (Kenya) [9, pp. 13, 16] or "broad health and development needs" (South Africa) [13, p. 3], the declaration states that scientific and technological progress should advance: access to healthcare and medicines; adequate nutrition and water; improved living conditions and environment; elimination of marginalisation and exclusion; and reductions in poverty and illiteracy [30].

Benefit Sharing—Article 15

The declaration is similarly specific with regard to the sharing of benefits, giving seven examples of what form this could take, including sustainable assistance to research participants and provision of new health products stemming from research [20]. It is the latter of these examples which features most prominently in the national guidelines. In Kenya, if research produces positive results, treatments should be available to participants [9]. Also, before HIV/AIDS vaccine research can take place, the "availability, affordability and accessibility" of its potential products must be considered [11, p. 30]. Research proposals in South Africa must indicate whether there is a reasonable likelihood that participants will benefit from the research and whether they will receive long-term therapy after the study [13]. More widely, research findings must "be translatable into mechanisms for improving the health status of South Africans" [13, p. 3]. In practice, ethics committees in both countries try to assess the extent to which participants will benefit from a research project (interviews, K_25:2005 and SA_19:2006), although they do not always find this a straightforward endeavour (interviews, SA_10:2006 and SA_35:2006).

Transnational Practices – Article 21

This article calls on states to combat illicit trafficking of organs, tissues, samples, genetic resources and genetic-related materials [10]. Transfer of tissues overseas has been a particular concern in both Kenya and South Africa, as reflected in their guidelines. The Kenyan *vice versa* guidelines aim to eliminate the unauthorised transfer of research materials and to this end contain a sample Biological Material Transfer Agreement [1]. Under chapter 8 of the South African National Health Act, an appendix to the DoH guidelines, the Health Minister may regulate the importation and exportation of tissue, human cells, blood, blood products or gametes [2] pp. 70, 62]. Ethics committees in both countries take tissue transfer equally seriously, examining closely any research protocol that involves movement of samples across borders. Generally they prefer a project to train people to analyse data in-country (interviews, K_17:2005, K_21:2005, K_25:2005, SA_19:2006, SA_21:2006 and SA_30:2006).

Bioethics Education, Training and Information – Article 23

Under this article states are invited to foster bioethics training and education at all levels and to encourage information dissemination on bioethics [11]. Such training and education is perhaps more widespread in South Africa than Kenya, although the UNESCO National Commission was in the process of setting up a bioethics centre to serve the East Africa region at the time of interview (interviews, K_01:2005 and K_16:2005). Several South African universities run courses in ethics or bioethics and two training initiatives, IRENSA and SARETI, serve sub-Saharan Africa as a whole (including Kenya). All three set of guidelines advocate bioethics training [9, 11, 13].

Universal Principles in the National Context

The South African guidelines read:

The challenge to international research ethics is the development of universal rules for research at a time when health care is being delivered within very different health care systems and in a multicultural world in which people live under radically different economic conditions [3] p. 7]

This paper asks whether the UNESCO declaration has met this challenge. Although promulgated with the expressed purpose of stating universal principles, the declaration acknowledges that such cultural and economic differences exist, through its articles on

¹⁰ Chapter 8 was yet to be operationalised when fieldwork was conducted.

¹¹ IRENSA is the International Research Ethics Network for Southern Africa, based at the University of Cape Town. SARETI is the South African Research Ethics Training Initiative and is run by a collaborative partnership between the University of KwaZulu-Natal, the University of Pretoria and Johns Hopkins University.

community consent, cultural diversity, vulnerability, social responsibility and benefit sharing. The Kenyan and South African guidelines demonstrate how the declaration might be applied at state level, with their prescriptions concerning, for example, how researchers should engage with communities and which particular members of society should receive special attention as vulnerable persons. That states may need to adopt particular interpretations of the declaration's principles in order to realise them in national and local contexts is highlighted by ten Have in his paper on UNESCO's ethical activities. He describes the adoption of the declaration as only the "start of a long process of detailed elaboration and consequent application" [42] and in the context of the articles on consent and social responsibility states:

As principles they are universally adopted, but in practice their application must be tailored in multiple ways to accommodate different types of research and health care, categories of patients and problems, and cultural settings and traditions. [6, pp. 342Ð343]

The need for any national implementation of the UNESCO declaration to be adequately contextualised is brought out in the interview data from Kenya and South Africa, as are differences in opinion as to the usefulness of international guidelines in general. In Kenya, an academic scientist and advisor to both the government and UNESCO stated that it would be necessary to work with those government officers responsible for effecting international documents in law, in order to "translate it [the declaration] into what is happening locally" (interview, K_13:2005). Similarly, the head of a research institution attested:

Something which became more and more legalistic in the detail and binding but which ignored local realities would be unhelpful. Something which tried to establish clear, agreed principles, which had been widely consulted, not just between member states, but with the kind of communities that are affected, would be very useful. (Interview, K_07:2005)

In South Africa, one ethics committee member thought that, given different cultural contexts and sensitivities, declarations such as the UNESCO one would have to be formulated as generally as possible to enable universal applicability (interview, SA_08:2006). Another was of the view that national and local ethics guidelines are "the things to follow," because what is applicable in one country may not be applicable in another (interview, SA_19:2006). Several saw at least some value in the UNESCO endeavour, but cautioned that universal principles must not be applied unthinkingly. Perhaps mirroring ten Have's prediction that elaboration of the declaration will be a long process, they described how working out how to apply such principles in different contexts is often the most challenging aspect of implementing international instruments (interviews, SA_10:2006, SA_17:2006 and SA_24:2006).

Added Value of the UNESCO Declaration

The UNESCO declaration is considered to be of added value because it is the first intergovernmental instrument on bioethics. Ten Have describes the commitment by

governments to an agreed set of principles on bioethics as the "innovative dimension" of the declaration [342]. The Helsinki declaration and the CIOMS guidelines, by contrast, have been adopted by professional organisations (although CIOMS is in official relations with the World Health Organization). Where the former is officially directed at physicians or researchers, however, the latter, like the UNESCO declaration, are to be used in designing national policy on biomedical research ethics, particularly in developing countries [21].

It may take time for the significance of the UNESCO declaration's governmental backing to filter through to those who practise research ethics. An anonymous reviewer of this paper described the declaration as the "common denominator of global ethical thought," but for many stakeholders the Declaration of Helsinki and the CIOMS guidelines fulfil this role, their professional origins notwithstanding. The Helsinki declaration is generally considered the foremost document globally on medical research ethics [5] and, with the CIOMS guidelines, forms the bedrock of research ethics in many developing countries. In Kenya and South Africa, where policy-makers and ethics committees have looked to these two documents for guidance at the global level, several of those interviewed were unconvinced that the UNESCO declaration, which they saw as simply another international instrument on bioethics, was necessary. As the declaration was adopted only relatively recently, such perceptions may change as both its contents and its intergovernmental status become more widely established (particularly as it construes bioethics in broader terms than only medical research ethics).

If the UNESCO declaration is not to remain paperwork, as a non-binding instrument it must be effected by states [343]. Kenya and South Africa already have national bioethics guidelines that complement the declaration to a large degree. They also have research ethics committees at institutional and national levels, or plans for constituting them. For those countries which have not already established bioethics systems, however, the UNESCO declaration could act as a catalyst to galvanise them into doing so. To this end, UNESCO's ethics programme supports states in building bioethics capacity, through various activities. The first is to construct a database with information on ethics experts, institutions, teaching programmes and policies around the world. The second is to promote bioethics education, through teacher training and curriculum development. The third is to support the setting up of ethics committees and their subsequent operations [4]. These activities were broadly welcomed among those interviewed in both countries, with the caveat that they should not overlap too far with the initiatives of other organisations. UNESCO is in fact piloting an ethics teacher training course in Kenya in July 2007 [6], where there are fewer bioethics courses available than in South Africa.

One area where ethics committees in Kenya and South Africa are in need of support is in the monitoring of research projects once they have been approved, as required by all three sets of national guidelines [1, 13]. In practice, as found by Kass et al., funding can be an issue. One prominent Kenyan ethics committee had only recently carried out its first on-the-spot inspection at the time when interview data were obtained in November 2005. Prevented from conducting these inspections more often by financial constraints, the committee generally relies on reports from

investigators and word of mouth (interviews, K_17:2005 and K_25:2005). The South African DoH guidelines require at a minimum that ethics committees request annual reports from principal investigators and establish a complaints procedure [13]; members of two different ethics committees described such measures as “passive monitoring”. As in Kenya, committees do not have the resources to carry out site visits (interviews, SA_10:2006 and SA_17:2006). The UNESCO declaration itself does not offer much by way of assistance, the only article that could possibly be taken to relate to post-approval monitoring stating, “Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.” [10].¹² Perhaps UNESCO’s ethics programme could help with training in these areas or encourage better funding, however. As highlighted by Singer and Benatar, capacity building is likely to advance research ethics further than are reformulations of bioethical principles. It may be, then, that the added value of the declaration will prove to lie more in UNESCO’s follow-up activities than in the document itself, at least in the medium term, the innovative sections on social responsibility and benefit sharing notwithstanding.

Conclusion

This paper has revealed something of a loose consensus, at least between UNESCO and those involved in bioethics in Kenya and South Africa, on two counts. With regard to universal principles, any attempt to implement them at national levels must be contextualised. Working out how to apply such principles in particular social and economic contexts is arguably as challenging as reaching agreement on how they should be constituted in the first place. With regard to the usefulness of the UNESCO declaration, the significance of its adoption as the first intergovernmental instrument on bioethics must be matched by action in the form of capacity building for it to be of added value in the realm of biomedical research ethics.

The scope of this paper has been limited to a primarily pragmatic analysis of how universal principles can be applied at national level. The paper has not commented on whether the value of the universality that UNESCO has aimed towards in terms of a foundation for humanity is compromised if these applications are very different. Deeper reflection on the nature of universality in this context would require the input of trained bioethicists and philosophers. This paper highlights, then, the need for a cross-disciplinary approach to the analysis of international bioethics instruments. The scope of the study that engendered this paper was necessarily limited by the time and resource constraints of doctoral research. Further research could explore whether the experiences of other African countries have been similar to those of Kenya and South Africa. Francophone and lusophone states, in

¹² Note that until the final draft of the declaration the article on risk assessment and management was more detailed. This was changed for “just a generality” because delegates were unable to agree on anything more substantial (interview with participant F_01:2005).

particular, may have quite different bioethical traditions and thus have had very different experiences in implementing bioethics policies.

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