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Research ethics policies and practices in health research institutions in sub-Saharan African countries: results of a questionnaire-based survey

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Abstract

Objective: To describe the state of research ethics policies and practices in health research institutions in sub-Saharan African countries.

Design: A structured questionnaire was used to solicit information on research ethics from health research institutions.

Setting: Forty-two sub-Saharan African countries.

Participants: Key informants from the health research institutions.

Main outcome measures: Existence of institutional ethics review policies and mechanisms.

Results: About half (51%) of respondent institutions reported having policies on research ethics and 58% had written policies requiring that researchers obtain informed consent of research participants. About one-third of respondent institutions (34%) had established ethics review committees, 42% required that studies went through ethics review committees and 46% had linkages with national or regional ethics organisations. Regarding operating procedures for ethics review committees, 53% had adopted standard operating procedures. Less than one-quarter of respondent institutions reported having policies in place to monitor ongoing research. Of the institutions that monitored ongoing research, 34% did an annual ethical review and 74% required a periodic written report. Only 36% provided any type of ethics training for staff, including those conducting health research and those who were not members of the ethics review committee.

Conclusions: There are substantial gaps in the capacity of health research institutions in the WHO African Region to undertake ethical review of studies before, during and after studies conducted. There is a need to strengthen such capacity in order to ensure the wellbeing of individuals enrolled in studies and that of communities that host these studies.

Keywords

biomedical research, ethics, Africa

Introduction

The increasing global proliferation of medical research involving multiple sites and international collaboration has placed a great responsibility on national governments to ensure that participants in health research are protected, and that their well-being and rights are safeguarded.

A number of key international documents such as the Nuremburg Code, the Declaration of Helsinki and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* issued by the Council for International Organizations of Medical Sciences[1] set out conditions for the ethical conduct of research involving human subjects and emphasise the concept of securing voluntary consent of human subjects to participating in research. In 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights to promote attention to research ethics in the national legislation, regulations and policies of its Member States. However, concerns remain as to whether research proposals are adequately subjected to proper ethical review by independent committees, and if appropriate structures and policies are in place to ensure that the safety and human rights of research participants are protected.

A study by Hyder et al.[2] of ethics review practices in developing countries in Africa, Asia and South America found that 44% of survey respondents reported that their studies had not undergone any type of review (technical, scientific or ethical) by the ministry of health in the developing country where the research was carried out. A regional study carried out by Kirigia et al.[3] in 2003, based on data from 28 countries, found that 36% countries (10/28) did not have a national research ethics committee.

Although many of these countries did have *ad hoc* mechanisms for ethical review, the absence of an official structure to facilitate systematic ethics review of research proposals can put research participants at risk of being exposed to unethical research.[4]

Previous research also indicates that the national guidelines and legislation that govern health research and contain specific provisions on the conduct of ethical research are also fragmented within the WHO African Region.[5,6] Although ethics review committees are the main mechanism through which the review of research proposals takes place and are critical to ethics governance, as Chima[4] argues in his paper on the regulation of biomedical research in Africa, it is ineffective to have research ethics committees without national or regional policies to guide them. Kirigia and Wambebe's[5] survey of national health research systems of 10 countries in the Region found that only one had a law related to health research.

Other studies highlight a number of common constraints limiting the capacity of ethics committees to undertake ethical review of research. Many of these constraints are related to infrastructural issues such as the lack of funding, inadequate facilities and administrative support, as well as limited training on research ethics for both committee members and researchers.[6,7] Milford et al.'s study[8] on research committees reviewing HIV vaccine trials in 15 African countries noted that 70% of research ethics committees included in the study reported moderate, limited or no capacity to review HIV vaccine trial protocols. All of the research ethics committees, except for one that reported excellent capacity, stated that the lack of training with relation to ethics and HIV vaccine trials was a challenge to effective review.

The lack of training in bioethics is also seen as a result of the limited attention paid to ethics in medical curricula in most countries in the Region.[9] Other problematic areas that may limit the effectiveness of ethics review processes are given below:

- A lack of standard operating procedures for research ethics committees, including mechanisms to deal with potential conflicts of interest
- Inadequate composition of committees by sex and professional background
- Limited or non-existent oversight mechanisms such as accreditation of research ethics committees and monitoring of research following ethics approval[6–8,10]

Limited information is also available on the existence of compensatory procedures for research participants who are adversely affected through their participation in health research trials.

Data collected from across the Region on ethics policies and practices are a critical component towards establishing baseline information and identifying regional and country needs for building capacity in conducting ethics review. This is also a key step towards strengthening attention to research ethics within countries so that they meet the standards of protecting participants in research as outlined in key international documents such as the Declaration of Helsinki and the Council for International Organizations of Medical Sciences guidelines.[1]

Studies looking at ethics in health research in the Region reflect concerns around whether clinical trials are subjected to proper ethical review.[8,11] Many countries in the Region are host to a large number of clinical trials, particularly in the areas of HIV/AIDS, tuberculosis, malaria and other infectious diseases, which involve the participation of thousands of volunteers, many of whom are vulnerable due to high levels of poverty, low education and low levels of empowerment.[12]

Consequently, research attention is increasingly being paid to research governance mechanisms such as national laws and standards, legislation, ethics review committees and monitoring mechanisms to assess whether these structures are not only in place but also able to provide an effective framework through which to monitor the ethical conduct of health research.

There is much less information on research ethics policies and practices in developing countries than in industrialised nations. However, there are a growing number of studies from African countries that focus on the structures being implemented to promote ethical review of health research, such as national research guidelines and standards, legislation that protects research participants, research ethics committees and other mechanisms. These studies are very helpful in identifying the various 'models' of ethics governance employed by countries, as well as the structural gaps that require attention by policymakers within ministries of health. For example, previous surveys involving a number of countries in the Region examined various components of national health research systems such as the existence of a national health policy, health research legislation, ethics review committees and other mechanisms.[3,5] The two surveys on national health research systems administered by the WHO Regional Office for Africa in 2007 complement these efforts and are the first time data have been collected from almost all 46[a] countries in the Region on ethics structures and processes at both national and institutional level.

This paper describes some of the main findings following a preliminary analysis of the data from a survey of 847 institutions contributing to health research from 42 countries in sub-Saharan Africa.

Methods

The methods followed to assess national health information systems are described more fully elsewhere[13] but are summarised briefly here.

In 2007, two surveys were administered by the Regional Office on health research systems in countries across the Region, making use of two research instruments. The first was the Health Research Systems Analysis institutional survey. For this project, we used the seventh module of the survey, which was devoted to research ethics. The institutions included in this survey were medical schools, universities, teaching or non-teaching hospitals, independent research institutions, non-governmental organisations, charities and governmental agencies.

The second survey was a simple supplementary questionnaire, which was sent directly to the ministry of health in 46 countries in the Region. The results of this survey are reported elsewhere.[14] The institutional survey dataset includes responses from up to 847 institutions in 42 countries in the Region (all except Algeria, Angola, Sierra Leone and South Africa).

For response to questions where institutions were asked to rank items in the questionnaire, we used weighting schemes to arrive at composite ranks. For example, where the response requires ranking an item on a 1 to 5 scale, a weight of five was given to the first rank, four to the second rank and so on, with the fifth rank getting the least weight of one. The average of these was used to derive a composite rank of items.

We used *IBM® SPSS® Statistics* Version 19 statistical software to analyse the data.

Results

A total of 847 health research institutions in 42 African countries were approached and up to 484 responded to specific questions. The characteristics of the institutions are shown in Table 1. Altogether 51% of respondent institutions reported having policies on research ethics and 58% had written policies requiring that researchers obtain the informed consent of research participants (Table 2).

Some 79% of respondent institutions reported having a written policy on ethical review for all research involving human subjects conducted within the institution by staff, and 85% reported that ethical review was required for all research involving human subjects conducted anywhere in which the institution's researchers participate (Table 2). A total of 31% of respondent institutions reported having a written policy requiring ethical review for research involving traditional or complementary medicine.

About one-third of respondent institutions (34%) had established ethics review committees, 42% required that studies went through ethics review committees and 46% had linkages with national or regional ethics organisations. With regard to the operating procedures for ethics review committees, 53% had adopted standard operating procedures.

Of the institutions that responded to the question of whether a scientific review committee was used in lieu of an ethical review committee, 31% responded that this was the case. A total of 51% reported combining ethical review with scientific review.

Less than one-quarter of institutions included in the institutional survey reported that there were policies in place to monitor ongoing research. Of the institutions that monitored ongoing research, 34% did an annual ethical review and 74% required a periodic written report.

Results from the institutional survey indicate that only 23% of respondent institutions provided ethics training for ethics review committees members. Of all respondent institutions, only 36% provided any type of ethics training for their staff (such as those conducting health research), other than those who were members of the ethics review committee.

Discussion

It is of concern that only about half of all respondent institutions have a formal policy requiring informed consent, as this is a fundamental component of ensuring ethical research practice and is stipulated in all research ethics documents, including the Council for International Organizations of Medical Sciences guidelines (Guideline 4).[1] Relatively few institutions have mechanisms for addressing conflict of interest and this could undermine the independence and objectivity of ethics review committees. The findings of these surveys also support previous research indicating that ethics committees experience a lack of institutional support. Similarly, data from the surveys are consistent with those in other studies in the Region, which indicates that training on research ethics is limited across both countries and institutions, both for members of research ethics committees and health researchers. However, it is encouraging that there is an increasing number of capacity-building initiatives on research ethics being developed in the Region. These include the Pan-African Bioethics Initiative, the South African Research Ethics Training Initiative, the International Research Ethics Network for Southern

Table 1. Characteristics of health research institutions in 42 sub-Saharan African countries, 2009.

Characteristics	Health research institutions No.*	%
Age of institution (years) ($n = 694$)		
<30	426	61
30–59	200	29
≥60	68	10
Sector the institution belong to ($n = 762$)		
Public	536	70
Private not-for-profit	132	17
Para-state	37	5
Private for-profit	26	3
Other	31	4
Type of institution ($n = 847$)		
Government agencies	257	30
Hospitals	154	18
Medical schools	108	13
Independent research institutions	106	13
Other research institutions (non-governmental organisations, charities)	105	12
Other universities	95	11
Other	22	3
Level at which institution functions ($n = 751$)		
National	483	64
Local	140	19
Regional	60	8
International	55	7
Other	13	2
Primary functions of institution ($n = 697$)		
Conduct research on health topics	374	54
Academic	373	54
Provide health services	338	48
Conduct research on non-health topics	122	18
Product development or distribution	74	11

(continued)

Table 1. Continued.

Characteristics	Health research institutions No.*	%
Other	128	18
National official or working language ($n=847$)		
French	445	53
English	285	34
Other	117	13.8
Institution has mandate on		
Research of all types	571	79 ($n=723$)
Health research	563	77 ($n=731$)

*Number of respondent health institutions, out of 847 surveyed.

Table 2. Institutional policies and practices related to ethical review of studies on human subjects in health research institutions in the WHO African Region, 2009.

Institutional policies and practices	Health research institutions No.*	%
Existence of institutional policies		
Institutional policy on ethics on research by staff	222	51 ($n=435$)
Institutional policies on research ethics exists	247	51 ($n=484$)
Institutional policies on informed consent exists	268	58 ($n=462$)
Institutional policy on ethics by collaborators	223	79 ($n=282$)
National or international guidelines referred to	246	85 ($n=289$)
Existence of ethics policies		
Requiring special review on particular subject matter	81	21 ($n=386$)
Research involving animals	67	22 ($n=305$)
Conflict of interest on ethics review committees	92	24 ($n=383$)
Traditional or complementary medicine	98	31 ($n=316$)
Establishing an ethics review committee	139	34 ($n=409$)
Selecting members of ethics review committee	144	35 ($n=411$)
Requiring ethics review committee	160	42 ($n=381$)
Linkages with national or regional ethics organisations	185	46 ($n=402$)
Ethical review committee procedures		
Established pursuant to formal governing rules	137	55 ($n=249$)

(continued)

Table 2. Continued.

Institutional policies and practices	Health research institutions No.*	%
Adopted standard operating procedures	135	53 ($n=255$)
Substance of disagreement recorded/communicated	93	42 ($n=221$)
Selection of the chair of the largest committee		
Appointed by senior official of the institution	73	39 ($n=187$)
Elected formally by review committee members	56	30 ($n=187$)
Nomination by peers	19	10 ($n=190$)
Elected by staff of the institution	10	5 ($n=200$)
Self-appointed	3	2 ($n=150$)
Self-volunteered	3	2 ($n=150$)
Other	21	11 ($n=191$)
Types of policies applied to monitor ongoing research		
Annual ethical review	58	34 ($n=171$)
Required periodic written report	125	74 ($n=169$)
Unannounced audit	36	21 ($n=171$)
Other	68	40 ($n=171$)
Institutional support for ethical review		
Provide training for members of committees	76	23 ($n=330$)
Provide training on ethics for its staff	110	36 ($n=306$)
Support staff to complete applications for review	104	36 ($n=289$)
Administrative support for ethical review	86	37 ($n=232$)
Training required for members	62	61 ($n=102$)
Scientific and ethical review		
Use the scientific review committee in lieu of an ethical review committee	88	31 ($n=284$)
Ethical review combined with scientific review	85	51 ($n=167$)

*Number of respondent institutions out of 847 surveyed.

Africa and Training and Resources in Research Ethics Evaluation for Africa. Workshops on research ethics have also been held in some countries,[9,15] but it is unclear from the data received in these surveys how widespread these are across countries.

Although there was a high response rate for both surveys, there were a number of gaps in the responses, with many countries and institutions not responding to all the questions. Therefore, it is difficult to know whether these countries and institutions did not have the policy or structure under investigation in place, or if they simply 'selectively' answered the questionnaire.

Conclusions

This study shows substantial gaps in the capacity of health research institutions in the Region to

undertake ethical review of studies before, during and after studies conducted. It also indicates the need to strengthen such capacity in order to ensure the well-being of individuals enrolled in studies and that of the communities that host these studies.

Declarations

Competing interests: None declared

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Ethical approval: Not required because the survey did not touch on ethical issues requiring individual consent, but rather was devoted to understand the broad ethical review process.

Guarantor: CZ

Contributorship: CZ wrote the paper, DK reviewed the paper, PEM, IS and WK assisted with the fieldwork, PSLD reviewed the initial design of the study and provided support and overall leadership.

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Note: [a]Subsequent to the research described in this paper, South Sudan joined the WHO African Region by World Health Assembly Resolution WHA66.21, bringing the total number of countries to 47.

References

1. Council for International Organizations of Medical Sciences. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: Council for International Organizations of Medical Sciences, 2002.
2. Hyder AA, Wali SA, Khan AN, Teoh NB, Kass NE and Dawson L. Ethical review of health research: a perspective from developing country researchers. *J Med Ethics* 2004; 30: 68–72.
3. Kirigia JM, Wambebe C and Baba-Moussa A. Status of national research bioethics committees in the WHO African region. *BMC Med Ethics* 2005; 6: 10.
4. Chima SC. Regulation of biomedical research in Africa. *BMJ* 2006; 332: 848–51.
5. Kirigia JM and Wambebe C. Status of national health research systems in ten countries of the WHO African Region. *BMC Health Serv Res* 2006; 6: 135.
6. Networking for Ethics on Biomedical Research in Africa. *Final Report: Networking for Ethics on Biomedical Research in Africa (NEBRA)*. Neuchatel: University of Neuchatel, 2006. See http://elearning.trree.org/file.php/1/NebraReport/FinalReport-2006-english.pdf (last checked 1 October 2013).
7. Kass NE, Hyder AA, Ajuwon A, et al. The structure and function of research ethics committees in Africa: a case study. *PLoS Med* 2007; 4: e3. doi: 10.1371/journal.pmed.0040003.
8. Milford C, Wassenaar D and Slack C. Resources and needs of research ethics committees in Africa: preparations for HIV vaccine trials. *IRB Ethics Human Res* 2006; 28: 1–9.
9. Ogundiran TO. Enhancing the African bioethics initiative. *BMC Med Educ* 2004; 4: 21.
10. Elsayed DE and Kass NE. Assessment of the ethical review process in Sudan. *Dev World Bioeth* 2007; 7: 143–8.
11. Moodley K and Myer L. Health Research Ethics Committees in South Africa 12 years into democracy. *BMC Med Ethics* 2007; 8: 1.
12. Kent DM, Mwamburi DM, Bennish ML, Kupelnick B and Ioannidis JP. Clinical trials in sub-Saharan Africa and established standards of care: a systematic review of HIV, tuberculosis, and malaria trials. *JAMA* 2004; 292: 237–42.
13. Kebede D, Zielinski C, Mbondji PE, Issa Sanou, Kouvividila W and Lusamba-Dikassa P-S. Surveying the knowledge landscape in sub-Saharan Africa: methodology. *J R Soc Med* 2014; 107(suppl. 1): 13–21.
14. Mbondji PE, Kebede D, Zielinski C, et al. Overview of national health research systems in sub-Saharan countries: results of a questionnaire-based survey. *J R Soc Med* 2014; 107(suppl. 1): 46–54.
15. Ajuwon AJ and Kass N. Outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university. *BMC Med Ethics* 2008; 9: 1.