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TRAINING NEEDS ASSESSMENT IN RESEARCH ETHICS EVALUATION AMONG RESEARCH ETHICS COMMITTEE MEMBERS IN THREE AFRICAN COUNTRIES: CAMEROON, MALI AND TANZANIA

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Keywords
Africa,
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training program,
curriculum

ABSTRACT

Background: As actors with the key responsibility for the protection of human research participants, Research Ethics Committees (RECs) need to be competent and well-resourced in order to fulfil their roles. Despite recent programs designed to strengthen RECs in Africa, much more needs to be accomplished before these committees can function optimally.

Objective: To assess training needs for biomedical research ethics evaluation among targeted countries.

Methods: Members of RECs operating in three targeted African countries were surveyed between August and November 2007. Before implementing the survey, ethical approvals were obtained from RECs in Switzerland, Cameroon, Mali and Tanzania. Data were collected using a semi-structured questionnaire in English and in French.

Results: A total of 74 respondents participated in the study. The participation rate was 68%. Seventy one percent of respondents reported having received some training in research ethics evaluation. This training was given by national institutions (31%) and international institutions (69%). Researchers and REC members were ranked as the top target audiences to be trained. Of 32 topics, the top five training priorities were: basic ethical principles, coverage of applicable laws and regulations, how to conduct ethics review, evaluating informed consent processes and the role of the REC.

Conclusion: Although the majority of REC members in the targeted African countries had received training in ethics, they expressed a need for additional training. The results of this survey have been used to design a training program in research ethics evaluation that meets this need.

BACKGROUND

The role of the Research Ethics Committee (REC) as an independent actor protecting human research participants is well described in key international guidelines.[1]

[1] World Medical Association (WMA). 2008. *Declaration of Helsinki.* Ferney-Voltaire, France: WMA. Available at: http://www.wma.net/e/policy/b3.htm [Accessed 20 Sept 2009]; Council for International Organizations of Medical Sciences (CIOMS). 2002. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: CIOMS. Available at: http://www.cioms.ch/frame_guidelines_nov_2002.htm [Accessed 15 Jun 2009]; International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). 1996. *Good Clinical Practice: Consolidated Guidelines.* Geneva: ICH. Available at: http://www.ich.org/LOB/media/MEDIA482.pdf [Accessed 15 Jun 2009]; World Health Organization (WHO). 2002. *Operational Guidelines for Ethics Committees that Review Biomedical Research.* Geneva: WHO.

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This role requires that the REC be properly constituted, provided with adequate resources, and has competent members and an appropriate regulatory framework.[2] In Africa the status of RECs varies from a country like South Africa, where most RECs are well organised and possess the minimum conditions to fulfil their roles, to others where there were no RECs as recently as 2003.[3] According to a study conducted by World Health Organization (WHO),[4] 15% of African countries did not require ethical approval before implementing research protocols. Another survey reported that 44% of respondents admitted that their studies were conducted in developing countries without any review from the Ministry of Health, and 25% of them conducted their studies without submitting them to ethics review.[5] In these circumstances the protection of research participants in African countries is clearly inadequate, resulting in exploitation, physical and psychological damage.[6]

Where RECs do exist in Africa, studies have shown that their composition often does not reflect an appropriate balance between different health professions and lay members, which raises questions about their competence and independence.[7] Other findings from these studies indicate that few African RECs have adequate operating funds; some members have not yet received any training in ethics evaluation; some RECs do not have standard operating procedures; and most do not have a mechanism to prevent conflicts of interest and preserve independence.[8] A survey conducted in 14 central and western African countries indicated that there were three categories of countries: those with no specific legislation on research participant protection, those with a draft of specific legislation and those with legislation that was not necessarily applied.[9] As a consequence, the competence and independence of RECs is vulnerable to pressures from sponsors, political authorities and biased committee members.

Numerous recommendations have been put forth to ameliorate this situation, for example: every country should set up an operational research ethics review system with appropriate policies and legislation to guide it, including mechanisms to guarantee the competence and transparency of RECs; RECs should be established in medical, nursing and public health schools; they should be appropriately structured and allocated adequate resources; their members should receive training in initial and ongoing research ethics evaluation.[10]

In partial response to these recommendations, stakeholders, both national and international, have individually and/or in partnership implemented many actions to enhance and promote biomedical ethics and, more specifically, research ethics in Africa. Examples include the creation of the Pan African Bioethics Initiative (PABIN) in June 2001 and later on its national chapters in some African countries with the aim of strengthening ethical awareness and discussion across the African continent;[11] the organization of multiple workshops to train researchers, members of RECs and others in various aspects of biomedical ethics;[12] the institutionalization of biomedical ethics teaching in some African universities;[13] the provision of online courses on research ethics evaluation;[14] and the rapidly increasing number of African countries that are drafting or have drafted research regulations.[15]

[2] WHO, ibid.

[3] M. Keymanthri & M. Landon. Health Research Ethics Committees in South Africa. 12 years into Democracy. *BMC Med Ethics* 2007; 8(1): 1–8; J.M. Kirigia, C. Wambebe & A. Baba-Moussa. Status of National Research Bioethics Committees in the WHO African Region. *BMC Med Ethics* 2005; 6(10): 1–7.

[4] Kirigia, ibid.

[5] A.A. Hyder et al. Ethical Review of Health Research: A Perspective from Developing Country Researchers. *J Med Ethics* 2004; 30: 68–72.

[6] E. Mills et al. Media Reporting of Tenofovir Trials in Cambodia and Cameroon. *BMC Int Health and Human Rights* 2005; 5(6): 1–7; J. Wise. Pfizer accused of testing new drug without ethical approval. *BMJ* 2001: 322(7280): 194.

[7] Keymanthri & Landon, *op. cit*. note 3; Kirigia et al. *op. cit*. note 3; N.E. Kass et al. The Structure and Function of Research Ethics Committees in Africa: A Case Study. *PLoS Med* 2007; 4(1): 1–6; C. Milford, D. Wassenaar & C. Slack. Resources and Needs of Research Ethics Committees in Africa: Preparations for HIV Vaccine Trials. *IRB: Ethics & Human Research* 2006; 28(2): 1–9.

[8] Kass et al., *op. cit*. note 7; Milford et al. *op. cit*. note 7.

[9] Training and Resources in Research Ethics Evaluation for Africa (TRREE). 2006. *Network for Ethics on Biomedical Research in Africa (NEBRA) Final Report*. Neuchatel, Switzerland: TRREE. Available at: www.trree.org/site [Accessed 20 Sept 2009].

[10] Kirigia et al., *op. cit*. note 4; Kass et al., *op. cit*. note 7; Milford et al., *op. cit*. note 7; S. Benatar. Research Ethics Committee in Africa: Capacity Building. *PLoS Med* 2007; 4(3): 135–136; N.E. Kass et al. Research Ethics Committees in Africa: Authors' Reply. *Plos Med* 2007; 4(3): 135–136.

[11] Pan African Bioethics Initiative (PABIN). 2001. Terms of Reference. Addis Ababa: PABIN. Available at: http://www.pabin.org/downloads/PABIN%20Constitution.pdf [Accessed 20 Sept 2009].

[12] African Malaria Network (AMANET), Workshop on Good Clinical Practice for African Researchers, Livingstone Hotel, Bagamoyo, 19–23 April 2004; Pan African Bioethics Initiative (PABIN),Workshop on Developing Ethical Review in Africa in Light of Contemporary Issues in the Biomedical Research Ethics, Africa Medical University, South Africa, 8–9 November 2001; Workshop on Ethics Review Committees in Africa, Lusaka, Zambia 29–31 January 2001; PABIN International Conference on Good Health Research Practices in Africa, Addis Ababa, Ethiopia, 28–30 April 2003; Fourth PABIN Conference on the Millennium Development Goals and the Ethics of Health Research in Africa, Yaoundé, Cameroon, 5–7 June, 2006; Seminar on the Ethical Review of Biomedical Research in African Countries, Arusha, Tanzania. 5 November 1999.

[13] Benatar, *op. cit*., note 10.

[14] African Malaria Network Trust (AMANET). Web-based Courses. Dar es Salaam: AMANET. Available at: http://webcourses.amanet-trust.org/ [Accessed 20 Sept 2009].

[15] TRREE, *op. cit*., note 9.

All this shows that biomedical ethics is progressing in Africa. But more still needs to be done in order to have a positive impact on research participant protection. The expansion of training programs is especially important because it has been demonstrated in several countries that training individuals can positively influence policy, attitudes and practice regarding research ethics.[16] In focusing on training in research ethics, there is a need to coordinate training programs, to agree on the objectives and content of training modules, and to coordinate workshops and online courses in order to reach all REC members. This coordination is one of the preconditions that may really help to improve the efficiency, relevance and effectiveness of training programs for research ethics evaluation. There is also a need to involve REC members when designing the training programs, thus taking into consideration their perceived training needs and ensuring their participation in the programs.

It is for this reason that the Training and Resources in Research Ethics Evaluation (TRREE) for Africa project was established to provide on-line and CD-ROM training modules and other resources in research ethics evaluation to a diversified audience involved in research with human participants in Africa, including research ethics committee members, researchers, students, institutional authorities, regulators and other political authorities, and any other potentially interested parties. The first phase of the project was to document training needs in three African countries, namely Cameroon, Mali and Tanzania. The choice of training modules to be developed was based on the results of this study.

TRREE is a consortium of partners from Africa (Mali, Cameroon, Tanzania, Senegal, Nigeria and South Africa) together with partners from the North (Canada, Germany and Switzerland). Besides providing on-line and CD-ROM training modules in research ethics and regulation it aims at developing a participatory website of resources to make research ethics and regulatory resources available (e-resources) (www.trree.org). TRREE is based on a dual objective of addressing the specific needs of the targeted audience, namely the members of research ethics committees, and of integrating each partner in every step of its development. One of TRREE's major objectives is to be bilingual, thus responding to the specific and, relative to Anglophone countries, under-funded needs of the French speaking Sub-Saharan region. It is supported by the European and Developing Countries Clinical Trials Partnership (EDCTP), as well as the Swiss National Science Foundation, the Swiss Academy of Medical Sciences, the Commission for Research Partnerships with Developing Countries and the Canadian Institutes of Health Research.

[16] Kass et al., *op. cit.* note 7; Benatar, *op. cit*. note 10.

METHOD

This was a cross sectional descriptive study that took place among REC members from Cameroon, Mali and Tanzania. A survey questionnaire was developed by the TRREE members, with representation from the three target countries as well as Nigeria, South Africa, Switzerland and Canada. The first draft of the questionnaire was piloted among the partners of TRREE and was then revised before distribution.

Ethical considerations

Risks and potential benefits of answering the questionnaire

Results of the Needs Assessment Questionnaire were to be used to design and develop bilingual training modules to address the expressed needs.

Respondents were asked for candid, professional opinions related to training needs in research ethics evaluation. Responding to the questionnaire was substantially similar to the professional activities of the respondents. Therefore, the risks were similar to those encountered in their everyday jobs and were considered to be minimal. However, there could be some risk that a respondent could be inadvertently identified and that a particular view could be attributed to that respondent. In order to minimize risks of inadvertent identification, the questionnaire was answered anonymously. To ensure the privacy of respondents, written consent to participate was not sought.

Informed consent process

All respondents were capable of giving a valid informed consent. Potential participants provided tacit consent by deciding to fill out and return the questionnaire.

Submitting the protocol to independent ethics review committee

The protocol was submitted to the inter-cantonal REC of Neuchatel, Fribourg and Jura (Switzerland) and to ethics review committees in Cameroon, Mali and Tanzania. This protocol was approved in March 2007 in Switzerland and by August 2007 in Cameroon, Mali and Tanzania.

Privacy of respondents and confidentiality of data

The questionnaire did not collect any personal identifiers. In addition, national coordinators kept secure or

Table I. Coverage of the Targeted Population by Questionnaire Distribution

Countries	*Estimated Number of R.E.C Members*	*Number of R.E.C members who received questionnaires*	*Proportion (P) of R.E.C members who received questionnaires (%)*	*Confidence limits around P (%)*
CAMEROON	48	36	75.0	[60.9; 89.3]
MALI	57	45	78.9	[68.1; 89.8]
TANZANIA	150	28	18.7	[4.2; 33.1]
Global	255	109	42.7	[30.2; 54.3]

destroyed all questionnaires once the data was extracted. Questionnaires were not accessed by anyone outside the research team. Publications resulting from this study will be based on aggregate data and will not allow the identification of respondents or any other information that could be prejudicial.

Protocol development and data collection

A literature search was conducted and was used to guide the development of the needs assessment protocol. The protocol was shared with the TRREE for Africa team via the web site for discussion and input. Later on, the original version of the questionnaire in English was translated in French and both versions were adopted. After approval of the protocol by the different RECs, the questionnaire was distributed to every accessible committee member between August and October 2007 in each targeted country. Participants were invited to self-administer the questionnaire and return it to the surveyors. The questionnaire collection ended in Cameroon and Mali in October 2007 and in November 2007 in Tanzania.

Data entry and analysis

Data from the three targeted countries were entered in a web database. It was later exported to Excel, Codepack and SAS versions 9.1. It was analysed by Excel version 5.0, Epi info version 3.2 and SAS version 9.1. The T student test, the Khi-2, was used as the statistical test. The alpha error above the value of 5% was not accepted. Data were analysed by calculating and comparing frequency, means and by ranking. Ranking of the perceived importance regarding training content, targeted groups and training objectives was discussed and decided.

When ranking the perceived priorities regarding training content, targeted groups and training objectives, the list of priorities chosen by each respondent was scored as follows: 3 for their first priority, 2 for the second priority and 1 for the third priority. The score for each item was then calculated, and the results were tabulated.

RESULTS

Demographic information

Participant characteristics

The coverage rate of the questionnaire distribution among REC members is indicated in Table I. Of the 109 REC members who received questionnaires, 74 returned them, making a global participation rate of 67.9%. By country the number of respondents was 25 in Cameroon (33.8% of respondents; response rate of 69.4%), 29 in Mali (39.2% of respondents; response rate of 64.4%) and 20 in Tanzania (27.0% of respondents; response rate of 71.5%). Primary disciplines of respondents were Medicine (44.0%), Basic Sciences (28.0%), Pharmacy (6.0%), Social Sciences (4.0%) and others (18.0%). 47.6% of respondents were serving as members of institutional RECs, 30.2% as members of the national REC, 3.3% as members of both and 19.2% as members of local RECs. 76.3% of respondents were ordinary REC members, whereas 23.7% were holding administrative positions.

Training on research ethics evaluation

Of all the respondents, 70.8% had received some sort of training on research ethics evaluation and 29.2% had not. In detail, 56.5%, 18.5% and 15.0% respectively from Cameroon, Mali, and Tanzania reported that they had not yet received any training on research ethics evaluation. Reported sources of training are presented in Table II. Types of training were workshops (64.6%), online courses (16.9%), fellowships (7.7%) and others (11.4%). Table III indicates which guidelines respondents reported as grounding research ethics evaluation.

Regarding difficulties encountered in applying regulations, 52.7% of respondents reported that they have no difficulty whereas 47.3% were having some difficulties. Table IV indicates the difficulties faced by respondents.

Training content

The ranking of scores attributed to the perceived importance and priority of training topics are presented in

Table II. Sources of Training on Research Ethics Evaluation Reported by Respondents

N°	*Sources*	*Cameroon*	*Mali*	*Tanzania*	***Total***	*%*
1	AMANET	2	0	7	**9**	**16.3**
2	NIH	1	7	0	**8**	**14.5**
3	National Institutions	5	11	1	**17**	**30.9**
4	Other external Institutions	5	2	14	**21**	**38.2**
	Total	**13**	**20**	**22**	**55**	**100.0**

Table III. Proportion of Respondents using each Research Ethics Guidance Document as a Tool to Evaluate Research Protocols

	Number				
Regulatory	*Cameroon*	*Mali*	*Tanzania*	*Total*	*%*
Declaration of Helsinki	14	12	3	29	22.5
CIOMS Guidelines	10	5	1	16	12.4
The Nuremberg Code	2	6	0	8	6.2
The Belmont Report	0	7	0	7	5.4
Guidelines of the Medical Research Coordinating Committee, Tanzania	0	0	6	6	4.7
National constitutions	1	4	0	5	3.9
Universal Human Rights Declaration	2	5	0	7	5.4
"Declaration droit de malade"	4	2	0	6	4.7
Others	18	21	6	45	34.9
Total	51	62	16	129	100.0

Table IV. Types of Difficulties faced by Respondents in Applying Guidance Document

Types of difficulties	*Cameroon*	*Mali*	*Tanzania*	*Total*	*%*
Adaptation to local context	3	8	1	12	42.9
Interpretation difficulties	1	1	0	2	7.1
Difficulties applying to particular context	1	4	2	7	25.0
Other difficulties	3	1	0	4	14.3
Understanding difficulties	1	0	0	1	3.6
Working with some research teams	0	0	1	1	3.6
Discrepancy with local regulations	0	0	1	1	3.6
Total	9	14	5	28	100.0

appendix 1 and appendix 2. This ranking shows that among training topics identified as important, the top five were: basic ethical principles: what they are, what they mean and how they can be interpreted; coverage of applicable laws and regulations; how to conduct ethics review; evaluating informed consent processes; and the role of the REC: its authority, mandate and responsibilities.

Target audience or potential users

With regard to the perceived importance of targeted groups for training, the top five groups, ranked by decreasing order according to attributed scores, were: researchers, members of research ethics committees, broader research teams (including nurses, coordinators etc.), authorities of research institutions, and postgraduate students expecting to conduct research with humans. Appendix 3 and appendix 4, respectively, present the scores and ranking related to the importance of the targeted audiences to be trained and the ranking and scores related to the priority of these audiences.

Training objectives

According to the respondents, the top five priorities for the training objectives were: to be able to identify ethical principles relevant to the ethical review or the conduct of research involving humans; to be able to identify relevant international, regional and national regulatory texts; to understand the importance of ethical evaluation in the promotion of the highest ethical standards and the protection of human subjects; to understand the role and mandate of research ethics committees; and to understand the key roles and responsibilities of members of RECs. Appendix 5 and appendix 6, respectively, present the scores and ranking related to the importance of the

training objectives and the scores and ranking related to the priority of training objectives.

DISCUSSION

Characteristics of study population

The representativeness of each of the three targeted countries was not statistically different considering the overlapping confidence limits calculated on proportions of respondents from each of the targeted countries (Cameroon (33.8 ± 10.6)%, Mali (39.2 ± 11.3)%, Tanzania (27.9 ± 11.6)%). The primary disciplines of respondents were Medicine (44.0%), Basic Sciences (28.0%), Pharmacy (6.0%), Social Sciences (4.0%) and others (18.0%). There were neither nurses nor lay members among respondents. This respondent representation was from those who were reached by surveyors, answered and returned their questionnaires; so they should not be considered as representative of RECs' composition. Only part of the total targeted population was reached; some of those who were reached did not respond; and the data collected did not deal with the RECs' composition. Thus the respondents' primary discipline composition could not be correlated to what is recommended in Guideline 2 of the CIOMS Guidelines[17] concerning RECs' composition.

The CIOMS Guidelines note that ethics review committees may function at the institutional, local, regional or national level and in some cases at the international level. The results of this study reveal that RECs in the three targeted countries were functioning at national and institutional levels. Surveyors did not confirm the existence of local RECs of which 19.3% of respondents claimed to be members.

Guidance on the ethics of medical research

According to the results of the present study, in each of the three targeted countries there are diverse guidelines for grounding research ethics evaluation. Among them, the Declaration of Helsinki was the most frequently named (22.5%). Only respondents from Tanzania reported using national guidelines (Guidelines of the Medical Research Coordinating Committee, Tanzania). In using these guidelines, respondents reported facing varied difficulties among which the most frequent was adaptation to the local context (42.9% – see Table IV). This information gives a global picture on which guidelines respondents would like to receive training. The use of the Declaration of Helsinki to ground research ethics and the absence and the neglect of national guidelines while evaluating research protocols, pose problems for research participant protection in developing countries. The Declaration of Helsinki is criticised for not fully protecting local populations because it does not have the force of law, it lacks procedures for enforcement and it does not provide sufficient guidance on the role of local research ethics committees, informed consent procedures, standard of care and compensation following injuries arising from research project implementation.[18] The reported problem of adaptation of guidelines to the local context could be partly explained by the fact that very few respondents indicated using national guidelines when evaluating research protocols. Furthermore, some researchers come from countries in which national guidelines are legally binding, obliging them to follow these guidelines no matter where the research is conducted.[19]

Training received by respondents

Many respondents were not trained in research ethics evaluation. The proportion of untrained respondents was respectively 56.5 ± 2% in Cameroon, 18.5 ± 12.2% in Mali and 15.0 ± 11.8% in Tanzania. Some studies previously conducted in Africa describe similar situations.[20] From these results we can presume that there is a significant proportion of REC members that were not trained. This proportion could be higher where the duration of REC membership may be brief. On the other hand, data were not collected on what kind of training was received by those who said they have been trained, if they were satisfied and the impact of training on their competence in evaluating research protocols. It is also questionable whether the motivation of respondents and the contents, objectives, design and implementation of training received by 70.8% of respondents were objectively relevant, appropriate and adequate to produce a significant impact on their knowledge, attitude and practice that could improve their competence in research ethics evaluation.

There was great variation in the duration of individual training. Some reported having received just a few training hours; others have participated in numerous training programs of various types (mostly workshops); while still others have diploma-level training on research ethics evaluation.

Training received by respondents was diverse and from multiple sources but workshops (64.6%) and online courses (16.9%) were the two most frequently reported methods. 69.0% were provided by international

[17] CIOMS, *op. cit*. note 1.

[18] C.C. Sylvester. Regulation of Biomedical Research in Africa. *BMJ* 2006; 332: 884–851.

[19] A. Zumla & A. Costello. Ethics of Healthcare Research in Developing Countries. *J R Soc Med* 2002; 95(6): 275–276.

[20] Keymanthri & Landon, *op. cit*. note 3; Hyder et al., *op. cit*. note 5, p. 1.

institutions (NIH, AMANET and others) and 31.0% by national institutions. Having workshops as the main type of training, and receiving training mostly from international institutions is questionable regarding the relevance of the training for the competence of trainees in research ethics evaluation for research in Africa. This is because workshops are limited to a few days of activities; the number of participants is necessarily limited and they usually lack funding and the motivation to deliver the training to their local colleagues. Moreover, the interests and motives of the sponsoring agencies and local conference organizers determine the place, date, duration and number of participants in the workshops.[21] These factors influence the aims, contents, selection of facilitators, participants and objectives of the workshops.

Training content and objectives

As noted previously, the top training topics are basic ethical principles: what they are, what they mean and how they can be interpreted; coverage of applicable laws and regulations; how to conduct ethics review; the role of the REC: its authority, mandate and responsibilities. No data were collected that could help to interpret this choice but it can be partly explained as follows: training respondents in basic ethical principles will provide an analytical structure for solving ethical problems resulting from research on human beings.[22] Those principles include; respect for persons, which requires respecting people's autonomy and protecting people with diminished autonomy; beneficence, which requires minimizing harms and maximizing benefits; and justice, which requires fairness in the distribution of benefits and burdens of research. In the African context, the process of ethics evaluation must take into consideration these three principles and their adaptation to socioeconomic and cultural realities. This implies for example: understanding how to evaluate the involvement of spouses and/or communities in the individual decision making process; minimising individual participants' risks; collaborating for greater equity; and sharing the burdens and benefits of research.

'Coverage of applicable laws and regulations' is a topic that needs to be mastered by REC members in their respective countries. This is because during research ethics evaluation, the rights and protection of research participants have to be based on national laws and regulations. This is true even in some African countries where specific laws and regulations on research ethics evaluation are still to come.[23] In these countries international regulations can be used, along with laws that are not specific to research ethics evaluation, for example, the national constitution.

Training on 'how to conduct an ethics review' and 'the role of the REC' was seen to be essential for the protection of research participants and the improvement of the ethical and scientific quality of the protocols to be evaluated.

The high ranking of 'evaluating informed consent processes' and 'informed consent with vulnerable populations' indicates that respondents are aware of the obligation of respecting community and individual autonomy and the need to help protect their interests. Respect for informed consent in Africa is problematic. In some countries only 49.5% of researchers obtain informed consent,[24] and during a vaccine trial 90%, 93%, and 74% of three participant cohorts did not understand the withdrawal criterion, the possibility of side effects and the fact that they were enrolled in an investigation as opposed to receiving therapy.[25]

Target audience to be trained

According to the respondents, the top five target audiences to be trained were researchers, members of research ethics committees, broader research teams (including nurses, coordinators, etc.), authorities of research institutions and postgraduate students expecting to conduct research with humans. No data were collected to explain this ranking. It can be explained partly by the recommendations in paragraphs 10 and 15 of the Declaration of Helsinki,[26] stating that:

> Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. . . . and;
>
> . . . . committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

[21] AMANET, *op. cit*. note 14.

[22] Department of Health, Eductaion and Welfare (DHEW). 1979.*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Bethseda, MD: DHEW. Available at: http://ohsr.od.nih.gov/guidelines/belmont.html [Accessed 20 Sept 2009].

[23] TRREE, *op. cit.* note 9.

[24] D.E.M. Elsayed & N.E. Kass. Attitude of Researchers on obtaining Informed Consent from Study Subjects involved in Health Research. *Sudanese Journal of Public Health* 2007; 2(2): 95–102.

[25] M.T. Krosin et al. Problems in Comprehension of Informed Consent in Rural and Peri-urban Mali, West Africa. *Clin Trials* 2006; 3(3): 306–313.

[26] WMA, *op. cit*. note 1.

Limitations of the study

An important weakness of this study was that the needs assessment questionnaire was distributed only to 42.8% of the estimated members of RECs from the targeted countries and that about 32.1% of those who received the questionnaire did not respond. The overlapping of the confidence limit among the coverage rate of questionnaire distribution globally, in Cameroon and Mali, indicated that the observed difference among the three rates was not significant. The absence of overlap between these rates and that from Tanzania indicates that the observed coverage rate was significantly smaller in that country. According to the surveyors' reports, the fact that all REC members did not receive questionnaires could partly be explained by the fact that not all were available or accessible during the study period. The fact that the Tanzania coverage rate was significantly smaller than the global rate and that of the other countries was due to the fact that membership in Tanzania RECs was very dynamic. We did not collect information on the characteristics of those who did not return the questionnaire or assess why some of those who received the questionnaire did not return it. This information could have been useful for the interpretation of the results. We cannot be certain how far those who responded understood the questionnaire (questionnaires were self-administered) or were motivated to recall and give full and exact answers. In these situations we cannot totally exclude the possibility of selection and information bias. It would have been preferable to have better validity and reliability by distributing the questionnaire to all REC members from the three targeted countries and have a 100% response rate. But we have to respect the position of those who did not return their questionnaire.

CONCLUSION

The general objective of this study was to document training needs in three African countries, namely Cameroon, Mali and Tanzania. In spite of its limits, this needs assessment study clearly achieved this objective. The study documented that up to 70.8% of respondents had received training on research ethics evaluation. It also documented that the type of training was mostly workshops and mainly provided by various international organizations. These sources and types of training have been regarded as having serious limitations for producing real impacts on improving research ethics evaluation. The majority of respondents reported grounding research ethics evaluation mainly on international regulations, especially the Declaration of Helsinki. They reported facing various difficulties using these guidelines, the predominant difficulty being adaptation to the local context. Among the needs identified were the development of laws and guidelines adapted to the local context. Respondents expressed their views on priorities for training in research ethics evaluation and the targeted audiences to be trained.

Having analysed the results of the needs assessment, TRREE for Africa has developed three on-line and CD-ROM training modules and other resources in research ethics evaluation for a diversified audience involved in research with human participants in Africa. Module 1 is an introduction to research ethics; module 2 deals with the roles and responsibilities of RECs and; module 3, which is specific to each country, provides references to applicable laws, regulations and guidelines. Subject to funding, additional modules will be developed in the coming years on the other topics identified as priorities in the needs assessment.

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Biography

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Appendix 1: Ranking according to principal component scores associated to respondents' perception of importance of proposed training topics

Ranking by decreasing order of importance	*N°*	*Principal component scores*	*Training topics*
1st	b	3.98100	Basic ethical principles: what they are, what they mean and how they can be interpreted.
2	n	1.97998	Role of REC: authority, mandate and responsibilities.
3	y	1.88602	Informed consent with vulnerable populations.
4	o	1.60068	How to conduct ethics review: What is part of ethics review, deliberation & decision-making process
5	a	1.57203	Coverage of applicable laws and regulations
6	w	1.38077	Evaluating informed consent processes.
7	d	1.08699	Relevance of research to local health needs
8	q	0.85693	Independence of ethical review.
9	e	0.66429	Evaluation of scientific validity and value.
10	aa	0.44366	Protection of privacy and confidentiality.
11	cc	0.40573	Responsibilities of researchers.
12	j	0.38230	Evaluation of risk-benefit ratios.
13	c	–0.02985	Ensuring adequate community participation in research.
14	s	–0.03915	Continuing ethics review: adverse events, modifications to the protocol.
15	m	–0.08390	Compensation for damages.
16	l	–0.28879	Harm monitoring.
17	p	–0.34209	Relationship of ethical review to scientific review.
18	h	–0.34284	Relevant researcher qualifications.
19	ff	–0.53447	Ethical issues in research with students
20	ee	–0.61951	Scientific integrity.
21	x	–0.68867	Incentives, undue incentives and coercion.
22	i	–0.81920	Ensuring appropriate and fair selection of research participants.
23	t	–0.82131	Conflicts of interest of members of ethics committees.
24	z	–0.82280	Responsibilities to participants after research is completed
25	bb	–0.89197	Managing conflicts of interests of researchers.
26	g	–0.93770	What types of research require ethics evaluation
27	r	–0.98964	Record keeping.
28	dd	–1.36895	Publication and authorship issues.
29	u	–1.40316	Ethical requirements from other countries.
30	k	–1.51782	Standard of care.
31	f	–1.72285	Evaluating qualitative research.
32	v	–1.97571	Conflict resolution/negotiation skills.

Appendix 2: Ranking according to sums of scores associated to respondents' perception of priority of proposed training topics on research ethics

Ranking by decreasing order of priority	*N°*	*Sums of scores*	*Training topics*
1	b	101	Basic ethical principles: what they are, what they mean and how they can be interpreted
2	a	52	Coverage of applicable laws and regulations
3	o	46	How to conduct ethics review: What is part of ethics review, deliberation & decision-making process
4	w	24	Evaluating informed consent processes
5	n	21	Role of REC: authority, mandate and responsibilities
6	e	14	Evaluation of scientific validity and value
7	d	12	Relevance of research to local health needs
8	s	10	Continuing ethics review: adverse events, modifications to the protocol.
9	y	10	Informed consent with vulnerable populations
10	j	9	Evaluation of risk-benefit ratios
11	m	9	Compensation for damages
12	cc	9	Responsibilities of researchers
13	l	6	Harm monitoring
14	g	5	What types of research require ethics evaluation
15	i	5	Ensuring appropriate and fair selection of research participants
16	k	5	Standard of care
17	q	5	Independence of ethical review
18	f	4	Evaluating qualitative research
19	p	4	Relationship of ethical review to scientific review
20	z	4	Responsibilities to participants after research is completed

Appendix 2: Continued

Ranking by decreasing order of priority	*N°*	*Sums of scores*	*Training topics*
21	bb	4	Managing conflicts of interests of researchers
22	h	3	Relevant researcher qualifications
23	t	2	Conflicts of interest of members of ethics committees
24	v	2	Conflict resolution/negotiation skills
25	aa	2	Protection of privacy and confidentiality
26	dd	2	Publication and authorship issues
27	c	1	Ensuring adequate community participation in research
28	u	1	Ethical requirements from other countries
29	r	0	Record keeping
30	x	0	Incentives, undue incentives and coercion
31	ee	0	Scientific integrity
32	ff	0	Ethical issues in research with students

Appendix 3: Ranking according to principal components scores associated to respondents' perception of importance of targeted audience to be trained

Ranking by decreasing order of importance	*N°*	*Principal components*	*Groups to be trained*
1	a	1.82032	Researchers
2	d	1.58437	Authorities of research institutions
3	i	0.47600	Postgraduate students expected to conduct research with humans.
4	c	–0.15312	Members of research ethics committees
5	b	–0.16696	Broader research teams (including nurses, coordinators etc.)
6	h	–0.42532	Sponsors
7	f	–0.63068	Research participants
8	g	–1.11494	Media
9	e	–1.38968	Public or government authorities

Appendix 4: Ranking according to sums of scores associated to respondents' perception of priority of proposed targeted audience

Ranking by decreasing order of importance	*N°*	*Score*	*Groups perceived to be trained*
1	a	106	Researchers
2	c	88	Members of research ethics committees
3	b	23	Broader research teams (including nurses, coordinators etc.)
4	d	8	Authorities of research institutions
5	i	6	Postgraduate students expected to conduct research with humans
6	j	2	Other
7	g	1	Media
8	h	1	Sponsors
9	e	0	Public or government authorities
10	f	0	Research participants public

Appendix 5: Ranking according to principal components scores associated to respondents' perception of importance of proposed training objectives

Rank	*N°*	*Primary component*	*Training objectives*
1	b	2.51957	be able to identify relevant International, regional and national regulatory texts.
2	a	2.34712	be able to identify ethical principles relevant to the ethical review or the conduct of research involving humans
3	e	1.35665	understand the role and mandate of research ethics committees
4	l	0.01668	be able to lead a critical analysis of ethical principles learned in the preceding
5	f	–0.02908	understand the key roles and responsibilities of members of RECs
6	c	–0.06518	understand the importance of ethical evaluation in the promotion of the highest ethical standards and the protection of human subjects
7	g	–0.18679	be able to conduct an ethical evaluation based on the application of ethical principles and relevant normative documents (scientific validity and value, risk-potential benefit assessment, fair selection of subjects, consent process, etc.)
8	d	–0.52708	be able to identify regulatory documents that apply to a given study
9	m	–0.66358	have a better understanding of how to avoid or manage conflicts of interests
10	h	–0.81196	be able to identify research ethics principles and understand, or be reminded of, how they apply to the conduct of research involving human participants
11	j	–1.08052	understand the national regulatory framework of particular countries (African, European, etc.)
12	k	–1.0821	understand in greater detail, and be better prepared to address issues raised by pressing ethical issues
13	i	–1.79373	be able to identify relevant international guidelines and legal provisions and understand, or be reminded of, how they apply to the conduct of research involving humans

Appendix 6: Ranking according to sums of scores associated to respondents' perception of priority of training objectives

Ranking by decreasing order of importance	*N°*	*Score*	*Training objectives*
1	a	103	be able to identify ethical principles relevant to the ethical review or the conduct of research involving humans
2	b	41	be able to identify relevant International, regional and national regulatory texts
3	c	37	understand the importance of ethical evaluation in the promotion of the highest ethical standards and the protection of human subjects
4	e	30	understand the role and mandate of research ethics committees
5	f	28	understand the key roles and responsibilities of members of RECs
6	g	19	be able to conduct an ethical evaluation based on the application of ethical principles and relevant normative documents (scientific validity and value, risk-potential benefit assessment, fair selection of subjects, consent process, etc.)
7	h	19	be able to identify research ethics principles and understand, or be reminded of, how they apply to the conduct of research involving human participants
8	d	13	be able to identify regulatory documents that apply to a given study
9	k	9	understand in greater detail, and be better prepared to address issues raised by pressing ethical issues
10	j	7	understand the national regulatory framework of particular countries (African, European, etc.)
11	i	5	be able to identify relevant international guidelines and legal provisions and understand, or be reminded of, how they apply to the conduct of research involving humans
12	l	4	be able to lead a critical analysis of ethical principles learned in the preceding modules as they apply to a precise issue.
13	m	1	have a better understanding of how to avoid or manage conflicts of interests