Role of E-Learning in Teaching Health Research Ethics and Good Clinical Practice in Africa and Beyond

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Introduction

Despite the recent increase in health research involving humans on the African continent, the level of knowledge in health research ethics (HRE) and good clinical practice (GCP) is arguably still very poor in Africa. Conventional training opportunities in HRE or GCP are not widely accessible to the majority of people in Africa. Most of the currently available e-learning courses are clearly designed for either different contexts or from different perspectives, which, to some extent, reduces their relevance to research conducted in African settings. Although short-term, face-to-face workshops as well as long-term training play a significant role in training researchers or ethics review committee members in HRE and GCP, there is need to cater to candidates who may not be able to leave their work stations. E-learning is a convenient mode of teaching that suits candidates in many different circumstances and thus complements other forms of training.

A package of e-learning courses was developed and made freely available to any interested candidates in Africa or elsewhere. The package consisted of a basic HRE course in English and French, an advanced HRE course in English, and a GCP course in English. More than 2,500 candidates have enrolled, with more than 1,000 having successfully completed and been awarded certificates for the respective courses. This article presents trends and descriptive statistics of collected data and discusses future prospects.

International guidelines such as the Declaration of Helsinki[1] and the Council for International Organizations of Medical Sciences[2] stipulate that review and approval of proposed research projects by independent ethics review committees (ERCs) is a prerequisite for any research involving humans. Indeed most African countries have now developed national ethical guidelines and regulations that make it mandatory for research projects to be reviewed and approved before implementation. It is therefore imperative that ERCs that review and approve studies be well equipped to be able to judge whether or not the proposed research is ethical. Because most ERCs are composed of members who have other full-time duties besides serving on the committees, web-based HRE courses could prove an important tool for them.

On the other hand, it is increasingly accepted that trials involving human

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participants must be conducted to an international ethical and scientific standard that guarantees credibility of the results. Indeed, there is consensus that the International Conference on Harmonization (ICH) GCP guidance, as described in its E-6 guidelines,[3] serves as a unified standard with which investigators and ERC members need to be well versed. Training in GCP is also critical for national regulatory authorities in order to effectively and efficiently review and oversee clinical trials.

The recent increase in health research, compounded by the increasing complexity of the research, has led to concerns about the effectiveness of ethical review systems in the United States.[4,5] Burman and colleagues[6] attributed this crisis in the operations of ethics committees to the drastic increase in their workload, a main factor of which is the unprecedented upsurge in multicenter clinical trials. The impact of such dynamics of health research in Africa, a resource-constrained continent, is bound to be worse than in developed countries like the United States. For instance, between 1987 and 2003, a total of 77 trials on HIV/AIDS were conducted in 18 sub-Saharan African countries, which translates to an average of about 4 trials per country.[7] Although this number of HIV/AIDS trials may not be commensurate with the HIV/AIDS disease burden in the sub-Saharan region, the negative overall impact of the increased workload and complexity caused by such studies on the capability of the ethical review systems in Africa to effectively review and monitor the studies is a cause for concern.

In some worst-case scenarios, the studies proceed without any ethical approval, let alone oversight, in the developing countries where participants are recruited. A survey of 203 researchers in African countries showed that 44 percent of the respondents conducted their studies without any ethical review at all.[8] In their study, Hyder and colleagues[9] reported 67 percent of researchers as being of the view that developing countries depended on American ethical regulations, yet 83 percent considered the American regulations to be insensitive to local cultural settings.

However, the importance of health research ethics as part and parcel of health research continues to be appreciated, if the numbers of ERCs that are being set up and the numbers of players involved in efforts to provide short-term informal GCP training are anything to go by. Although there are no empirical data that specifically give the total number of ERCs for individual African countries or for the continent as a whole, various surveys conducted have shown that there is a gradual increase in the number of ERCs across Africa.[10,11,12] One survey conducted previously showed that many institutions did not have functioning ERCs, despite the fact that they were approving many health research projects involving humans.[13] Presently, various players are involved in capacity building in HRE in Africa. Although these capacity-building efforts have included web-based courses in addition to face-to-face training workshops and long-term programs, we are not aware of web-based courses that were developed from an African perspective.

There is a dearth of formal training opportunities for research ethics and GCP outside of large international collaborative research study settings in Africa. Research ethics coverage in most university curricula is generally very poor. Questions regarding GCP, on the other hand, are only raised in the context of product-development-type trials. Indeed, opportunities for training in these fields remain few, and where they do exist, the trend is to be restrictive through competitive sponsorship schemes or inevitably prohibitive by

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cost. Despite the increase in biomedical research activities in Africa, research ethics as a discipline has not received a commensurate increase in attention. On the continent, most ethics committees still fall short of recommended international standards. Until recently, most research institutions considered ethics as a peripheral activity created to pacify concerned stakeholders in order to proceed with their ''scientific work.'' Other reasons as to why these standards remain low include poorly supported committees, lack of legal frameworks for establishing the committees, lack of operational budgets, lack of career incentives for young Africans in the field, and finally and possibly most importantly, lack of adequate understanding of what research ethics is all about.[14]

It is thus not surprising that in most African countries, ethics committees reviewing health research are typically constituted of part-time volunteers who seldom have opportunities to receive formal training either on joining the committees or thereafter. For instance, all the 365 ERC members of the 31 ERCs that were surveyed by Nyika and colleagues in 2007[15] were volunteers who had other full-time core duties that did not include participation in the ERC work. Ezekiel and colleagues[16] point out that for research to be ethical, independent review is one of seven critical elements; this brings up societal assurance that the risks imposed by clinical research are checked and that some segments of society will not benefit from abuse of others.[17] The competence and independence of the ethical review that has been and continues to be applied to a myriad of study designs in Africa today can thus be questioned. Indeed most ethics committees are made up of poorly motivated, part-time volunteers who may not be able to make sound judgments on the protocols they are called on to review, because they lack any ethics training whatsoever.

In order to improve the ethical review system within Africa, flexible opportunities for training in HRE or GCP have to be created without compromising the quality of the training. Recently, there has been an increase in the use of computers and access to the internet in Africa. Indeed most institutions now at least acknowledge the need to have offices and basic furniture dedicated to their ethics review systems. These developments present us with a unique opportunity to make ethics education available for individuals who may not have the opportunity for full-time study but who can spare a few hours for Internet access every week.

The African Malaria Network Trust (AMANET) set out to create a system of delivering HRE and GCP education to reach a wider African audience. With initial financial support from the European and Developing Countries Clinical Trials Partnership (EDCTP), a phased approach was taken to develop web-based courses from an African perspective.

Methods

Overall Approach

A faculty of individuals known to be providing ethics training or to be actively practicing research ethics within Africa was assembled. Individuals with expertise in the field of information technology and e-learning were incorporated as critical support members. The development of the web courses was staggered, starting with a basic HRE course in English, followed by translation of the basic course into French. Thereafter, an advanced HRE course and GCP courses were developed in English. Faculty review meetings were

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organized to evaluate the training materials, identify gaps, and standardize the presentation format. The learning objectives for each module were agreed on, and multiple-choice-type questions were set up for each module in order to enhance comprehension.

Development of Course Curricula

The curricula of the courses were developed in such a way that the basic HRE course formed a foundation for the advanced HRE course, whereas the GCP course contained introductory modules as well as modules tackling special topics. The introductory modules covered historical background as well as fundamental principles and important terminologies. The advanced HRE course tackled topical and practical issues or challenges that are encountered by researchers in the field. Deliberate efforts were made to address topical issues or challenges from an African perspective with real-life examples wherever possible, thus making the course relevant to research conducted in developing country settings. The basic HRE course was developed with five compulsory modules, which must be completed and passed for a student to receive a certificate, plus an additional five modules that are optional (Table 1). The French version of the basic course was developed with similar modules and requirements as the English version. The advanced HRE course was composed of seven compulsory modules (Table 2), whereas the GCP course had ten compulsory modules (Table 3). For each module, the training material was in the form of PowerPoint slides as well as lecture notes. Additional relevant literature was included in the modules for in-depth reading. Each module contained a test that has to be taken on completion of the module.

Web Program Development and IT Support

In parallel, the IT specialists were focused on finding the appropriate platform for carrying the course on the web. Appropriate software was sourced from Blackboard learning systems®, the Netherlands. Based on the Blackboard hardware specifications, a suitable server was procured. Key to the selection of web hosts and the delivery platform was consideration of guaranteed Internet security by the provider, capacity to handle at least 1,000 users simultaneously at good speed, automatic and user-friendly self-registration, and availability of announcements and discussion forums. The course materials were fitted into the Blackboard system and uploaded on the website, but with restricted access. The web platform used enables automatic marking of the tests and randomly reshuffles the order of the questions to minimize the chances of students sharing answers that are in a specific fixed sequence. Once enrolled, the student had to complete the course within 100 days; otherwise the system dropped them out. The setup further required a dedicated IT officer to provide support for resolving any problems participants may encounter when using the system.

Validation Workshop and Pilot Testing

The courses were validated by representatives of the target audience, who took the modules and provided feedback. Junior- to middle-level African researchers and members of ethics committees averaging 25 per class convened for a weeklong face-to-face pilot process. They worked through the course modules online, providing both positive and negative feedback on the course content, presentation of materials, time required for each module, and

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Table 1. Overview of the Contents of the Basic HRE Course Modules

Module*	Title	Brief synopsis of contents
1	Evolution of Biomedical Research Ethics	Gives a historical perspective of HRE and a background understanding of ethics. Part I goes through the what, who, and why of health research ethics and provides an overview of the major international codes and guidelines. Part II presents historical abuses that led to current regulations and raises awareness of some of the recent African examples and the current ethical environment within Africa.
2	Fundamental Ethical Principles	Focuses on fundamental principles: respect for persons, nonmaleficence, beneficence, and justice. Reference is made to major international guidelines.
3	Ethical Review Boards	Part 1 focuses on the history of ethics review in Africa, the roles of ethics committees, their composition, and models of ethical review in Africa. Part 2 looks at operational aspects of ethics committees and makes recommendations.
4	Informed Consent	Addresses informed consent, specifically requirements and issues encountered in application.
5	Ethical Requirement of Research Studies	Introduces the components of ethical research and builds on module 2 by taking the fundamental principles into consideration in the design of research protocols.
6	Vulnerable Groups in Research	Introduces the concept of vulnerability in research, identifies its characteristics, describes various categories of vulnerable groups, and gives a perspective on approaches to protect vulnerable research populations.
7	Standards of Care	Deals with standards in the context of international collaborative research.
8	Researcher Responsibilities	Aims at clarifying the role of researchers and defines their key responsibilities with regard to study participants and communities, to the sponsor, to the institution, and to the scientific community at large.
9	Scientific Misconduct	Discusses background issues related to misconduct and presents case examples (including aspects related to publication, ownership of research results, and authorship).
10	Ethical Issues in Genetic Research	Introduces the basic science of genetics and its applications. It discusses the ethical issues related to genetic research and recommends ways of addressing its challenges.

*Modules 1 to 5 are compulsory; modules 6 to 10 are optional.

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Table 2. Overview of the Contents of the Advanced HRE Course Modules

Module	Title	Brief synopsis of contents
1	Ethical Principles in Health Research and Review Process	Covers the definition of research ethics, morality and ethical principles, historical background, application of ethical principles in reviewing research, and case studies.
2	Responsibilities in Health Research	Addresses the responsibilities of researchers, participants, communities, community representatives, sponsors, research institutions, data safety and monitoring boards, regulatory authorities, and ethics review committees.
3	Ethical Issues in Research Design and Recruitment	Discusses pertinent issues surrounding biomedical research, clinical trials, genetic studies, genomic epidemiological studies, genetically modified organisms (GMOs), and stem cell research.
4	Community Engagement	Examines the definition of community engagement, different models of engagement, the effectiveness of community engagement, and practical challenges in the field.
5	International Collaborative Health Research	Explores north-south and south-south collaborative research, research agendas, ethical approval requirements, standard of care issues, ownership of samples and databases, intellectual property rights issues, and authorship.
6	Animal Research Ethics	Describes the use of animals in research; the principles of reduction, refinement, and replacement; legal and ethical frameworks; and protection of the welfare of animals.
7	Ethical Issues in Traditional Medical Practice and ''Research''	Discusses the definition of traditional medicine, the dynamics of diseases and the need for research on traditional medicines, the separation of traditional medical practice from ''research'' on traditional medicines, and traditional medicines as a natural resource for developing countries.

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Table 3. Overview of the Contents of the Good Clinical Practice Course Modules

Module	Title	Brief synopsis of contents
1	GCP Background	Discusses the place of research in routine clinical settings, including research versus practice, historical perspectives and the evolution of GCP, general principles of GCP, and GCP in resource-constrained areas.
2	The Product Development Process	Addresses the pipeline concept, preclinical activities, clinical development, and registration/marketing and post-marketing issues.
3	Key Players in the Trial Setup	Examines sponsors, investigators, ethics committee regulatory authorities, and data safety monitoring boards.
4	Planning the Clinical Trial	Covers protocol development; questionnaires, forms, and case report forms (CRFs); and trial preparations (approvals, training, staff, facilities, and trial registration).
5	Conduct of the Trial	Describes informed consent: recruitment, screening, and enrollment and safety and efficacy assessment.
6	Quality Control and Quality Assurance	Discusses the accuracy of data, SOPs, tracking tools, good clinical laboratory practice, monitoring and the role of a monitor, and audits and inspections.
7	Data Processing and Management	Explores source documents, case record forms, data reconciliation and validations and audit trails, and database lock and analysis.
8	Essential Documents	Provides a background to essential documents before, after, and during the study, as well as managing the study file.
9	End of Study	Addresses study close-out activities; premature termination of the study; reports, including clinical study reports; and public relations, that is, communication to the study communities, scientific community, lay public, and other audiences.
10	Additional Topics	Describes preparing study budgets, trial site management, risk management, and external proficiency testing schemes.

examination questions. This feedback was considered in reformulating the course modules and in setting the average pass mark for each module and estimated average time required for each module.

Further, before final release of the courses, some more carefully selected individuals across Africa were invited to enroll and complete the modules. Finer improvements were made, especially with regard to general instructions on self-registration and access to the courses. After the validation and pilot testing, the courses were then released to the public. Announcements were made through the various communication channels available to AMANET, including the MIM circulation list, AMANET listserv, Afronets, and SHARED. The course faculty members retained instructor's privileges and were able to monitor progress from the back end of the system.

Results

The web-based courses have to some extent received global response, with the highest response coming from African countries. The English version of the basic HRE course has received the highest number of candidates (560 enrollees). This could be attributed to the fact that it was the first course to be launched, before the rest of the other courses were introduced. The response rates for the French basic HRE course have been the lowest (34 enrollees). Out of the three additional courses that were launched in the second phase of the project, the GCP course (328 enrollees), followed by the advanced HRE course (233 enrollees), has been the most popular. In terms of successful completion of the courses, the advanced HRE course had the highest completion rate—57% of the enrolled candidates—whereas the basic HRE in English, basic HRE in French, and GCP had completion rates of 46%, 30%, and 34%, respectively.

At least 80% of the candidates who attempted advanced HRE tests passed all seven modules. For the basic HRE in English, more than 80% of the candidates who attempted the tests passed all the modules except for module 8, which was passed by 77.13% of the candidates. As for the French version of the basic HRE, less than 80% of candidates who attempted modules 3, 8, and 10 passed the modules, whereas at least 80% passed the rest of the modules. Only module 3 of the GCP course has a pass rate of less than 80%.

Discussion

This project has demonstrated that e-learning could complement other efforts aimed at teaching health research ethics in Africa. As Internet connectivity improves in many parts of Africa, the role of e-learning will continue to increase. The statistics described in this article show that in general candidates from all over the world enrolled in the web courses, although the majority were from Africa. This is an encouraging trend, because nowadays health research is becoming more global, rather than being localized in specific countries or continents. However, utilization of the French course has not been as frequent as the other courses in English. This could be attributable to the fact that AMANET conducted fewer HRE training workshops in French in Francophone countries than HRE training workshops in English in Anglophone countries. It could also be due to the availability of alternative training programs, which may be catering to most of the candidates needing training. Another interesting observation is that some candidates in Francophone countries took the English version of the

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basic HRE course and not the French version.

It would be a waste of resources if web courses were to be developed and made available online by various players without making efforts to ensure, first, that the courses are being utilized and, second, that they are making the intended impact on the users. Utilization could be enhanced by such approaches as the following:

1. Research institutions could make conditions that oblige all research staff to show certificates of ethics training before they are allowed to work with human subjects.
2. Ethics committees could arrange for members to take the basic courses on joining and the advanced courses as part of continuing education for members. The committees could facilitate accessibility of the Internet to members, especially members such as community representatives and others who may not be affiliated with any particular institution and may not have easy access to the Internet.
3. Sponsors and funding authorities could also make research ethics training a requirement for investigators who are awarded grants for projects that involve humans as participants.
4. Institutions could also ensure that all their researchers who intend to conduct health research involving humans are trained through online courses or other face-to-face training programs.

For all the courses, the average marks for the modules are high, with averages of 80% or above for most of the modules. The fact that the platform used randomly reshuffles the questions and answers makes it difficult for candidates to assist others who may not want to read and understand the reading materials of the courses. The system ensures that, even when a candidate fails a particular module and has to repeat it, she or he has to read the material again in order to understand and be able to pass the tests. Such a system is better than one that can easily be cheated by candidates who may get certificates without reading, let alone understanding, the course materials. The ultimate goal of the web-based courses is for candidates to understand health research ethics and good clinical practice so as to be able to ensure that health research conducted in Africa meets internationally acceptable scientific and ethical standards. It is therefore critical that checks and balances are put in place to ensure that the ultimate goal of the web-based courses is achieved.

Notes

1. Declaration of Helsinki. World Medical Association. *Ethical Principles for Medical Research Involving Human Subjects*. Edinburgh: World Medical Association; 2008.
2. Council for International Organizations of Medical Sciences (CIOMS). *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: Council for International Organizations of Medical Sciences; 2002.
3. International Conference on Harmonization (ICH). *Good Clinical Practice (GCP) ICH Harmonized Tripartite Guideline on Good Clinical Practice*. Geneva: World Health Organization; 1996, ICH/GCP, E6. (R1).
4. Levine RJ. Institutional review boards: A crisis in confidence. *Annals of Internal Medicine* 2001;132(2):161–3.
5. Sugar AM. The crisis in local institutional review boards. *Annals* 2002;136:410–7.
6. Burman WL, Reves RR, Cohn DL, Schooley RT. Breaking the camel's back: Multicenter clinical trials and local institutional review boards. *Annals of Internal Medicine* 2001;134: 152–7.
7. Siegfried N, Clarke M, Volmink J. Randomised controlled trials in Africa of HIV and AIDS: Descriptive study and spatial distribution. *British Medical Journal* 2005;331:742–7.

https://doi.org/10.1017/S0963180112000436 Published online by Cambridge University Press

8. Hyder AA, Wali SA, Khana AN, Teoh NB, Kass NE, Dawson L. Ethical review of health research: A perspective from developing country researchers. *Journal of Medical Ethics* 2004;30:68–72.
9. See note 8, Hyder et al. 2004.
10. Kirigia JM, Wambebe C, Baba-Moussa A. Status of national research bioethics committees in the WHO African region. *Journal of Medical Ethics* 2005;6:10–16.
11. Kass NE, Hyder AA, Ajuwon A, Appiah-Poku J, Barsdorf N, Eldin Elsayed D, et al. The structure and function of research ethics committees in Africa: A case study. *PLoS Medicine* 2007;4:e3. doi:10.1371/journal.pmed.0040003.
12. Nyika A, Kilama WL, Chilengi R, Tangwa GB, Tindana P, Ndebele P, et al. Composition, training needs and independence of ethics review committees across Africa: Are the gatekeepers rising to the emerging challenges? *Journal of Medical Ethics* 2009;35:189–93. doi:10.1136/jme.2008.025189.
13. Kilama WL. Ethical perspective on malaria research for Africa. *Acta Tropica* 2005;95:276–84.
14. See note 12, Nyika et al. 2009.
15. See note 12, Nyika et al. 2009.
16. Ezekiel JE, Wendler D, Grady C. What makes clinical research ethical? *JAMA* 2000;283(20):2701–11.
17. See note 16, Ezekiel et al. 2000.

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