Development of an Online Research Ethics Training Resource Specific to South African Health Law and Guidance
A Ukzn-Mepi Funded Project

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Abstract: This paper describes the development of an online learning course aimed at building capacity in the field of research ethics. E-Learning is a popular tool to train large numbers of students and professionals across the world. This learning tool has been adapted to different fields and disciplines. In developing countries, there is a need to improve research ethics capacity. Generic and specific research ethics modules are being used to build capacity in Africa through various online websites. This paper describes the development of a South African online module for the Training and Resources in Research Ethics Evaluation (TRREE) website.

1 INTRODUCTION

This paper describes the development, aims and objectives of an online research ethics training module designed to familiarise researchers, members of research ethics committees and other stakeholders with applicable South African health law and research ethics guidance. This work was an integral component of a UKZN-based Medical Education Partnership Initiative (MEPI) grant from the US National Institutes of Health Fogarty International Centre to build sustainable medical education capacity in South Africa.

It is not known when e-learning emerged but e-learning has become a popular and powerful training technique both internationally and locally in South Africa. E-learning in this digital age, is a popular medium for the acquisition of knowledge and sharing of information from any area or location in the world. Globally, many tertiary institutions utilise e-learning as a common learning technique for training and capacity building in various disciplines. Online learning and distance learning are thought to be synonymous with e-learning but many see these two terms as different and separate but inter-related (Moore et al. 2011). Although not all distance education involves e-learning, e-learning is a common form of distance learning (Moore et al. 2011).

There is no consensus amongst academics about the definition and essential characteristics of e-

learning, but authors (Ellis 2004) and (Nicholis 2003) suggest that e-learning can be defined as "being accessible using technological tools that are web-based, web-distributed, or web-capable. The belief that e-learning not only covers content and instructional methods delivered by CD-ROM, the Internet or an Intranet but also includes audio- and videotape, satellite broadcast and interactive TV" (Benson et al. 2002) and (Clark 2002 cited in Moore et al. 2011: 130). Despite a lack of consensus on its characteristics, e-learning can be identified as applications, programs, objects, and websites that ultimately provide a means to improve capacity and learning.

As technology evolved and improves, e-learning has become increasingly beneficial to individuals across the world and especially to those who reside in remote locations (Aggarwal et al. 2011). Distance learning, in the form of e-learning enables teaching and learning to take place in areas that are geographically distant and where infrastructure is underdeveloped (Silverman et al. 2013), either as a stand-alone resource or to supplement other capacity building formats and activities. Furthermore online learning is thought to be more attractive than traditional face-to-face training because it is available to a greater audience, is more cost effective, time-effective, scalable and sometimes an efficient tool (Aggarwal et al. 2011 and Fordis, King & Ballantyne (2005) cited in Williams et al. 2013).

E-learning is cost effective in areas where

teaching and learning are under-resourced or not readily available in terms of teaching skills, experience and local facilities. In a study conducted by Aggarwal et al. 2011, Indian subjects were randomly assigned into two groups, in the first group students attended a 3.5 day onsite training on biostatistics and 3.5 week online course. In the second arm students attended a 3.5 onsite in research ethics and completed a 3.5 week online biostatistics course. The findings suggest that online training is as effective as onsite training. We further argue that e-learning might also be more sustainable as technology evolves and improves; content can be easily upgraded, edited and revised which facilitates better learning and improved knowledge.

Developers and providers of e-learning workshops from three continents met recently to discuss standards for introductory courses in human participant research ethics (Williams et al. 2013). Proceedings of this workshop highlight the importance of aims and standards of online training, and the importance of clear descriptions of these standards (Williams et al. 2013). It is argued that standards are important when developing online programmes and that they should be specifically tailored for the target audience. Williams et al. (2013) suggest that standards ensure that there is some uniformity across programmes in terms of quality of information provided to target audiences. Firstly, all important sections should be easily identified; secondly, all requirements for the programmes should be specified; lastly, an evaluation by users of the programme should be provided for. The meeting (Williams et al. 2013) identified seven standards for introductory research ethics e-learning courses. They are summarised as follows: (a) Developer/provider qualifications: Requires that authors' qualifications be provided, including a description of how the module and its contents were developed. The authors should provide a description of the educational principles used and whether the module has been peer-reviewed. (b) Learning goals: the goals of the module should meet a specified educational gap that exists in literature and the module should be designed for a specific target audience. (c) Learning objectives: Authors should provide a description of the intended usefulness of the programme. (d) Content: the content of the module should cover the basic concepts and include comprehensive background information about the topic of the module. Important and relevant concepts and principles should also be included. (e) Methods: the methods should be in line with the learning objectives. This includes details about the time

needed to complete the module, background literature and articles referred to and language/s the module. (f) Assessment of participants: assessment is necessary to ensure that students have gained knowledge and understanding from the module. (g) Assessments of the course: learners taking the course should be allowed to provide feedback about the course and their learning experiences. There are several different areas to evaluate and different methods of obtaining responses. These standards ensure that all modules are the same in terms of quality and meet the needs of the target audience. A related but different set of e-learning evaluation standards is proposed and utilised by Silverman et al. (2013). It is nevertheless argued that e-learning has a growing evidence base as an effective tool for efficiently training individuals in disciplines where capacity is lacking and where disseminated training is required internationally, such as is the case in research ethics.

2 RESEARCH ETHICS CAPACITY BUILDING

There are various learning and teaching techniques available, viz. onsite and online training and it is argued that online training is a useful primary or supplementary tool for building health research capacity. Building health research capacity is a key driver to the development of efficient health systems. An important aspect of building health research capacity is ensuring that research follows ethical guidelines. Specifically, in Africa there is a documented need for research ethics capacity building (Ateudjieu et al. 2010; Kirigia et al. 2005 and Milford et al. 2006). These studies found that Research Ethics Committee (REC) members are appointed with very little or with no ethics training (Kirigia et al. 2005). Although there have been major investments in international research ethics capacity building by the US NIH Fogarty International Centre (Millum et al. 2013) and others (e.g. EDCTP and WHO/UNAIDS) in the past decade, more effective and diverse techniques of teaching and learning are needed to bridge the remaining gaps. In order to meet this need international organisations partnered with each other to develop short online courses – not all of them specifically targeting Africa. Several e-learning sites now offer training such as Training and Resources in Research Ethics Evaluation (TRREE) (see http://elearning.trree.org/),Collaborative Institutional Training Initiative (CITI) (see www.

citiprogram.org) and the National Institutes of Health (NIH) online training (see http://researchethics.od.nih.gov/) , FHI the science of improving lives (see http://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/index.html) and National Centre for Professional and Research Ethics (see https://nationalethicscenter.org/) to name a few, in addition to those described by Silverman et al. (2013). Most of these sites have generic modules provide a general overview of the requirements for the ethical conduct of health research.

3 TRAINING AND RESOURCES IN RESEARCH ETHICS EVALUATION (TRREE)

3.1 Background & Format of TRREE

In 2007 a study was conducted to investigate training needs for competent ethics review from a list of identified African and European countries (Ateudjieu 2010). The sample consisted of a total of seventy four respondents from across Africa and Europe. Participants were expected to complete a questionnaire which requested information to be given about their ethics training (Ateudjieu 2010). It was found that REC and researchers mostly received training and that majority of the participants were trained in international institutions as opposed to national institutions (Ateudjieu 2010). A list of topics was identified as important information for all researchers and REC (Ateudjieu 2010). The TRREE e-learning site was developed based on the findings from this research (Ateudjieu 2010). TRREE provides basic online training on ethics and health research regulation. It was primarily designed to provide "online 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" (Ateudjieu 2010 : 90). The main objective of TRREE is to build capacity in research and ethics evaluation and to increase the existing capacity in Africa and European countries. Another major aim of TRREE is to be bilingual, to meet the needs of individuals living in Francophone countries (Ateudjieu 2010).TRREE is aimed at research ethics committee members, research teams involved in health research, health authorities, funding

agencies, universities, the general public and any other health professionals who are interested in the protection in the well-being of research participants.

Of the e-learning courses described above, TRREE is unique as comprises two main sections: one section provides a growing number of country-specific modules outlining each country's specific health law and research ethics related law and guidance, in addition to a growing list of modules covering specific topics in health research ethics, such as informed consent and ethical issues in HIV prevention research.

The topic-specific e-learning modules are certificate-generating web-based learning programmes. Participants are required to read the basic and linked supplementary learning material and answer questions based on the material they have covered. Upon completion of the e-learning modules students are graded and successful participants receive a certificate if they attain over 70% correct. The national supplements are country specific e-learning modules where local experts in the field of research ethics present an overview of relevant legal and ethical guidelines that inform the practical application of research. Most TRREE national supplements are not certificate-bearing but the modules on Nigeria and South Africa includes a quiz into the module which tests students' knowledge and generates a certificate if the 70% threshold is met. TRREE learning material and resources are available in different languages based on where the module was written and who are the beneficiaries or intended audience. For example, the module written for Cameroon is available in English and French whereas the Swiss module is available in French and German. TRREE requires low bandwidth to enable participation from users in countries with poor internet accessibility, is free of charge to all users and requires the students to create an online account which is stored on the database. An active email account is needed for account confirmation and password recovery. TRREE maintains a consistent link with its users and informs them when new modules are available and when modules have been updated. TRREE also provides tools and resources such as a bibliography and a glossary. A record is kept of how many students registered and completed all modules and these statistics are used to evaluate the module and its effectiveness.

3.2 Design

All TRREE modules follow a specific template

designed to standardise legal and ethical sub-headings in all the country-specific modules to facilitate ease of comparison and structured coverage. The country-specific modules also cover a standard range of subheadings which provide supplementary literature such as health law and other ethical guidelines on research for each particular setting. The module development process itself requires experts in health law and research ethics to collaborate, facilitating national and international capacity development. As all TRREE modules are available online free of charge an infinite number of users can benefit from the module. Students are required to obtain a pass mark/ grade of 70% in order to pass the module. The certificate is also acknowledged by Swiss organisations such as the FMH (Swiss Medical Association) and FPH (Swiss Association of Pharmacists). TRREE is a user-friendly learning site and the support team can be easily contacted by email if problems occur.

3.3 South African National Module

As in most countries, the ethical conduct of health research requires familiarity with and compliance with several laws and guidance documents, including the South African Health Act, the South African research ethics guidance (2004), South African Good Clinical Practice Guidelines (2006) and ethical guidelines on the conduct of HIV vaccine trials (MRC 2003). It was felt that UKZN MEPI resources would be well used if a dedicated South African TRREE module could ensure that all researchers working in South Africa, in addition to members of the over 35 registered RECs in South Africa, could have access to a module covering the essential requirements of the national laws and guiding documents in an easily accessible online format such as provided by the TRREE platform.

The first draft of the South African module was written in 2011. The module underwent several external reviews by three experts in research ethics and South African health law. In 2012, the South African authors decided to include a quiz to the national supplement which is certificate-generating and allows individuals to use the module as documenting proof of introductory-level research ethics training for the South African setting. The module and quiz was accepted in September 2013 for final programming and the module has been uploaded and is now available on the TRREE website. We are beginning to collect user statistics and user feedback. It is envisaged that this South African MEPI-sponsored TRREE module will become compulsory for all ethics applications to the UKZN Biomedical Research Ethics Committee and it is likely that other major South African health research institutions will follow suit.

4 CONCLUSIONS

E-learning is a very useful evidence-based method of preliminary or supplementary training and building capacity in the field of health research ethics. It has become especially useful in the African continent where a lack of capacity has been identified. The advantages of online training sites are that they can easily be updated and edited; they are available to an infinite number of users at relatively low cost and are readily available for asynchronous use. The lack of capacity in the field of research ethics continues to decrease as more and more training institutions commit to online learning (Silverman et al. 2013). In a digital age, international funders and training organisations can be seen utilising the internet and online mediums to train a greater number of individuals cost-effectively and we are yet to see further evolution and upgrades to online training in the field of research ethics and other disciplines.

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