eLearning Helps to Promote Ethics in Medical Research

A malaria vaccine is still the best tool to fight the malaria epidemic in many developing countries. Since 2005, the first human trials of a vaccine have been conducted with encouraging results. Most of the volunteers who received the vaccine developed strong and in some cases long-lasting immune responses. However, as researchers know from earlier vaccine trials, the crucial question is whether these immune responses mean that vaccinated people are actually protected against malaria. One way to test this is to expose the vaccinated trial participants to malaria and see if they are protected. However, this risky test is not ethically justified during the early stages of vaccine testing.

What is ethical in research that involves humans? What makes a clinical trial protocol comprehensive and adequate? What constitutes an informed consent? And what are the main difficulties in carrying out a vaccine trial in sub-Saharan countries? TRREE is a new training resource that helps to answer these questions. The project promotes ethics in medical research and is aimed at researchers and physicians involved in medical research in Africa.

TRREE for Africa, which stands for Training and Resources in Research Ethics Evaluation, is a consortium of partners brought together in 2006 from African and developed countries working together for the promotion of high-quality research and the protection of research participants in Africa. The main objective of the project is 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. These include research ethics committee members, researchers, students, institutional authorities, regulators and other political authorities and any other potentially interested parties.

Clinical trials are complicated and comprise numerous detailed clinical and laboratory assessments lasting several months or even years. Different stakeholders are involved until a new vaccine or drug is ready to be tested: research teams, pharmaceutical companies and ethics committees.

The central question is always how the dignity of the human beings involved in the research can be best protected. It touches upon many issues such as privacy and confidentiality, free and informed consent, and the ability of subjects to withdraw from research projects.

“Medical researchers and physicians who conduct the research have to consider all these issues in order to make informed and responsible decisions”, says Dominique Sprumont, Professor at the Institute of Health Law of the University of Neuchâtel. “And they need training,” he adds.

Sprumont coordinates TRREE for Africa, a capacity-building initiative on the ethics of research involving humans that is conducted in African countries. TRREE provides basic web-based training on all issues that concern medical ethics.

Until now, the project group, which involves partners from six African countries, Canada, Germany and Switzerland has developed three text-based training modules. Trainees approach issues such as regulation of research, are provided with an overview of the history of medical research, learn what is necessary to draft research protocols and, finally, learn about the practical application of their protocols for ethical review in a specific country. So far, there are

country oriented modules available for Mali, Cameroon, Tanzania and Switzerland. The eLearning resources will be accessible free-of-charge through the TRREE website from the end of February on. Participants will receive a certificate via e-mail after successfully completing the three course modules.

Learning Content available for all

"We opted for an open access programme," explains Sprumont, "as we wanted to gain the highest reach with the little resources we had. In offering the courses as an open education resource, we hope to reach the many target groups that are involved in medical research: students, researchers, physicians, nurses as well as health authorities and members of research ethics committees."

The learning content is based on an extensive needs-assessment analysis conducted by the TRREE consortium in 2007 in three African countries: Mali, Cameroon and Tanzania. "Only through an in-depth investigation into the training needs of the respective research communities could we make sure that the training will be relevant and help to promote highest ethical standards in medical research," comments Sprumont. The study revealed that training was needed in: the fundamental principles of ethics, the production of an applicable normative framework, the knowledge of how to conduct ethics reviews, the evaluation of consent processes as well as defining the role of research ethics committees, their authority, mandate and responsibilities.

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A parallel assessment conducted in the Swiss research community showed a quite astonishing resemblance to the results of the African study: the training priorities were quite similar. "We realised that with TRREE, we touched universal issues. Ethical standards in medical research are more or less the same all over the world. Researchers need support in understanding laws, regulations, policy guidelines in their national contexts. They need a framework that helps them to apply universal standards to their work," explains Sprumont. "This is also what motivated us to expand to Switzerland and other European countries the project that was initially designed for Africa. TRREE grew therefore quickly into a true South-North initiative."

TRREE is financed by EDCTP (European and Developing Countries Clinical Trials Partnership), the Swiss Academy of Medical Sciences, the Commission for Research Partnerships with Developing Countries, the Swiss National Science Foundation and the Canadian Institutes of Health Research.

In a second step, TRREE intends to progressively include new partners countries in Africa and in Europe. The team around TRREE aims at building and strengthening a network of institutions and experts in research-ethics evaluation. "There are many institutions and individuals involved in these issues and TRREE could provide an ideal platform to gather all these efforts and to exchange experiences and best-practices," says Sprumont. "We hope to be able to promote this idea also at the eLearning Africa conference."

TRREE Project Coordinators
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Links:

TRREE for Africa: www.trree.org

EDCTP European and Developing Countries Clinical Trials Partnership: www.edctp.org/

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