

KEMRI BIOETHICS REVIEW



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From the Director

Welcome to the third issue of the The KEMRI Bioethics Review, the quarterly electronic publication on Bioethics. The newsletter continues to take a lead in bioethics updates in the institute and provides a forum for serious discussion on the social implications of biomedical research. A quick glance at this issue verifies again our continued commitment and resolve to publish a newsletter of the highest standards devoted exclusively to research ethics.

All research activities carried out by the Institute's research centres have to be vetted and approved by the Centre Scientific Committee (CSC). The CSC appraises the research proposals before they are forwarded to the institute's central committee - the Scientific Steering Committee (SSC). The SSC, which consists of Assistant Directors, Centre Directors and Heads of other research programs, reviews the scientific content of research proposals. Furthermore, the Animal Care and Use Committee (ACUC) of the Institute review protocols that have an animal component.

Once SSC grants approval, the proposals are forwarded to the Ethics Review Committee (ERC) which



provides the final approval before implementation of the research. Besides KEMRI reviews, ERC also receives requests for review from other investigators not affiliated with KEMRI. These external reviews currently constitute up to 15% of new proposals.

The volume and complexity of research conducted at KEMRI has significantly increased in recent years. Consequently, the current review system is sometimes strained by the numbers of submissions that include: new, renewed and ongoing protocols. This desirable increase has nevertheless occasioned some delayed reviews, delayed implementation of research, and concern that there could be some loss of strategic opportunities. Since research is the core business of the institute, we, as management, have commissioned a review of the system to see how best

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From the Director

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to ensure efficiency without compromising the quality of the scientific and ethics review of all protocols approved through the system. We also expect that the review will inform appropriate continuing oversight for ongoing approved research. With the growth of science at the Institute, we shall endeavor to expand and strengthen the secretariat and office facilities for ERC as well as other services offered within the protocol review chain. The KEMRI system serves not only the institute, but also several international and local NGOs involved in diverse research activities in Kenya.

In this issue we shall describe how the review and restructuring process will be undertaken, as well as introduce the secretariat of the KEMRI Ethical Review Committee involved in research administration within the ERC office. We also

highlight the ongoing and planned capacity building efforts as well as providing some bioethics updates.

As we continue to improve on research ethics, we encourage researchers to take up online training that is available for free use on the Institute's website. This training introduces researchers to important concepts, tools, principles, and methods that are useful in resolving ethical dilemmas that one may encounter in the course of reviewing or implementing an approved protocol.

We appreciate your interest in 'The KEMRI Bioethics Review', and hope that you will find this issue both informative and a useful resource that will help you understand the future we envision as we embark on restructuring the protocol review process at the Institute.

I wish you enjoyable reading.

Solomon Mpoke, PhD.

Director KEMRI

Meet the ERC Secretariat Team

KEMRI Ethical Review Committee (ERC) is mandated to review all research project proposals that involve both human and animal subjects. The Committee is a multi-sectoral and multidisciplinary with most of the representation recruited externally from the Institute, thereby maintaining its independence from any institutional influence. Any project proposal which requires ethical clearance will only be cleared for implementation by Ethical review committee after it has been duly approved by the Scientific Steering committee.

Secretary (acting) KEMRI Ethics Review Committee

Dr Wasunna served as a member of the KEMRI Ethics Review Committee (ERC) from 2006, when she was appointed as assistant secretary and in February 2012 she was appointed acting Secretary to the ERC. In this capacity, she provides ongoing expert ethics consultation to all researchers at KEMRI and KEMRI collaborators. She is the head of the ERC Secretariat and reports to the Deputy Director Research and Training administratively and maintains the link between the KEMRI management and the ERC. She strives to build strong relationships between the research community and the ERC through education and counsel and also provides avenues for achieving the highest standards of creativity and intellectual attainment while promoting a culture of compliance with research regulations.



Dr Wasunna was instrumental in the development of the current ERC standard operating procedures. She has expertise in

the ethical conduct of human investigations specializing in genetic studies of African population and broad administrative experience in research regulatory affairs including, protocol review, informed consent form development, regulatory compliance and clinical safety.

In the past two years, she participated in the development and implementation of a bespoke post-graduate diploma course for Clinical Research Monitors in Africa. Since August 2011, Dr Wasunna has been collaborating with researchers at the University of Massachusetts Medical School thereby enhancing her background in human genetics. She is currently a member of MALARIAGEN's International Data Access Committee and Secretary for a regional network - the Africa Research Ethics Network. Dr Wasunna has also been instrumental in the establishment of the National Clinical Trials Registry through partnership with the Pharmacy and Poisons Board, Kenya – the National Drug Regulatory Authority funded by the EDTCP. She contributes regularly to professional and scientific articles.

Dr Serah Gitome



Dr. Serah Gitome joined the ERC Secretariat as a Research Review Analyst in February 2012. Her main responsibilities include: supporting real-time review of reported adverse events from ongoing studies approved by the KEMRI

ethics review committee; development and maintenance of a database on reported adverse events from ongoing studies approved by the KEMRI ERC; supporting the ethics review committee and scientific steering committee in scientific review of proposed studies. Dr. Gitome's overall career objective is to work towards attaining evidence-based provision of quality and comprehensive health care for people in resource-poor settings through conduct of high quality, relevant research. Prior to joining the ERC secretariat, Dr. Gitome had worked for close to 3 years as a study doctor/ assistant study coordinator for vaginal microbicide trials in Kisumu as well as an assistant coordinator in a national family planning service delivery point survey, within the Centre for Microbiology Research. Dr. Gitome graduated from the University of Nairobi with a Bachelor of Medicine and Bachelor of Surgery degree in 2006 and has recently got a scholarship to study MPH in Epidemiology at the University of California, Berkeley, USA.

Caroline Kithinji



Caroline Kithinji is the full time research administrator for the KEMRI/ERC. She attained her BSc in Biochemistry and Zoology from the University of Nairobi and MSc in Medical Parasitology from the London school of Hygiene

and Tropical Medicine. She joined KEMRI as a research administrator in 2004 and during this time she completed a two year fellowship program in bioethics at the Johns Hopkins School of Public Health. As part of the course, she was required to carry out a practicum which she did on assessing the comprehension of English and Kiswahili consent forms in Kilifi. The findings were published as; Assessing the readability of non-English language consent Forms: The case of Kiswahili for research conducted in Kenya 2010. The findings were published in the IRB journal:

Ethics and human research. She has also published a commentary of the female condom, society and public health in organization ethics 2006. She was the PI of the concluded AMANET capacity building of RECs in Africa grant. Her main interest lies in training and to this end she has facilitated several regional training workshops.

Dr Betty Njoroge

Betty Njoroge, MBChB, MPH (Epidemiology) is a Senior Research Officer at the Center for Microbiology Research, KEMRI. She received her master's training in Epidemiology at the University of Washington, Seattle and has received a Certificate in Research Ethics: Conducting Research Responsibly at the University of the Witwatersrand, Steve Biko Centre for Ethics, Johannesburg, South Africa. Her areas of expertise include: research methodology, Research Ethics and training/ mentorship in ethical issues. Dr Njoroge works at the Ethical review office as a Senior Researcher/ Review Analyst. Her duties include: review of clinical research applications, safety reports and Data Safety Management Board (DSMB) reports. She has created and maintains a safety report database and advises the ERC on matters in the clinical domain and safety reports requiring their attention.



Naomi Githae

Naomi works as a secretary at the ERC office where she is involved in screening of protocols for completeness and preparing agendas for monthly ERC meetings. She also maintains identifiable and accurate records of all documents and files. She also keeps records and track of ERC protocols and services at the ERC Secretariat. Naomi has been working at KEMRI for the last 12 years in various departments. She has worked at the ERC Secretariat office for more than five years now. She has gained a lot of experience in ERC protocol management while at her current station. As part of the requirements for working as a secretary at the ERC Secretariat, she has successfully completed the Collaborative Institutional Training Initiative (CITI) online course, which has exposed her to various concepts in the field of bioethics.



Review and Restructuring of the Research Regulatory Process in KEMRI

KEMRI has experienced tremendous growth in research. As a consequence of this desirable growth, the current review systems have experienced a persistent strain and backlog due to the increased volume of research proposal submissions. This has necessitated the need for restructuring and expansion of office facilities, secretariat staff, and services.

Building on the longstanding research collaboration between the University of California, San Francisco (UCSF) the institute has developed a project called ADILI- The KEMRI bioethics Center. The

overall goal of ADILI is to restructure and strengthen the process of ethics review at the KEMRI.

In 2010, KEMRI obtained funding from the European and Developing Countries Clinical Trials Partnership (EDCTP), and University of Cape Town (UCT). These grants would be used to strengthen and enhance the Institute's bioethics capabilities and restructure the research review system in KEMRI thus enabling the Institute to set up an independent bioethics unit. The Bioethics unit will not only build capacity at KEMRI, but also at other institutions in the country involved in research

which may seek research ethics support and training from KEMRI.

A task force has been appointed to oversee the restructuring and implementation of the project. The team developed a study tool that was used to conduct an institute wide survey on the current system to understand the processes undertaken by the different players in the ethics review system. The data collection process was closed in May 2012 and the team is currently developing a report on the survey.

KEMRI Protocol Management and Tracking System

The Protocol Tracking and Management System (PTMS) will be a secured, web-based information management system designed to make protocol submission, review and approval processes more efficient, well-organized, and accurate throughout the life cycle of a research protocol.

The Information and Communication Technology (ICT) department has developed a protocol management & tracking system for the institute's Scientific Steering Committee (SSC) and the Ethical Review Committee (ERC) as a first step in this process. The system was piloted and is now online for both the SSC and

ERC. Information on the SSC tracking system is up to date, and shows all the protocols that have been submitted to SSC since (May 2011 to date).

The ERC system has current information on the Non-SSC protocols (protocols reviewed by KEMRI but have no KEMRI investigator) submitted to KEMRI and the ICT department is working on keying in information on protocols received from the KEMRI SSC and tracking them in from the SSC into the ERC system.

Once the full system is completed, it is envisioned that it will enable the principal investigators to initiate, track and organize all types of clinical studies, monitor

review processes, view status changes, and quickly respond to reviewers or SSC/ERC requests for additional information, etc. In addition, this system will allow the secretary of the Scientific committees at the centre level track and manage the entire review and approval processes as well as regulatory reporting requirements.

When the system is up and running it is likely to completely eliminate the need for paper process and enable the SSC/ERC office to fully automate the protocol review processes from its initial submission, review to final approval.

Research Assistant Officers at ADILI

In October 2011 six assistant research officers (Research Ethics) joined KEMRI as research Interns for ADILI Project data collection and to help in strengthening the systems at the research regulation units (ERC and SSC office). The pool of successful applicants was drawn from graduates who had completed their Bachelor's degree in Biological Sciences (e.g. zoology, biochemistry), Health Sciences (e.g. medicine, pharmacy and nursing), Social Sciences, Anthropology or Economics, Law, Mathematics, Statistics, Information and Communication Technology and Administration. The Research Assistants have been assisting in the data collection process for the Adili project and in creating a data base for protocols submitted to both SSC and ERC offices with the assistance of the KEMRI ICT department.



Assistant Research Officers: From left to right - Timothy, Daisy, Jeremiah, Fridah, James and Miranda

James Nguya

James Nguya graduated from the University of Nairobi with a Bachelor of Arts degree in Social Work. He is currently a research Assistant Officer (Bioethics) on internship at the ERC office. He has successfully completed basic CITI training. The online course on research involving human subjects has exposed him a lot in the field of bioethics. Previously, James was stationed at the KEMRI SSC secretariat office where he was involved in protocol screening to ensure all required submission documents are present in addition to other research administrative duties. While in the SSC office, he was also involved in developing a database for all the protocols received by the SSC. At the ERC Secretariat office, James has been involved in research administration including prescreening shipment of biological samples requests and processing them. He has developed interests in Bioethics as he continues to be exposed to research ethics in addition to his keen interest in social-behavioral studies.

Daisy C. Ronoh

Daisy Ronoh completed her BSc in Information Technology studies from Jomo Kenyatta University of Agriculture in 2010, and also holds a certificate in psychological counseling from the Kenya institute of professional counseling and a CISCO (CCNA) certification at Cisco Academy Network. She is currently stationed at the Scientific Steering Committee (SSC) office. She has gained knowledge in protection of human subjects and protocols screening processes to ensure completeness of documents submitted to the SSC office for review. She has also been able gain experience in handling daily research activities in KEMRI including: receipt and screening of protocols, database development and maintenance, and other administrative roles. A chance to be directly involved in the ADILI project has precipitated her interest in research ethics. She seeks to gain additional knowledge in data security especially in health research.

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Kaaria Fridah Karimi

Fridah Karimi is currently pursuing a Master's degree Public Health at the ITROMID, JKUAT. She holds a BSc in medical laboratory science from JKUAT, a higher diploma in community health and HIV/AIDS from Kenya Medical Training College (KMTCC) and a diploma in project management from Kenya Institute of Management (KIM). She successfully completed Collaborative Institutional Training Initiative (CITI) online course on research with human subjects which exposed her to the field of bioethics, and over time she developed a keen interest on clinical trials as well as social-behavioral research studies. The internship at KEMRI has enabled her gain skills on protocol review; correspond with Principal Investigators on various issues ranging from the status of their protocols and amendments that need to be made among others. She developed an enormous interest in bioethics and aspires to develop her career in the field of research ethics.

Timothy Kiplagat

Timothy Kiplagat graduated in 2011 with a bachelor's degree in biochemistry from Egerton University. During his undergraduate studies he successfully completed courses directly related to research and bioethics. His internship at KEMRI has been an eye opener and has accorded him the opportunity to successfully complete CITI training thus giving him a deeper insight into this field of bioethics. The time spent at KEMRI has enabled him to learn how research is administered and regulated in KEMRI and furthered his desire to pursue a career in the field of research administration. He currently is providing some part time support for the newsletter.

Jeremiah Omari Zablon

Jeremiah Omari Zablon graduated in 2009 with a BSc in Medical Laboratory sciences from Jomo Kenyatta University of Agriculture and Technology (JKUAT) and is currently pursuing a Master's of science in Molecular Medicine at the KEMRI Graduate School of Health Sciences (KGSHS) a collaboration with JKUAT. As a result of the exposure to research ethics he has received during his academic studies and his internship in KEMRI, Jeremiah has developed interest in both clinical practice and research on clinical trial and the regulation of the clinical trials. He developed interest in research during his time working with the University of Washington/ University of Nairobi collaborative research projects, in particular the Couples against Transmission (CAT) Project as an assistant research officer. He has learned how to review proposals and to review sample shipment requests. His current work KEMRI as an assistant research officer has sparked his interest in research ethics.

Miranda Barasa

Miranda Barasa graduated in 2010 with a Bachelor of Science degree in Environmental Health from Kenyatta University and is currently pursuing a Master's degree in Public Health (Monitoring and Evaluation option) at Kenyatta University. Her experience working under the ADILI Project has encouraged her to develop a growing interest in the field of bioethics and she would like to pursue it in relation to her public health background. She is currently enjoying her work at the SSC where she is learning a lot about the research regulatory system in the institute and hopes to further develop her skills while at the SSC secretariat office.

Wit Corner

A prize is offered for the first two correct entries received. Send your answers to ddrt@kemri.org

1. What is cloning?
2. Name the first mammal to be cloned
3. Name two ethical challenges on cloning
4. Name one advantage of cloning
5. Name one disadvantage of cloning

Last Issue's Winner:

Mogaka Mong'are an ICT Officer 1 in the Information & Communication Department.



Mr Mogaka Mong'are receives his prize from Dr Elizabeth Bukusi

Ongoing Ethics Training in KEMRI

As an effort to improving research regulatory process and building capacity for ethical conduct of research, KEMRI has made it mandatory for all the PIs submitting protocols for review to include in their submissions evidence of ethics training. To facilitate this training KEMRI is registered with the online Collaborative Institutional Training Initiative (CITI)

The CITI Program is a subscription service providing research ethics education to all members of the research community. This online training is offered as a platform for initiating the ethics training for the members and can be accessed at (<https://www.citiprogram.org/default.asp?language=english>). Ethics certification can be obtained by completing the online introductory tutorials for both the CITI and AMANET programs. The tutorials for the CITI program cover biomedical research/refresher courses, Responsible Conduct of Research (RCR) and Good Clinical Practice (GCP) course. This tutorial only needs to be completed every two years. Other available free online ethics training sites include: Africa Malaria Network Trust (AMANET) <http://webcourses.amanet-trust.org/course/category.php?id=3> and the National Institute of Health (NIH, <http://phrp.nihtraining.com/users/login.php>).

In addition to the online tutorials members of the ADILI task force have been conducting training throughout the different centers in KEMRI with the Center Scientific committee members. This training currently focuses on informed consent. This is done in an interactive manner with some provoking questions, showing of a movie and then the opportunity to discuss the movie. The movie titled "WIT" is an intensely emotional, heartbreaking story that portrays the devastation of one woman's (Vivian) battle with not only her terminal illness, but also with her own self-perception. Dr. Kelekian (Christopher Lloyd) outlines in very technical jargon the extent of her cancer and his desire that she should undergo an eight-treatment course of experimental chemotherapy. As her treatment progresses,



Staff at the Centre of Geographical Medicine Research Coast (CGMRC) watching the movie WIT

Vivian's illness and the side effects of her treatment become more debilitating, but she valiantly and stoically endures the 'full dose' that Dr. Kelekian insists upon.

The movie touches on different principles of ethics and how the doctors and hospital staff violate these principles. This movie highlights different elements associated with informed consent including 1) adequate disclosure of information; 2) patient freedom of choice; 3) patient comprehension of information; and 4) patient capacity for decision-making.

The ethical issues observed in this film are the conflict of interest witnessed between clinical therapy and clinical research. Furthermore, there is evidence of clinical incompetence, issues of informed consent and end of life decisions. The investigative team is seeking to maximize patient care and welfare but is also pushing the boundaries of scientific knowledge. This can present a conflict of loyalties relating to a raft of issues e.g. that of 'professional integrity'. The relationship between the investigator and the study participant must be ethically sound and decisions must be made with the greatest moral scrutiny to ensure the participant's non-maleficence.

ETHICS UPDATE

Scientific Misconduct: The Willowbrook Hepatitis Experiment

Source: Rothman, D., and Rothman, S. 1984. The Willowbrook Wars

Hepatitis means inflammation of the liver and also refers to a group of viral infections that affect the liver. The most common types are Hepatitis A, Hepatitis B, and Hepatitis C. Viral hepatitis is the leading cause of liver cancer and the most common reason for liver transplantation.

The Hepatitis studies were carried out from 1956 through 1971 at the Willowbrook State School, a New York State institution for “mentally defective persons”. These studies were designed to gain an understanding of the natural history of infectious hepatitis and subsequently to test the effects of antibodies in preventing the disease. Antibodies are produced by the body’s immune system in response to foreign substances.

Willowbrook State School housed and cared for mentally disabled children. Dr. Saul Krugman from the New York University School of Medicine and his coworkers began conducting hepatitis studies there in 1955 and continued for more than 15 years. Hepatitis was a major problem at Willowbrook for patients and staff, and Krugman believed that most newly admitted children became infected with hepatitis within the first year of residence in the institution. The more recent estimates put the risk of a child contracting hepatitis at Willowbrook at 30 to 50 percent. The subjects, all children, were deliberately infected with the hepatitis virus; early subjects were fed extracts of stools from infected individuals and later subjects received injections of more purified virus preparations.

More than 700 children at Willowbrook were involved in the studies, which fell into two categories. The first used children who were already admitted at Willowbrook. Researchers injected some with protective antibodies (the experimental group) and did not inject others (the control group). Then, they observed the children’s degree of immunity to hepatitis. Krugman thought that if a child was infected with hepatitis after he or she had been injected with these protective antibodies, a mild case of hepatitis would result, and the child would

have long-lasting protection against future, potentially more serious, infections. His goal was to find the best ways to protect children from hepatitis.

In another series of studies, researchers gave newly admitted children protective antibodies. Subsets of these children were then deliberately infected with hepatitis virus (obtained from sick children). Those who had received protective antibodies but were not deliberately infected served as the controls. The children in this experiment were housed in a well-equipped and well-staffed facility where they could be given special care and be kept away from the other types of infections at the institution.

As the studies progressed, researchers noticed differing symptoms caused by different virus samples. They concluded that there are two strains of hepatitis, A and B. Hepatitis B is more difficult to pass on to others because it is spread through blood and sexual contact. In addition, Hepatitis B can lead to long-term (chronic) infection.

The children who were deliberately infected with hepatitis A virus had a mild reaction (a swollen liver, yellowing of the skin and eyes, and a few days of vomiting and lack of appetite). The researchers justified their behavior by citing that many children would become infected during their stay at Willowbrook, anyway. Children who naturally got hepatitis from other children had worse symptoms than those who got it from the study.

A research oversight committee had reviewed the study proposal and parents had been asked for and had provided consent in an era when that was not uniform practice. Parents gave permission for their children to participate in this study, often because it guaranteed acceptance into the overcrowded facility. During the course of these studies, Willowbrook closed its doors to new inmates, claiming overcrowded conditions. However, the hepatitis program, because it occupied its own space at the institution, was able to continue to admit new patients. Thus, in some cases, parents found

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that they were unable to admit their child to Willowbrook unless they agreed to his or her participation in the studies.

When protest arose regarding his exposure of these children to hepatitis virus, Dr. Krugman defended his work. If he had not infected the children as part of research, they would have developed hepatitis anyway because of their school's communal housing. This research, he said, was akin to an experiment in nature, and no level of improved hygiene would have protected the children. He noted, too, that he had been given permission from parents to experiment on their children. It is true that children were enrolled with parental consent. A letter explaining the research was sent to parents whose children were on a waiting list for admission to Willowbrook. Immediate admission was the reward for parents who signed the letter; parents who did not provide consent were not assured of immediate admission. This case caused a public outcry because of the perception that parents and their children were given little choice about whether or not to participate in research.

Relevant Ethical Considerations in the Experiments

The outcome of the research provided valuable information about viral hepatitis and its treatment. It established that two types of hepatitis (A and B) occurred at Willowbrook and that injections of gamma globulin can have a protective effect against infection by hepatitis A virus. In addition to this larger benefit to society, the research benefited the participants and everyone in the institution. The research reduced the amount of hepatitis among patients and employees by 80 to 85 percent because of better care. Many of the children who participated lived in a special facility where they were less likely to get sick from other diseases that were common at Willowbrook and their health could be monitored closely. Some children benefited from the vaccination as well as from the better health conditions in the special facility

However, respect for persons and fairness were violated. The study provided an undue coercion because students were given a coveted spot in Willowbrook in a newer part of the facility if they participated in the research. Furthermore, parents and their children were not truly informed about the risks of the study. Also, the study could have been done with adults in the facility instead of children who are a vulnerable population.

Respect for Persons

- Children in a mental health facility can't fully understand the risks of a study they are participating in.
- The methods by which children were recruited are also questionable. Parents were unduly coerced to give their consent. For example, when the main school was closed to new admissions in 1964 due to overcrowding, parents were told there were openings in the hepatitis unit for children who could participate in the study. The public outcry over this case was largely due to the impression that parents had little choice over whether or not to participate in the research. Parents who wanted care for their children may not have had any other options.
- It is not appropriate to use a vulnerable, institutionalized population for experiments. Feeding live hepatitis virus to mentally disabled children in order to deliberately infect them does not respect them as persons.

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INTEGRATION FOR IMPACT

REPRODUCTIVE HEALTH & HIV SERVICES IN SUB-SAHARAN AFRICA

The Kenya Medical Research Institute (KEMRI) plans to host the first Integration for Impact Conference. The dates for this conference are September 12th to 14th 2012 at the Safari Park Hotel, Nairobi. The conference will be jointly co-hosted by the National AIDS & STI Control Programme (NAS COP) and the Division of Reproductive Health (DRH) (MOPHS and MOMS).

According to the Kenya Demographic Health Survey, conducted in 2008, there are three to five total births per woman. Maternal mortality is high (490/10000 live births) and the unmet need for family planning for married women is at 25%. Furthermore, the Kenya AIDS Indicator Survey, 2007 showed the national HIV prevalence rate is 7.1% with women having a prevalence of 8.7% compared to men 5.6%. This means that three out five HIV infected Kenyans are female.

Although HIV/AIDS prevention, care and treatment programs are rapidly expanding in sub-Saharan African countries, in most settings Maternal, Neonatal and Child Health (MNCH) services including Antenatal Care (ANC) and Family Planning (FP) services are offered in separate clinics from HIV care and treatment services. Initially Comprehensive Care Clinics (CCC) offered HIV care and treatment separately to avoid stigma for those infected. But in recent years, program managers and policy makers have begun to recognize the missed opportunities and inefficiencies created by these vertical approaches. Experiences in some sub-Saharan African settings suggest that integrating reproductive health (RH) and HIV treatment services may better meet the reproductive needs of this population and result in improved access to contraception for HIV-infected individuals, increased uptake of prevention of mother-to-child transmission (PMTCT) services, and earlier initiation of Anti-Retroviral Therapy (ART).

Despite lack of rigorous evidence, the integration of MNCH/FP/HIV services has advanced with support from various stakeholders. These include governments, international organizations and donors. This meeting will provide a picture of the

current state of MNCH/FP/HIV integration in sub-Saharan Africa and ensure that policy makers, program implementers, donors, and researchers are presented with the current developments, practices, and new evidence from research conducted on the integration of MNCH/FP/HIV care. RH/HIV Integration offer a rational, cost effective and efficient way of accelerating the progress towards achieving Millennium Development Goals 5 (Improving Maternal Health) and 6 (Combating HIV & AIDS, Malaria and Other Diseases).

This conference will provide an opportunity to present the findings of two important studies that have demonstrated the significance of integrating FP into HIV care and treatment, and integrating HIV services into the maternal and child health (MCH) clinics. These important studies were conducted in Nyanza province, where the HIV prevalence is 15% according to KAIS, 2007 by KEMRI in collaboration with the University of California, San Francisco (UCSF).

Conference participants

This will be a two day conference targeting about 600 participants with representatives from Ministries of Health, Non-Governmental Organizations (NGOs), academic institutions, World Health Organization (WHO), community advocates, and donor organizations such as PEPFAR, the Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID) and the Bill and Melinda Gates Foundation and members of the media. Representatives will be invited from 13 Sub Saharan countries which have high fertility and HIV rates including Kenya, Uganda, Ethiopia, Tanzania, Rwanda, Mozambique, Zambia, Malawi, South Africa, Nigeria, Cameroon, Gabon, and Equatorial Guinea.

Kenya is one of the leading countries that has implemented of MNCH/FP/HIV programs. FP/HIV integration has been the focus of much research and policy level support but documentation and evaluation of implementation experience is lacking. Therefore this conference will generate and document research findings and experiences with implementing MNCH/FP/HIV integration

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from different Sub Saharan African countries. We will also document the research priorities identified by the participants and the suggested strategies for strengthening integration policies and translating research findings into practice.

Conference Planning

Four committees were formed to aid in organizing the conference and have been holding regular meetings in preparation for the conference. There are four committees involved with the conference planning: the Steering Committee, Chaired jointly by KEMRI, NASCOP and Department of Reproductive Health (DRH); the Scientific Committee chaired by KEMRI, the Publicity Committee chaired by Population Service International (PSI) Kenya and the Logistics Committee chaired by KANCO.

Organizations represented in the Committees include:

- African Population and Health Research Center (APHRC)
- Bixby Center for Global Reproductive Health at the University of California, San Francisco
- Center for the Study of Adolescence (CSA)
- Division of Reproductive Health (DRH) of the Kenyan Ministry of Health (MOH)
- DSW Kenya
- Family Health Options Kenya (FHOK)
- Family Health International (FHI360)
- International Planned Parenthood Federation (IPPF)
- IntraHealth International
- Kenya AIDS NGOs Consortium (KANCO)
- Kenya Ministry of Medical Services
- Kenya Ministry of Public Health and Sanitation
- Kenya Medical Research Institute
- Liverpool VCT & Care Kenya (LVCT)
- National AIDS and STI Control Program (NASCOP)
- Pathfinder International
- Population Council
- PSI/Kenya
- United States Agency for International Development (USAID)
- United Nations (UN)
- World Health Organization (WHO)

Conference Sponsors

The conference is sponsored by the World Health Organization (WHO) and Bill & Melinda Gates through the University of California San Francisco (UCSF).

Scholarships

A limited number of scholarships will be provided for persons who work for Ministries of Health, and reproductive health and HIV advocates from the target counties in sub-Saharan Africa including: Kenya, Uganda, Ethiopia, Tanzania, Rwanda, Mozambique, Zambia, Malawi, South Africa, Nigeria, Cameroon, Gabon, and Equatorial Guinea.

A scholarship may comprise of the following:

- Full conference registration for 46 participants
- Return economy airfare to Kenya
- Accommodation in Kenya for up to 4 nights (at the discretion of the organizers)
- Visa application fee
- Airport transfers in Kenya

Conference agenda

The first two days will be devoted to presentations and panels discussions on key findings from research and programmatic experiences in the integration of reproductive health and HIV throughout sub-Saharan Africa.

The third day will consist of a the gathering of a smaller group of researchers, implementers and policy makers that will split into two groups. The first group will discuss strategies to advance programming in reproductive health and HIV integration and a second group of individuals will work to develop a future research agenda in reproductive health and HIV integration in sub-Saharan Africa.

For more information visit <http://integration2012.org/>

From the Editor:

The *KEMRI Bioethics Review* is eager to relay information about ethics activities that occur at KEMRI and elsewhere, on a regular basis, and encourages newsletter submissions from all members of the Institute staff. The editorial staff reserves the right to edit submitted items.

The Johns Hopkins-Fogarty African Bioethics Training Program

As part of the restructuring and strengthening of research review process, KEMRI seeks to train trainers of trainers for the institute in certificate, post graduate diploma and Master's level training at appropriate institutions. These trainers, under the guidance of the training coordinator at the ADILI Bioethics Centre will develop seminars and courses to meet the need for research ethics training for investigators and research staff at KEMRI.

The Johns Hopkins-Fogarty African Bioethics Training Program (FABTP) is a capacity development partnership in research ethics for institutions within Africa. FABTP forms annual collaborative partnerships with African institutions, in an effort to strengthen research ethics capacity within selected institutions. KEMRI has applied for this partnership programme with Dr Elizabeth Bukusi and Caroline Kithinji as the co-partnership directors.

If successful KEMRI will receive one-year training opportunity in research ethics at Johns Hopkins University (JHU) for two selected staff. Trainees will spend six months at JHU completing graduate training in research ethics, observing ethics committees, and receiving intensive mentoring. Trainees will then spend six months here in Kenya completing a funded practicum project related to research ethics. The programme also offers one month intensive training opportunities in research ethics at John Hopkins University and Georgetown University for two additional scholars, investigators, ethics committee members, or staff.



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Partners:

