KEMRI
BIOETHICS REVIEW

Volume 2, Issue 3, 2012

In this issue:

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ADILI - The KEMRI Bioethics Center
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From the Editor in Chief

I am pleased to present to you our volume two issue three of KEMRI bioethics review. KEMRI bioethics review is an initiative of ADILI task force mandated to review the research regulation system in KEMRI. The newsletter continues to provide bioethics updates and offer a platform for scientists to contribute, discuss and debate various research topics and ethical issues arising in the field of research.

Recently, there have been reported incidences of ethical misconduct - the newsprint media reported forced sterilization of HIV positive women by medical practitioners allegedly in public health facilities and also the use of anti retroviral drugs in making illegal brews. Such issues are of concern to all working in the field of health care and health research.

We seek to capture information on the provision of ARVs in Kenya. We also highlight updates from a recent first ever conference on integration for impact focusing on reproductive health and HIV services in sub Saharan Africa held between 12 -14 September 2012. The rights of all individuals to have access to health services and indeed the human right to reproduce is an ethical matter that remains a constant point of discussion and sometimes disagreement.

Dr Elizabeth Bukusi DDRT KEMRI

I kindly urge researchers to contribute by writing articles on any ethical issues of concern or interest and to respond by commenting on any articles featured in the KEMRI Bioethics review. I hope you enjoy this issue.

By Dr Elizabeth Bukusi,
Deputy Director Research & Training (DDRT), KEMRI

Call for Articles

The ***KEMRI Bioethics Review*** aims to carry information about ethics activities, initiatives and debate from the KEMRI fraternity and beyond, The editorial committee invites submissions from all members of KEMRI as well as other institutions engaged in biomedical research. Submissions should be sent to:

The KEMRI Bioethics Review
ADILI - The KEMRI Bioethics Center
P.O. Box 54840-00200, Nairobi, Kenya
Email: bioethics@kemri.org

Please note that the Editorial Committee reserves the right to edit submitted items for brevity and clarity

From the Director

Welcome to this latest issue. As is apparent from the previous issues, the Institute continues to fulfill its commitment towards improving the efficiency and expediency of the current Scientific and Ethics Review system within KEMRI. ADILI project was developed to review the existing system with recommendations for possible restructuring. An institute-wide survey conducted by ADILI project on the current system showed evidence that there is an increase in volume and complexity of protocols submitted, and this has placed a significant burden on our review system.

The ADILI task force continues to lead the restructuring process and possible setting up of an independent unit. The members are in the process of finalizing their findings and recommendations and will present this to the current board members. Establishment of an independent bioethics unit, the first of its kind in Kenya is intended to merge the Scientific and Ethics committees. This unit will monitor research quality, regulate research, provide regular updates on bioethics issues and build capacity by conducting ethics training.

The main goal of restructuring the process is to improve the safety and quality of research in KEMRI by ensuring that the review process is consistent, transparent and of high quality. We hope that the proposed restructuring will lead to improved accountability of the review process to subjects, researchers, funders, sponsors and institutions that support research, facilities in which research is conducted, and Scientific and ethics committees. Establishment of a bioethics center will facilitate provision of adequate resources for review that the Institute needs to fulfill its responsibilities.

Dr Solomon Mpoke

We anticipate that this restructuring will strengthen KEMRI to be a more competitive research site internationally notably in the field of clinical trials.

By Dr Solomon Mpoke, Director KEMRI

Proposal Review at The Center Level

All research activities carried out by the Institute's ten centers have to be vetted and approved by the Centre Scientific Committee (CSC).The main function of CSC is to scrutinize the research proposals of the center before they are forwarded to the institute's central committee. All the centers conduct monthly meetings scheduled by the center secretary and chaired by the center directors. The objective of this review is to ensure that the protocol contains all the essential elements of a good scientific proposal.

Researchers of a particular center send their proposals in soft and hard copies to the director of the center, or center committee secretary at some centers. In some centers, the secretariats receive and record proposals at two points, initially at the administration unit and thereafter at the Center Director's office while in other centers the administrative unit receive records and distributes them to reviewers. In the record book, details on when a particular proposal was received, the center number, title of proposal and the principal investigators name are captured. The center director or committee secretary identifies and assigns a proposal to two or three reviewers based on experience and specialization. The reviewers are given a maximum of seven to fourteen days depending on the center to review a proposal.

After reviewing some centers require the reviewer to forward the comments to the principal investigators while for other centers, the reviewers are asked to present their comments during the meeting. The agenda for the meeting is circulated one week before the meeting for all the centers.

At the meeting the Principal Investigator gives a 10 minute presentation of the proposal, and the two main reviewers present their comments. Other members present at the meeting are allowed to discuss the proposal and give their comments and recommendation. There are many possible recommendations that can be made from the CSC meeting. Members may decide on approval by voting while other centers by consensus that a proposal move to the KEMRI SSC with no amendments, the proposal move to SSC but with minor amendments and if poorly written, members will decide that the PI rewrite the proposal and resubmit it to the center committee.

Scientific Steering Committee Members

The Scientific Steering Committee (SSC) is composed fundamentally of all the Directors of Centers, Assistant Directors, Chairmen of Research Programme Committees, and any other persons appointed by Director of KEMRI to serve on it. The main role of SSC is to conduct scientific *r*eviews and approval of all research project proposals from Research Centers submitted by the respective Directors before they are forwarded to ERC. The Committee is also mandated to provide oversight by monitoring the progress of all research activities at Centers. The SSC through the chairperson also provides regular reports and updates to the Scientific Programmes Committee (SPC). The SPC is responsible for scrutinizing, evaluating and approving research programmes, performance and output of research projects at the Institute. Furthermore, the SSC is tasked with capacity building for all staff at the institute through continuous education programs.

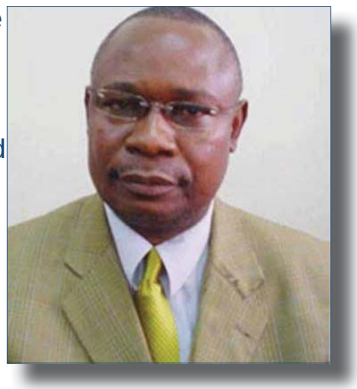
Dr. Elizabeth Bukusi

Dr. Elizabeth Bukusi is a Chief Research Officer and the Deputy Director Research and Training in KEMRI. She also chairs the Scientific Steering committee (SSC) at KEMRI and oversees the scientific regulation at KEMRI. Her main research interest focus is on sexually transmitted infections, reproductive health, and HIV prevention, care and treatment. In 1995, she established the Research Care and Treatment Program (RCTP) at the Kenya Medical Research Institute (KEMRI) in collaboration with Dr. Craig Cohen (UCSF). In addition to conducting research, the goal of the program is to enhance local capacity to conduct socio-behavioral and biomedical research and provide HIV care through training and infrastructure development. In addition to her substantial experience in conducting research in Kenya as well as providing HIV care, mentoring and training different cadres of health care and research personnel, she has a keen interest in Bioethics and the development of systems and structures for regulation of research in the Institute and the country. She has served on the MIRA (Diaphragm) study and the CAPRISA 004 DSMB study. Currently, she serves on the WHO Department of Reproductive Health Scientific Technical Advisory Board (STAG).

Dr Samuel Kariuki

Dr Samuel Kariuki is Director, Centre for Microbiology Research and a Chief Research Officer. He also co-ordinates the Medical Microbiology graduate course at ITROMID. Dr Kariuki is a Wellcome Trust Sanger Institute International Fellow, and a member of the World Health Organization Advisory Group on Integrated Surveillance of Antimicrobial Resistance. He obtained his PhD in 1997 from the Department of Medical Microbiology, University of Liverpool, UK, and since then he has continued to research on the epidemiology and molecular characterisation of enteric bacterial pathogens and antimicrobial resistance epidemiology, including invasive non-typhoid salmonellosis (NTS) and typhoid fever, which are endemic in sub-Saharan Africa. To-date, Dr Kariuki has co-authored over 70 papers in peer-reviewed journals and and has contributed immensely in three Medical Microbiology text books. He is a member of the Advisory Board of the Alliance for Prudent Use of Antibiotics (APUA) and chairs the Kenyan chapter of the Alliance. He also chairs the Global Antibiotic Resistance Partnership (GARP) Kenya Working Group.

Dr Juma Rashid



Dr Juma Rashid is the present Director of the Centre for Clinical Research at KEMRI. He received his medical and post graduate medical degrees from the University of Nairobi. His research focuses on drug development for Leshmaniasis and has served as the Project Manager for DNDi's Leishmania East Africa Platform (LEAP) in Kenya. He is a World Health Organization/Tropical Disease Research (WHO/

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TDR) certified clinical monitor and has overseen several clinical research studies in the East African region. Dr Rashid is a safety monitor for the Phase III trial of the RTS Malaria Vaccine Study. He has served on the board of several national bodies including the Drug Registration Evaluation Committee, the National Pharmacy and Therapeutics Committee and the Pharmacy and Poison's Expert Committee on Clinical Trials. From August 2007 to February2012, he served the Secretary for the Ethics Review Committee and was instrumental in the development of the current ERC Standard Operating Procedures. Dr Rashid contributes regularly to professional and scientific journals and has published several articles in peer reviewed journals.

Dr Sabah Ahmed Omar

Dr Sabah Ahmed Omar joined KEMRI in 1991 and as an Assistant Research Officer. She is currently the Center Director for Geographic Medicine Research Center (GMRC). She holds a PhD from the London School of Hygiene and Tropical Medicine where she specialized in Malaria Chemotherapy. Prior to her appointment as the Centre Director GMRC, she was the Head of the Malaria Unit at the Centre for Biotechnology Research and Development where she was successful in bidding for the malaria laboratory to be recognized as a Regional Designated Centre (RDC) in Africa. Her research interest include malaria therapeutics and human population studies investigating protection to malaria disease and prevalence of some human immune genes and other phenotypic markers. She served as an expert advisor to the World Health Organization (WHO) Steering Committee on Rapid Diagnostic Tests in Malaria for year and at the same time was the co-coordinator of the Antimalarial Drug Resistance Working Group on 'Intermittent Preventive Treatment in Infants (IPTi) Consortium in Africa. She is the lead investigator in malaria for the operational research arm of the East Africa Health Research Laboratory Networking Project (EAPHLNP) funded by the World Bank. Other responsibilities include: member of the Institute on Policy Analysis and Research organization (IPAR), and committee member of the Research Technical Working group of the Division of Malaria Control Programme. She has served for nine years as a Council Member, Moi University Council and is currently Vice Chair of Council of South Eastern University College, Constituent College of Nairobi University, this being her recent appointment.

Dr Patrick Anyango Orege

Dr. Patrick Anyango Orege graduated from the University of Nairobi with MBchB in 1978, obtained Master of Public Health (MPH) in epidemiology from Harvard School of Public Health, USA in 1983 and a PhD in Tropical Medicine (London University) in 1992. He also holds a diploma from the London School of Hygiene and Tropical Medicine and has received several certificates in leprosy control, dermatology, tuberculosis control, and epidemiology from various local and other institutions in USA, Japan, Korea, Ethiopia, Philippines among others. He joined Kenya Medical Research Institute in 1981 as an Assistant Research Officer, and progressed to attain the rank of Chief Research Officer/ Deputy Director (Research and Development) in 1998. He has been a member of the Scientific Steering Committee (SSC) since its inception in 1986 and has seen SSC grow to its present position. Between the years 1998 to November 2000, he served as the chair of SSC. Between 2000 and 2006, he was seconded to the National AIDS Control Council (NACC) where he was a founder member and was appointed the Director of NACC. In 2007 he returned to KEMRI. While back at KEMRI, he acted both as Deputy Director (Finance and Administration) and as Deputy Director (Research and Development). To date, Dr. Orege continues to serve as a member of the SSC.

Dr. Michael Kiptoo

Dr. Michael Kiptoo is the Head of KEMRI Graduate School of Health Sciences and Graduate program Coordinator at the Institute of Tropical Medicine and Infectious Diseases (ITROMID), which is a joint postgraduate program between KEMRI and Jomo Kenyatta University of Agriculture and Technology.He joined Kenya Medical Research Institute at the

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Centre for Virus Research as an Assistant Research Officer in 1998. In 1999, Dr. Kiptoo was awarded a scholarship by Japan International Cooperation Agency (JICA) to train in HIV culture systems and antigen purification for six months in Japan. In 2001, he enrolled for postgraduate training in Immunology at Kenyatta University where he graduated with M.Sc. (Immunology) degree in 2003 and obtained his PhD (Immunology) degree in 2008 from Kenyatta University. In 2009, he was appointed to head the HIV/AIDS section of the CVR until 2011 when he was appointed to the position of Graduate Program Coordinator ITROMID. Dr. Kiptoo has been serving at the Centre Scientific Steering Committee since he joined KEMRI. He has been a member of the Scientific Steering Committee since 2009 in his capacity as the acting Graduate Program Coordinator ITROMID. Dr. Kiptoo has also served in other secretariat committees including: publications, library and information, and Infectious Diseases Program. He is also a member of the Community Liaison Committee, Enhanced level 3 laboratories, University of Nairobi Institute of Tropical and Infectious Diseases (UNITID). In this capacity, he is currently supervising several masters and doctorate students and still actively involved in HIV research. He has published 14 manuscripts in peer reviewed journals and has co-authored a book titled “Recent Translational Research in HIV/AIDS”.

Dr Charles Mwandawiro

Dr Charles Mwandawiro joined KEMRI in February 1990 as an Assistant Research Officer and rose through the ranks to his current position as a Chief Research Officer in 2006. Administratively, he has served as Director, Eastern & Southern Africa Centre of International Parasite Control (ESACIPAC) from 2003 to 2009 when he was appointed Acting Deputy Director, Administration & Finance. In 2011, he was promoted to his current administrative position of Assistant Director, Partnership & Collaboration. Since 2003 to date, he is the Unit Lecturer (Medical Entomology and Parasitology), at ITROMID. Dr. Mwandawiro holds a PhD in Medical Entomology from the Institute of Tropical Medicine, Nagasaki University, Japan. He has served as a World Health Organization (WHO) as a Temporary Adviser on specific assignments, projects and workshops; of note was a meeting held in Lusaka to develop guidelines on integrated parasite control in 2006. As a medical entomologist and parasitologist, he has conducted research on several diseases topics such as Japanese encephalitis, Lymphatic Filariasis, Soil-transmitted helminthes, Malaria and Leishmaniasis with main focus on disease control and prevention. His current area of interest is school health and nutrition. He is the Principal Investigator (PI) for the National Deworming Programme (M&E) component and also the Home Grown School Feeding Project, a project looking at the impact of using locally produced food on the health, nutrition and educational outcomes in school children as well as on the small-scale farmers (income and socio-economic conditions).

Dr Christine Wasunna

Dr Christine Wasunna serves both as Acting secretary ERC and assistant secretary SSC. In this capacity, she provides ongoing expert ethics consultation to all researchers at KEMRI and KEMRI collaborators. 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. 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

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the development and implementation of a be spoke 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 thus 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 Poison's Board, Kenya – the National Drug Regulatory Authority funded by the EDTCP. She contributes regularly to professional and scientific articles.

Dr Gerald M. Mkoji

Gerald M. Mkoji, PhD, Chief Research Officer & Assistant Director (Training & Communication), is a parasitologist with expertise in schistosomiasis and other snail-borne parasitic infections, with a special interest in epidemiology, control strategies, molecular diagnostics, and snail biology. Besides his responsibilities as a research scientist, he teaches and mentors graduate students and younger colleagues, and has had several years, management experience. Dr. Mkoji is a member of the KEMRI Scientific Steering Committee (SSC), and has previously served as Director, Centre for Biotechnology Research and Development, KEMRI (1999-2011), and Ag. Deputy Director (Research & Training), KEMRI (2009-2011). In addition, he has served as acting chairman of KEMRI's Scientific Steering Committee (2009-2011), Secretary,Scientific Steering Committee (1999-2004), Secretary, KEMRI's Publications Committee (1995-1997), and as Chair, KEMRI's Animal Care and Use Committee (1994-1997). He is currently, Chair, KEMRI's Intellectual Property Management and Technology Transfer Committee, and member of KEMRI's Scientific and Ethical Review (ADILI) Task Force.

Dr Monique Wasunna

Dr Monique Wasunna is the Assistant Director, Research at KEMRI. She has served as Director Centre for Clinical Research from 1996 to August 2007 and more recently, was the Director KEMRI in an acting capacity from August 2007 to May 2009. Currently, Dr. Wasunna heads the Drugs for Neglected Diseases Initiative (DNDi) Africa. DNDi is a not for- profit drug development organization based in Geneva. DNDi Africa office is housed within KEMRI. Dr Wasunna is a physician and an infectious disease and tropical medicine specialist. She holds a Bachelor of Medicine and Bachelor of Surgery degree from the University of Nairobi. Her postgraduate training in medicine was at the London School of Hygiene and Tropical Medicine, University of London where she obtained an MSc and a PhD in medicine and a diploma in Tropical Medicine and Hygiene from the Royal College of Physicians of London. She is a Fellow of the Royal Society of Tropical Medicine and Hygiene, and member of the Kenya Medical Association and Kenya Association of Physicians. Dr. Wasunna's research interest is primarily focused on clinical trials in visceral leishmaniasis, malaria and HIV. From 2003 to date, Dr. Wasunna has been a member of the Leishmaniasis East Africa Platform (LEAP). LEAP is a clinical research platform that brings together scientists and institutions in East Africa to develop clinical trial capacity to bring new treatment options to neglected visceral leishmaniasis patients in the region. Dr. Wasunna co-ordinates all LEAP activities in the region supported by DNDi. She has published over 60 manuscripts in peer reviewed journals.

Dr Yeri Kombe

Dr Yeri Kombe joined KEMRI in 1986 and is currently Chief Research Officer and the Director of the Center for Public Health Research (CPHR). He holds Medical and Public Health degrees from University of Nairobi and a PhD from the London School of Hygiene and Tropical Medicine. Dr Kombe is involved in population based research in communicable diseases epidemiology, nutritional deficiencies particularly micronutrient and health systems Research.

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He has participated in different roles in the design, implementation and dissemination of various research undertaking at national and international levels. He also teaches and mentors students in various universities in Epidemiology, health systems research and other public health related disciplines at postgraduate and doctoral levels. Dr. Kombe collaborates widely nationally and internationally with higher institutions of learning, non-governmental organizations and other institutions. Currently, he is involved in the National Micronutrient Survey where he serves as the Principal Investigator. He has published widely in the same disciplines.

Dr Evans Amukoye

Dr Evans Amukoye is currently Principal Research Officer and Director of Center for Respiratory Disease Research. He holds a medical and postgraduate degree in Pediatrics from University of Nairobi and is a clinical fellow of Institutee of Child Health, UK. He also holds a PhD in Pulmonology from University of Saporo, Japan. Dr Amukoye is an executive committee member of the Pan-African Thoracic Society. He has carried out various research studies on malaria, tuberculosis diagnosis and chemotherapy and opportunistic infections. He has authored 18 publications in peer reviewed journals and has supervised one PhD student and six masters' students. Dr Amukoye is currently supporting five research projects on respiratory diseases. His career objective is to assist in building a critical mass of scientists capable of doing quality research that will provide solutions to combat infectious and non infectious respiratory illnesses and to cross pollinate with scientists across the world for the mutual benefit of mankind.

Dr Sammy Njenga

Dr Sammy M. Njenga is the current Centre Director of Eastern and Southern Africa Centre of International Parasite Control (ESACIPAC) at Kenya Medical Research Institute (KEMRI). He is also the current Secretary of the KEMRI Scientific Steering Committee (SSC). Dr Njenga has a PhD in Health research Parasitology from the Liverpool School of Tropical Medicine, UK. He has successfully competed for several research grants on Neglected Tropical Diseases (NTDs) including a prestigious postdoctoral fellowship by European Foundations Initiative for NTDs (EFINTD) to conduct research on schistosomiasis, soil-transmitted helminths, and lymphatic filariasis in Kwale district, Coastal Kenya. Dr Njenga is often invited by World Health Organization (WHO) as Temporary Advisor at NTDs technical consultative meetings. He has published widely in several peer-reviewed journals.

Dr Elijah Songok

Dr Elijah Songok joined KEMRI 1990 as an assistant research officer (HIV/AIDS) and has since been promoted of Principal Research Officer and HIV/AIDS Specialist. Dr Songok holds a PhD in virology from Kanazawa University, Japan and post doctorate in medical microbiology, from the University of Manitoba. He is the chairperson of the Infectious and Parasitic Diseases Research Program, KEMRI. Dr. Songok is consultant Virologist in Nyumbani Children's home, Nairobi. He is also Assistant Professor, in the department of Medical Microbiology, University of Manitoba, Canada and Adjunct Professor in the faculty of Medicine, Kanazawa University, Kanazawa, Japan. Dr.Songok's research focuses on HIV/AIDS where he has made immense scientific contribution to the field and has won numerous awards. He has co-authored 30 peer reviewed journals and supervised 3 PhD students and 10 master's students.

EXCERPTS FROM THE INTEGRATION FOR IMPACT CONFERENCE

Reducing HIV-related maternal mortality through community systems strengthening

By Ann Noon -The International HIV/AIDS Allianace

HIV accounts for more than 60,000 maternal deaths every year. Because Kenya, South Sudan, Uganda and Zambia all have a particularly high burden of HIV and maternal mortality, the International HIV/AIDS Alliance - together with its linking organizations in these countries, including KANCO in Kenya - implemented a 12-month programme during 2011. This was funded by the UK Department for International Development (DFID) to reduce HIV-related maternal mortality and improve health outcomes, in particular for mothers living with HIV and their children.

Aiming to address both the demand and supply side of health systems, the initiative sought to increase demand for health care services by pregnant women, including those living with HIV and their male partners, as well as strengthen referral systems and follow up through community mobilisation and awareness raising activities. In a generalized epidemic, HIV-positive mothers are four to eight times more likely to die during childbirth. But the heightened awareness generated by this programme has seen an uptake in prevention of mother-to-child transmission services and ante-natal care, and more women opting to deliver at health care facilities. This has substantially increased their chances of delivering their baby safely and HIV-free.

When prevention of mother-to-child transmission services are used, the chance of a baby born to an HIV-positive mother becoming infected is less than 1%. Without these services there is a 20-45% chance.Through the strengthening of community systems, in total more than 125,000 men, women, young people, people living with HIV, health care workers, traditional birth attendants, community and national leaders, decision makers and religious leaders were reached with information on the effects of HIV on maternal and child mortality, key danger signs during pregnancy, and the importance of giving birth at health facilities to improve the chance of survival for mother and/or baby if complications arise.

The programme also saw an increase in the number of pregnant women referred to available services – some 80,000 altogether - as well as in the number of women attending antenatal care and opting to deliver at health care facilities. In Kenya and Zambia, key informants cited more male involvement in supporting female partners through the pregnancy journey as a result of the programme. Interestingly, health care workers reported that when a man did accompany his female partner to antenatal care services, they were usually very willing to have an HIV test when this was offered, facilitating sero-status disclosure between couples.

The Integration for Impact conference is an important regional forum to specifically bring together SRH and HIV practitioners to ensure that people living with HIV and hardest to reach populations' needs are addressed through a comprehensive approach. As we move towards a post-MDG era, strengthening linkages between SRH and HIV will provide a valuable example of how integration increases efficiencies, maximises investment and above all makes sense for improving individuals' health and quality of life.

According to Felicia Wong, the International HIV/AIDS Alliance's policy advisor: "We need to join up safe family planning and HIV services in order to make real headway in reaching vulnerable and marginalised populations and respond more fully to their needs. We also need to be mindful of the fact that integration will only work if countries really own their response and harness the power of community mobilisation which we have seen used so effectively in the HIV response."She went on to say: "Raising awareness with communities on the types of health care services they have a right to receive strengthens national advocacy efforts, and leads to increased demand for services. The reality on the ground is that in many communities these services are of poor quality or may not even exist. It's vital that further advocacy and pressure is placed on governments to address the fundamental lack of primary health care services through increased funding, systems strengthening and increased human resources."

The writer is the media manager of The International HIV/AIDS Alliance (The Alliance) Kenya AIDS NGOs Consortium is the Linking Organization of the Alliance

The African King of Condoms

By Protus Onyango

His theatrics with the condom tickled many participants at the Integration for Impact Reproductive Health & HIV Services in Sub-Saharan Africa.He surprised the panelists at the meeting when, at the end of the morning session, he requested for five minutes to talk about condoms. Then Stanley Ngara sauntered on the podium and the audience burst into laughter when they saw him wearing a hat made of condoms. He promptly introduced himself as the African King of Condoms and proceeded to enthrall the guests with his practical lessons on how to properly use both male and female condoms.

Ngara proudly announced that he is also the first African to come up with a vaginal model which he uses to teach the masses on how to use condoms. He said that it his experience with condoms that made him seek for employment in an organization associated with them. That was ten years ago, when Stanley Ngara secured employment at Liverpool Voluntary Counselling and Testing Centre (LVCT) in Nairobi, Kenya.

As the person in charge of community mobilization, Ngara watched people die of HIV/AIDS and other sexually transmitted diseases."I had on many occasions accompanied my pals to clubs and realized that condoms were associated with promiscuity and people were not willing to be seen taking them. People thought that condoms were only for prostitutes," Mr Ngara said. He noted that condoms were hidden in dispensers in toilets so that people can pick them up in secrecy. That is why he embarked on popularizing the condom.

"I was motivated to come up with new approaches on how to promote use of condoms because people were just doing the same thing all the time and letting people die," Mr Ngara said.He was motivated by his boss, Dr Nduku Kilonzo who believes in innovation and likes people to try out new things.His breakthrough came when he invented the vaginal model and decided to promote the use of condoms in a new way."Once I came up with the model, all our 100 offices got one each and now I embarked on my job is to distribute condoms and demonstrate how to use them. I target the gay, lesbians, sex workers and couples," he said.

Ngara's crusade has taken him to many towns in Kenya and he says he has achieved a lot in a short time."I have been able to break the negative attitude and stigma associated with use of condoms. I distribute 10, 000 condoms daily to people of different cadres," Ngara said.He wants

Photo credit/source: www.keycorrespondents.org/2012/09/19/stanley-the-african-king-of-condoms/

The King of condom decked out in his royal regalia

people to understand that the use of condoms enhances relationships, promotes safe sex, prolongs sex and reduces anxiety."I have walked into garages, bars, matatu terminus and even houses and talk to people about condoms. Now I am called the Condom Master, Mr Condom or King of Condom," he said.

'The King' is now focused on the next stage of his campaign. "I want people to treat the condom the way they would car keys, wallets or clothes. I want condoms to become part of our sexual life, where before we carry on where and when to have sex, we must ensure that we have the condoms," Ngara said. His message to people is, "Condoms promote sex, but are not the answer for not contracting HIV. It is our responsibility to protect ourselves and others to reduce new infections. But our first step is to know our status."

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ETHICS UPDATE:
Ethics of Antiretroviral Access in Kenya

On 21st August a local television network aired a harrowing documentary titled 'Sisters of death'. The documentary was filmed in Korogocho slums, located within Kariobangi in Nairobi. The reporters highlighted that HIV positive women on anti- retroviral therapy were selling their life saving medication as a source of income. The buyers were women whose trade is brewing cheap illicit alcohol for the local residents.

ARVs are used to prolong lives by suppressing the virus in people living with HIV. This documentary highlighted a new use, for the drugs; an essential ingredient in alcohol brew. The HIV positive women on ARVs who were interviewed complained of experiencing side effects such as drowsiness after taking the drugs; this aroused the brewers'curiosity. They decided to test whether adding a tablet would enhance the potency of their illicit brew and to their surprise their customers favored the new concoction.

The demand for the new brew was at an all-time high. The brewers targeted HIV positive women on ARVs and offered them some money in exchange for a few tablets from their monthly supply. One of the HIV positive women interviewed was enrolled in two different programs as a way of ensuring that she had an adequate supply of drugs for personal use and for commercial use. Another woman had stopped taking the drugs but continued collecting her monthly doses to make money.

Seven tablets are bought at the price of KSh. 250, this is considered a lot of money where majority of the population live under a dollar (KSh. 80) a day. Given the circumstances above is it ethical for the government to intervene and stop issuing ARVs to these women?

According to the National AIDS and STI Control Programme (NASCOP), an estimated 430,000 HIV infected people in Kenya are on treatment. However, this is only 28% of the HIV infected population in need of treatment. Over the years, ARVs have improved the livelihood of individuals infected with HIV as is evident from the declining prevalence of 6.3% nationally; by preventing weakening of the immune system and preventing organ damage caused by HIVvirus [1]. Furthermore, several clinical studies conducted in multi-site countries have shown evidence that ART reduces acquisition. Several multi-country, multi-site clinical studies have shown evidence that ART reduces acquisition of HIV amongst HIV discordant couples. Therefore, increased availability of subsidized ARV treatment in low income countries has benefited and saved lives. However the ethical and equity issues surrounding provision of ART to people living with HIV in Kenya need to be addressed.

ARVs are provided free in the country, but stakeholders are now faced with the dilemma of whether to channel funds to providing these precious commodities if the recipients are misusing them. Consequently, numerous questions come to mind: Should NASCOP ration access to ART? Should clients be vetted before accessing ART? Should the Ministry of Health implement Direct Observed Therapy (DOT) to ensure that HIV positive clients adhere to their medication? Who will pay for these services if DOT is implemented? In order to make these decisions key ethical principles need to be considered at every stage of the decision making process.

Kenya's mode of rationing is almost fully implicit due to few fully defined modes. There are no clear measures currently to ration access of ARVs in Kenya Those who are educated and consent to be tested are advantaged to access treatment because they know their status. Absence of any other requirement has also led to facilities treating each one who is clinically eligible, until the supply of drugs, diagnostics or proficiency is exhausted[6].

The incident at Korogocho may not be sufficient to be used as a basis of rationing Anti-AIDS access, nevertheless it should stir concerned authorities to do further inquiry. The story highlights the kind of flaws and challenges yet to be addressed in ART provision in Kenya. Perhaps there is no clear monitoring policy or the monitoring system is defunct. Further Research

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should be conducted to establish the level of non adherence and defaulting surrounding anti retroviral therapy. As much as rationing is eminent globally due to economical challenges, decisions on rationing in Kenya will still have to be heavily backed up by sufficient evidence of wide spread misuse of this kind of medication. It would be ethically outrageous to ration and withhold the drugs from HIV positive individuals based on a single incident of misbehavior.

As the government continues to widen access, it is essential to focus on how to improve efficiency and success of treatment, bearing in mind challenges ahead as AIDS donors plan exit. Supply of HAART should be rationalized using the principle of Justice, more particularly distributive Justice and equity. The Government must find out who is more deserving of the drugs, who are more in need, who are heavily burdened with poverty, ignorance and disease. These are the ones that would require ARVs; this research needs to be carried out nationally. This information already exists and can be obtained from government and non-governmental organization reports. Perhaps a finger-printing data base should be in place to prevent co-enrollment into care programs. However, for this to be realized informed consent need to be sought from the patients and the patient identifiers remain confidential.

There is enough evidence that adherence to treatment regimens is the most essential determinant of the benefit of ART at the personal patient level. One way to progress the accomplishment of a comprehensive treatment program, while equally limiting access, could for that reason be to restrict therapy to patients who have been evaluated to possess the ability and readiness to adhere or who exhibit high adherence after initiating remedy [8, 9].

The level to which ART can curb HIV transmission is still debatable in literature [10]. If treatment decreases the chance of transmission by suppressing viral load, then a public health argument can be made the government to consider populations such as commercial sex workers, truck drivers, or intravenous drug users. Governments can also intentionally create eligibility requirements that result in rationing, without specifying particular target populations.

Conclusion

Efforts of the government in scaling up antiretroviral treatment should be lauded. Tremendous progress has been made considering in 2003 only 7,000 patients countrywide were receiving ART mainly from the private sector, but by the end of July 2008, over 230,000 patients had benefited from the provision of HIV care and treatment [11]. This rapid scale up of the ART program, has significantly reduced HIV related morbidity and mortality.

With prevalence being estimated at 1.5 million people, and only 430,000 currently on ART (www.who.int) , provision of HAART scale up is urgent. However, recent developments indicate that funding from developed countries will be cut and developing countries should strategize on ways of becoming self-sufficient(12). The reality is that it is going to be a struggle for Kenya to adequately sustain such programmes. Clear policy in monitoring access to treatment will ensure adequate supply of ART in high priority areas as well as evaluation of HAART. [13]

Much can be argued ethically for or against any form of rationing but when sustainability and effectiveness of treatment is at stake, big decisions need to be made. Because access to ARVs is a highly sensitive matter as we are dealing with human lives, the choice and basis of rationing systems are vital and must be deeply considered.

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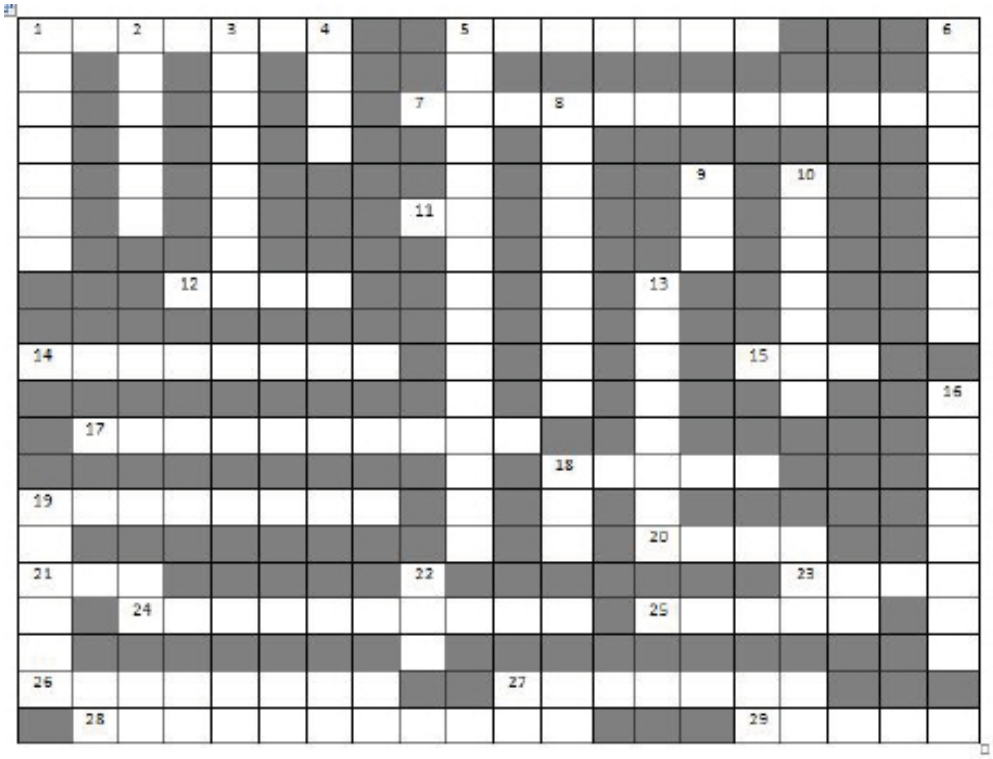
Wit Corner: Ethics Crossword Puzzle

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



CLUES:

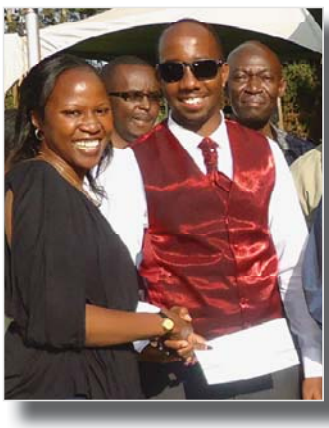
Down

1. The influential 1974 Report of the National Commission that defined the ethical principles that should inform research involving humans.
2. The branch of philosophy that deals with questions of morality and human rights
3. The ethics guidelines by the World Medical Association were first declared in the Finnish city of?
4. The principle of non-maleficence aims to minimize what?
5. Keeping data private
6. Code developed after World War II
8. A type of ethical review for studies that present no more than minimal risk
9. Code of Federal Regulations (abbr)
10. A major ethical principle that includes the right to fair treatment
13. A group that is considered vulnerable
16. Adequate consent to participate in a study requires that participation is voluntary and the participants are fully_____about the risks and benefits of the study
18. Food and Drug Administration (abbr)
19. Informal agreement to participate in a study by a minor
22. Institutional review board (abbr)

Across

1. The 1966 report that pointed out unethical research with humans published in well-respected research journals
5. A participant's permission to be in the study
7. A person qualified by education, training and experience to conduct human research
11. Numbers used in place of names to protect individual identities (abbr.)
12. The authorship granted upon one who does not strictly qualify for it.
14. A written document reviewed by an ethics committee that outlines the planned research
15. Good Clinical Practice (abbr)
17. Potential research subjects with diminished autonomy
18. Documents used to record consent are called informed consent_____
19. A major ethical principle that relates to respect for persons
20. The Government body that issues licenses for conducting research in Kenya (abbr.)
21. The KEMRI committee that conducts scientific review of research proposals
23. A fundamental right for study participants is freedom from_____
24. Appropriation of someone's ideas without proper credit
25. The Council for International Organizations of Medical Sciences (abbr)
26. The unethical experimental study on syphilis among black men in Alabama
27. The unintended effect of an intervention is an _____ event
28. A major ethical principle concerning maximizing the benefits of research
29. Someone who contributes substantially to a research project but is left uncredited is _____author.

Winners from the last issue:



Mr.Eddie Gitonga Receives His prize from Dr Stella Njuguna

Ms Caroline receives her prize from Dr Elizabeth Bukusi, Deputy Director KEMRI

UPDATE: Review and Restructuring of Research Regulatory System in KEMRI

Two years ago, the ADILI task force was appointed to spearhead the process of restructuring the current system of research regulation at KEMRI. It is evident that the current regulatory system is overwhelmed by the increasing volume of protocols submitted for review.

The ADILI project is on course towards improving communication between the researchers and research administrators by adopting a fully electronic system. This system will be implemented for electronic protocol submission and tracking the progress of regulatory review at the various stages. In addition, an independent bioethics unit will be established and its functions will include capacity building by conducting regular bioethics training to all cadres of staff as well as an administrative role in research within the Institute. The taskforce is optimistic that once the set objectives are realized, significant improvements on the current system will be evident.

The ADILI project is on course towards improving communication between the researchers and research administrators by adopting a fully electronic system.

On 2nd of September, members of the scientific steering committee with the ADILI task force team held a team building and writing retreat at KCB leadership center. During this retreat the report from by ADILI task force was presented to the SSC members and deliberation on the report commenced.

The SSC members endorsed most recommendations of the report with some minor suggestions on the implementation process. The task force is currently finalizing the policy paper which will be presented to SSC and ERC for consensus prior to presenting to the KEMRI Board of Management early next year. Ultimately the Board will make the final decision on the way forward, based on the recommendations of the ADILI task force.

Acknowledgements

ADILI-The KEMRI Bioethics Center is a project funded by the following grants:

- A Capacity Building Grant for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards from the European and Developing Country Clinical Partnership (EDCTP), Project Code: CB.2010.41302.016
- International Research Ethics Networks for Southern Africa (IRENSA), a Fogarty International center supplementary grant through the University of Cape Town (UCT), Contract No. 3R25TW006057-08S2 and;
- NIH stimulus grant via the University of California, San Francisco (UCSF), Grant No. 1S07TW008843-01

We would like to express our sincere gratitude to all of our collaborators and partners. Your support will enable capacity building for bioethics within KEMRI.

Partners: