



The Republic of Uganda

Uganda Virus  
Research Institute



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**WHAT NEXT?** MRC's Dr Eugene Ruzagira (L), IAVI Regional Representative Dr Sam Kalibala (2<sup>nd</sup> L), Dr Fiona Kalinda (in black) and UVRI-IAVI Principal Investigator, Dr Pontiano Kaleebu (M) ponder during the parliamentary dialogue. In the immediate background are some of the MPs who attended.

## Parliamentarians Pledge Full Support for HIV Vaccine Research in Uganda

"An ounce of prevention is better than a tonne of cure." These were the exact words of Hon Dr Elioda Tumwesigye, Chairperson of the Parliamentary HIV/AIDS Committee at a recent Parliamentary Dialogue on HIV Vaccine Research held at Kabira Country Club in Kampala.

The Uganda AIDS Commission (UAC), the Parliamentary Committee on HIV/AIDS in collaboration with the UVRI-IAVI HIV Vaccine Program organized this one-day dialogue to

brief Members of Parliament (MPs) in Uganda about the progress in HIV Vaccine research and other new prevention technologies. It was also aimed at emphasizing the MPs' role in promoting a supportive policy environment and infrastructure surrounding HIV Vaccine development and eventual access in Uganda.

More than 100 delegates attended the dialogue, including 24 MPs. Other participants at this meeting included; Parliament Staff on the HIV/AIDS Committee, Chairpersons of Key Parliamentary Committees, Partners in HIV Vaccine Research and Key UN and Bilateral organizations. The Minister of Health, Hon Dr Stephen Mallinga was Chief Guest.

On advocacy and policy implications, some economic/political barriers to HIV vaccine development like limited global spending and limited science capacity in developing countries were identified. The need for community mobilization, political and private sector support were also emphasized.

*"The Ministry of Health pledges full support towards HIV vaccine research and we expect that Uganda will again take lead in the search for the much-needed HIV vaccine," Dr Stephen Mallinga.*

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# From the EDITOR'S DESK

Angelo Kaggwa



Dear Readers,  
We believe that 2007 has begun on a good note for you all.

HIV vaccine research had many milestones in the previous year and we're looking at 2007 with even more optimism. In 2006, UVRI-IAVI HIV Vaccine Program launched a Phase II vaccine trial. The Program, together with key partners reviewed and launched the Uganda Guidelines for HIV/AIDS Vaccine Research. It also formed a Gender Advisory Committee and held key dialogues aimed at forwarding the HIV vaccine agenda, including those with religious leaders, gender advocates, the media and even Members of Parliament. The Site had a Pre-Site initiation visit for a new trial - V002. A great year 2006 was, but still, with some challenges! A lot is yet to be done to increase women participation in trials and there still exists scientific, economic and policy obstacles that limit progress in HIV vaccine development.

In this issue, you'll find Parliament's commitment to the search for the HIV vaccine. There is an insight on the recently ended male circumcision trials in Kisumu and Rakai. You'll also find out how advanced Good Clinical Practice takes the quality of research to another level, plus some recommendations to the increasing gender disparities in HIV vaccine research.

We continue to highly regard our partnership with the Uganda Government, our funders, stakeholders, the medical fraternity, the communities from which we recruit trial volunteers and all those involved in the fight against HIV/AIDS.

Together we will find a lasting solution to HIV/AIDS ☐

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## EDITORIAL BOARD

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Tel: 0414-322 377/8
7. Dr Fiona Kalinda  
Tel: 0414-322 377/8

## DESIGN AND PRINT

visualeffects ltd  
u4 printers arcade  
29a-29b nasser road  
p.o. box 8977 kampala - uganda  
tel: +256 312 264423  
e-mail: info@visualeffects.co.ug



For further information or to request additional copies please contact:

Angelo Kaggwa  
P. O. Box 49, Entebbe, Uganda  
Tel: 0414 - 322 377/8  
E-mail: akaggwa@iavi.org  
www.iavi.org/uganda

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## ...MPs Pledge

The dialogue's key discussants included Hon Dr Elioda Tumwesigye, UAC's Dr Kihumuro Apuuli, African AIDS Vaccine Program's Dr Pontiano Kaleebu, who is also UVRI-IAVI's Principal Investigator (PI) and Head of the MRC/UVRI Basic Sciences Program. The others were Prof Fred Wabwire, PI-MUWRP, Prof Francis Mmiro, PI-MUHJU, Dr Sam Kalibala, IAVI's Regional Representative, MRC-Masaka's Dr Eugene Ruzagira and UVRI-IAVI's Dr Fiona Kalinda.

Among the key issues raised at the dialogue were: the need for MPs to incorporate New Prevention Technologies like male circumcision, microbicides, an appropriate female condom and vaccines into their priority advocacy areas; the need for universal HIV testing; renewed political leadership for HIV/AIDS prevention at all levels; putting in place mechanisms and institutions to ensure that politicians at all levels are involved in the HIV vaccine development process; and the importance of women empowerment.



ATTENTIVE: Hon. Dr Elioda Tumwesigye, Dr Stephen Malinga, Bishop Barnabas Halem 'Imana and Prof. Fred Wabwire at the dialogue.

Hon Tumwesigye's message, "A woman should never need her partner's consent to protect herself," was one of the day's major highlights.

It was recommended that Parliament honours key vaccine researchers and that MPs pass bills favourable to HIV vaccine research. The MPs were also requested to prioritize advocacy for research, to actively be involved in these studies and to enact legislations that promote equality. The researchers on their part

were encouraged to utilise the funds that government is availing.

"The Ministry of Health pledges full support towards HIV vaccine research and we expect that Uganda will again take lead in the search for the much-needed HIV vaccine," revealed Dr Stephen Malinga.

The legislators too pledged their total support toward HIV vaccine development and called on the researchers to involve them in their activities all the way so that they can make research a priority component of their deliberations.

They also pledged to ensure that when the vaccine is eventually discovered, it will be accessible to all that need it. In all, the delegates concurred that there is need to continue with advocacy and supportive policies for scaling up HIV prevention and treatment, and that New Prevention Technologies will complement existing prevention methods and can move the world toward a long-term sustainable solution to HIV/AIDS. □

## Adult Male Circumcision Significantly Reduces Risk of Acquiring HIV

### Trials in Kenya and Uganda Stopped Early

The two National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), trials that were going on in Kisumu, Kenya and Rakai, Uganda, were ended early because an interim review of trial data revealed that medically performed circumcision significantly reduces a man's risk of acquiring HIV through heterosexual intercourse. The trials of 2,784 and 4,996 HIV-negative men in Kisumu and Rakai showed a 53 and 48 percent reduction of HIV acquisition in circumcised men relative to uncircumcised men in the two areas respectively.

"These findings are of great interest to public health policy makers who are developing and implementing comprehensive HIV prevention programs," says NIH Director Elias A. Zerhouni, M.D. "Male circumcision performed safely in a medical environment complements other HIV prevention strategies and could

*"Male circumcision performed safely in a medical environment complements other HIV prevention strategies and could lessen the burden of HIV/AIDS..." NIH Director Elias A. Zerhouni*

lessen the burden of HIV/AIDS, especially in countries in sub-Saharan Africa where, according to the 2006 estimates from

UNAIDS, 2.8 million new infections occurred in a single year."

"Many studies have suggested that male circumcision plays a role in protecting against HIV acquisition," notes NIAID Director Anthony S. Fauci, M.D. "We now have confirmation – from large, carefully controlled, randomized clinical trials – showing definitively that medically performed circumcision can significantly lower the risk of adult males contracting HIV through heterosexual intercourse. While the initial benefit will be fewer HIV infections in men, ultimately adult male circumcision could lead to fewer infections in women in those areas of the world where HIV is spread primarily through heterosexual intercourse."

Still, circumcision is only part of a broader HIV prevention strategy that includes limiting the number of sexual partners

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Community Advisory Board members put heads together to draft their 2007 work plan.

## CABs Reflect On Past, Plan for their Future at Jinja Retreat

By Edward Ssendawula Kimera, Rakai Health Sciences Program

Community Advisory Board (CAB) members, who are “the eyes and ears of the researcher” held a retreat themed “Reflecting on our Past, Planning for the future” from 12 to 13 October 2006 at Hotel Triangle in Jinja.

Its objective was to provide CAB members an opportunity to critically analyze their contribution especially in community involvement, support, education and volunteer recruitment. The retreat helped to review CAB performance while looking at their strengths, weaknesses, opportunities, threats and challenges (SWOT). The different CABs in Uganda also shared their experiences.

*The CAB is also committed to creating more awareness in the communities through advocacy, keeping the fire burning, while managing community expectations.*

CAB Chairpersons and Liaisons from the Makerere University Walter reed Project (MUWRP), Makerere University Johns Hopkins University Project (MUJHU), Medical research Council (MRC) and the Rakai Health Sciences Program (RHSP) also attended the retreat.

A SWOT analysis session intended to make CAB members appreciate the resources within them and then foster their support to the HIV vaccine development process was also included. According to the analysis, the CAB has succeeded in getting volunteers for the different trials and feasibility studies, has represented at different national and international conferences, is recognized as an important body by researchers, has addressed some of the community expectations and communities are more aware of vaccine research and development and has linked communities to researchers, among other things. The CAB is also committed to creating more awareness in the communities through advocacy, keeping the fire burning, while managing community expectations.

The UVRI-IAVI CAB made a work plan for 2007 and renewed their commitment to HIV vaccine research. The CAB members also got better skills in communication and stress management.

The workshop presentations emphasized the need for participants to mobilize all stakeholders i.e. the community, politicians, private sector, religious institutions, mass media, parliamentarians among others to actively support the vaccine development process.

Ultimately, the success and good outcomes of this retreat were due to a number of materials and the contribution of the different facilitators. A stress management session was the most relevant and timely session, one that the CAB members believe will not only help them as they advocate for and promote vaccine literacy, but also in their daily lives - at home and at work

▶ continued from pg 3

and using condoms during intercourse. “It is critical to emphasize that these clinical trials demonstrated that medical circumcision is safe and effective when the procedure is performed by medically trained professionals and when patients receive appropriate care during the healing period following surgery,” notes Dr. Fauci.

Researchers have noted significant variations in HIV prevalence that seemed, at least in certain African and Asian countries, to be associated with levels of male circumcision in the community. In areas where circumcision is common, HIV prevalence tends to be lower; conversely, areas of higher HIV prevalence overlapped with regions where male circumcision is not commonly practiced.

Results of the first randomized clinical trial assessing the protective value of male circumcision against HIV infection, conducted by a team of French and South African researchers in South Africa, were reported in 2005. That trial of more than 3,000 HIV-negative men showed that circumcision reduced the risk of acquiring HIV by 60 percent.

This article has not been published in full. These are only excerpts of an NIH December 13, 2006 news release. The full release can be accessed at [www.nih.gov/news/pr/dec2006](http://www.nih.gov/news/pr/dec2006).

It is important to know that ABC (Abstinence, Being faithful and Condom use) is the best way to avoid contracting HIV. Circumcised men can still get infected. [Editor]

# ADVANCED GCP - Taking Quality in Research A Step Further

By Dr Fiona Kalinda



The Johns Hopkins Bloomberg School of Public Health Centre for Immunisation Research conducted an International Conference on

Harmonization - Good Clinical Practice (ICH-GCP) from October 31st to November 2nd 2006 in Nairobi, Kenya. This IAVI-sponsored course drew Physicians, Nurses, Counsellors, Data Coordinators and Community Mobilizers from IAVI sites in Uganda, Kenya, Rwanda and Zambia.

The "Standards of Good Clinical Practice" were developed to protect the safety and well-being of volunteers in clinical trials and to provide consistency of data across drug and vaccine development. Now that researchers are in a place of heightened regulatory awareness and meticulous compliance with GCP, the advanced GCP course which provides a platform for examining systems, with emphasis on best practices, identification of weak points and applying appropriate collective actions is a necessity.

It covered revisiting of guidelines and US Food and Drug Authority (FDA) regulations, regulatory authority audits, quality assurance processes, site management plans as well as volunteer follow up. Participants were reminded about the importance of good leadership in research; delegation of duties to qualified GCP trained personnel and taking collective responsibility as a team during clinical trials.

One of the most outstanding activities was group work on auditing the master files. Here, participants had a chance to step into auditors' shoes, looking out for errors and failure to comply with GCP and regulatory guidelines. This role play was a practical way of clarifying the importance of audits in research and helped us to further understand the process and reporting requirements of audits as we revisited site responsibilities in preparing for and cooperating with audits. We also had an insight into ways



Fishing communities have been disproportionately affected by HIV/AIDS. Good quality research will make an HIV vaccine a reality, thereby bringing them hope.

to prevent GCP and Regulatory violations and identifying problems which occur if no quality management systems are in place. It also helped in finding ways to improve performance.

The role of regulatory bodies like the National Council for Science and Technology and the Uganda Virus Research Institute Science and Ethics Committee in overseeing clinical trials was emphasised as well as the informed consent process which is one of the foundations of ethical conduct in clinical trials. Volunteer safety assessments, including management and documentation of adverse and serious adverse events were revisited.

At the end of this workshop participants were equipped with knowledge and skills on the quality management process, site management plan, collective responsibilities, preparing for audits, master file management, preparing for regulatory assessment and approval among others. The response to the eloquent presentations, as well as robust discussions, group activities and sharing of experiences and best practices showed a new solidarity and indeed willingness to embrace quality in conducting clinical trials in Africa. Many thanks to the presenters Karen Charron and Dr Clayton Harro for a job well done and good luck to all the participants as they embark in uplifting the quality of research in Africa. □

*The role of regulatory bodies like the National Council for Science and Technology and the Uganda Virus Research Institute Science and Ethics Committee in overseeing clinical trials was emphasised as well as the informed consent process which is one of the foundations of ethical conduct in clinical trials.*

# IAVI Mourns Prof Job Bwayo

The International AIDS Vaccine Initiative (IAVI) mourns the tragic death of our friend and colleague, Professor Job Joab Bwayo, co-founder and director of the Kenya AIDS Vaccine Initiative (KAVI) in Nairobi, Kenya. Prof. Bwayo, a passionate AIDS advocate, dedicated much of his distinguished career to developing an HIV vaccine for communities throughout the African continent. Killed in a senseless act of violence on Sunday evening, February 4, he was unwavering in his belief that Kenya had a significant contribution to make to the global effort to end the AIDS pandemic, and was instrumental in building a world class clinical research facility in the country.

“This is a devastating loss for the entire AIDS vaccine field,” said Seth F. Berkley, President and CEO of IAVI. “Prof. Bwayo, a warm and engaging man, was a talented scientist, working diligently to find a final solution to the AIDS crisis. Under his stewardship, KAVI has played a leading role in driving research for AIDS vaccines globally.”

Born in the Bungoma District, Prof. Bwayo was a frequent lecturer at the University of Nairobi and former chairman of the Department of Medical Microbiology, College of Health Sciences. He also served as co-director of the Regional AIDS Training Network for STD/AIDS and as a senior member of the World Health Organization Collaborative Centre for STD/HIV Research Training. Prof.

Bwayo’s research interests included the epidemiology of sexually-transmitted diseases and HIV in men and women in Kenya, intervention studies to control and prevent STD/HIV infection, and immunobiology. He is the author of dozens of publications on public health issues and HIV/AIDS.

“Kenya’s well-earned prominence in the global HIV vaccine research arena is a great testimony to Prof. Bwayo’s scientific

scientists, community organizations and the greater global AIDS vaccine research and development field. Its successes included helping to conduct the first five AIDS vaccine trials in Kenya, beginning in 2001; building a world-class, accredited laboratory facility and scientific infrastructure to prepare for larger-scale trials; establishing rigorous quality control programs; and, contributing to Kenya’s National AIDS Vaccine Plan.

“Dr Bwayo was a renowned leader in the AIDS community, in the AIDS vaccine development field and in his own country, understanding that Kenya was at the forefront of AIDS research and discovery,” concluded Berkley. “He often commented, ‘HIV vaccine development is a marathon, not a sprint and – as we all know – Kenyans are very good at marathons.’ IAVI and KAVI will continue to work together to find an effective AIDS vaccine, our best hope of ending the AIDS epidemic – a goal Prof. Bwayo, above all else, cherished.”



This obituary has been reproduced from the IAVI Website [www.iavi.org](http://www.iavi.org).

## Message from the UVRI-IAVI Site Principal Investigator, Dr Pontiano Kaleebu

Prof Bwayo’s tragic death is a big loss not only to KAVI and Kenya but to the whole global HIV vaccine field. We at the UVRI-IAVI site in Uganda have worked with Prof Bwayo to address a number of key issues ranging from community to laboratory activities.

We will remember him for the wise leadership in East Africa particularly in building vaccine trial capacity including the training of young scientists. We send our condolences to his family and KAVI. May his soul rest in eternal peace ☐

leadership and determination, and to his broad vision that getting a vaccine required understanding and commitment across all of Kenyan society, as well as strong research partnerships to bring African and international capabilities together,” said Geoffrey Lamb, Chairman of the Board, IAVI. “What a great achievement, and what a bitter loss.”

“Prof. Bwayo’s contributions to fighting the AIDS epidemic and more recently to the HIV vaccine field will be remembered,” said Pontiano Kaleebu, Chairman of the African AIDS Vaccine Programme. “He was very active in our AAVP activities, especially in the development of national strategic frameworks. His critical work in shaping HIV vaccine policy in East Africa will be one of his many lasting legacies.”

A Kenya-based research organization developed under the University of Nairobi and in collaboration with IAVI and Oxford University, KAVI is one of the premier AIDS vaccine development organizations in East Africa. Led by Prof. Bwayo, it strongly endorsed links among Kenya

**“Dr Bwayo was a renowned leader in the AIDS community, in the AIDS vaccine development field and in his own country, understanding that Kenya was at the forefront of AIDS research and discovery,” Dr Seth Berkley.**

# HIV Vaccine Information now available at AIC



*Counseling enables informed decision making.*

Information is key to enabling people make informed decisions and at UVRI- IAVI we endeavor to ensure that potential volunteers, key stakeholders and partners know what we are doing and planning to do. This promotes support and engagement

To fulfill the above, the UVRI-IAVI HIV Vaccine Program, in collaboration with the AIDS Information Centre (AIC) started an HIV vaccine information satellite office within AIC Offices in Mengo, Kisenyi. The vaccine information satellite office was put in place as a recruitment strategy to enable the Program give information to clients coming for VCT services at AIC so that they can make decisions on participation in vaccine trials and other related studies.

At this office and information about HIV

vaccine trials, related studies is given by trained volunteers so that people interested in participating in current or future trials get details to enable make informed decisions.

Three hundred fifty people have visited the satellite office to get information on HIV Vaccine research and possible participation in future studies/trials since April 2006.

Next time you are near the AIDS Information Centre, remember to pass by the Vaccine Information Office for an update about our work and future studies which you can participate in.

This Vaccine Information Office is open on Mondays, Wednesdays and Fridays from 9:00 am to 5:00 pm

## World AIDS Day; Feelings of a Person Living with HIV

By Lule James, MUJHU CAB Vice Chairman



World AIDS day (WAD) is an annual event held to recognize that HIV/AIDS is still a challenge and to reflect on progress made in prevention, care,

treatment and research.

I first attended WAD events in 2003. I learnt about the event from different FM radio stations that publicize it. I was motivated to attend the WAD because I wanted to learn more about HIV/ AIDS and to find out if there were any new findings regarding treatment or even a cure. I am living positively with HIV and had already spent one month on antiretroviral treatment (ART). This was a very important time in my life because at one time treatment was only heard of in conferences as people waited desperately for the cost to come down while others died.

The first time I attended WAD, I heard of

the expanding HIV pandemic around the world. I learnt that the spread of HIV is rising every day! People have become complacent and no longer pay much attention to HIV/AIDS messages.

I was happy with last year's theme, "Unite for children, Unite against AIDS" because it gave special attention to children infected with and affected by HIV/AIDS.

There is usually a mixture of uncertainty, challenge, struggle and hope in the air during WAD commemoration. HIV counseling and testing is now availed for those who choose to know their sero status. Testing for HIV remains a challenge because there are many people who still fear to know their sero status.

### So, why celebrate World AIDS Day?

The challenge is with us and it increases day and night. We need to commemorate WAD so as to constantly remind people how serious a health, social and economic problem HIV/AIDS is.

The good news now is that there are treatment programs for people living with HIV/AIDS and even new HIV prevention technologies are being investigated such as HIV vaccines, microbicides and male circumcision. Three different studies from Uganda, Kenya and S. Africa have now shown that male circumcision can substantially reduce the risk of HIV infection among men. Ten years ago there was no hope. WAD is a symbol of a global effort, global achievement and hope.

Every time I leave the WAD event, I retire with hope and take back information to other peer educators, the community and the Community Advisory Board (CAB). I would like the WAD event to

***We need to constantly remind people how serious a health, social and economic problem HIV/AIDS is.***

continue being celebrated because many people receive information, educational materials and change their behavior.

I urge those who do not know their sero status to seek early VCT. For those who turn out to be positive, don't despair. You'll be counseled about positive living and available care and treatment services

# Balancing Scales: Gender Advisory Committee Holds Public Dialogue

By Angelo Kaggwa

The number of women infected with HIV worldwide continues to increase at a rapid pace. Women are disproportionately infected and affected by HIV/AIDS than men due to a host of socio-economic factors. Despite the above scenario, women participation in research aimed at stopping the HIV epidemic remains low compared to males.

The UVRI-IAVI HIV Vaccine Program acknowledges the fact that addressing these gender challenges in new preventive technologies (NPTs) requires concerted efforts by the different players. As such, the Program together with the Uganda Women's Network (UWONET) and the Gender Advisory Committee (GAC) organized a public dialogue on gender disparities in New Preventive Technologies (NPTs) on 30 November 2006 at Kampala International University (KIU).

It was aimed at creating more awareness on gender issues in regard to HIV/AIDS NPTs, to mobilize support for participation in HIV vaccine trials and to address gender issues in HIV Vaccine research and other NPTs. The dialogue, whose theme was 'New HIV Preventive Technologies: Balancing the Scales' attracted up to 340 students, lecturers and non-academic staff at the University. The Dean of Students and the Students' Guild were instrumental in ensuring success of this dialogue.

*"If we don't break the gender inequality, we'll never be able to overcome HIV/AIDS," Dr Stephen Lewis*



*Addressing Gender Inequalities is vital in the successful fight against HIV/AIDS.*

## The dialogue

In order to transform gender relations, the participants were informed that there is need to sensitize both men and women about the unique role women play in a household. It is this that will empower them to know the unique role they play in the fight against HIV/AIDS broadly and the search for the HIV vaccine particularly. At the dialogue, the public was sensitized about the importance of the vaccines and the need for women participation so that women can ultimately be helped to participate in studies to find an HIV vaccine that works for them too.

The Makerere University Walter Reed Project (MUWRP) and the Makerere University Johns Hopkins University Collaboration (MUJHU) gave updates of their progress and the way forward. An overview of the developments in Africa was also given.

A quote, by Dr Stephen Lewis, outgoing UN Special Envoy for AIDS in Africa, "If we don't break the gender inequality,

we'll never be able to overcome HIV/AIDS" was used to emphasize the need to involve women in these trials.

The dialogue was a success, not only to HIV and HIV vaccines, but to the future. It showed the need to transfer the success Uganda has made in care and treatment, to prevention. It showed the need to empower women to be part of a lasting solution to HIV/AIDS. It also demonstrated the need to look at new interventions like Pre-Exposure Prophylaxis (PrEP), Post Exposure Prophylaxis (PEP), male circumcision, microbicides and vaccines. There is need to involve women more, as they are severely affected and are more vulnerable to HIV/AIDS than any other group.

"The epidemic is here. It is our problem and we need to be part of the solution," were the closing remarks from IAVI Regional Representative, Dr Sam Kalibala

# VAX Primer: Understanding the Benefits and Risks of Participating in Clinical Research

## What are the major considerations influencing the decision to volunteer for an AIDS vaccine trial?

**M**aking the decision to participate in an AIDS vaccine clinical trial is a complex and personal process and it is important that all potential volunteers fully understand what is involved in the trial when making this choice. Researchers and staff conducting AIDS vaccine trials take several measures to ensure that, to the best of their ability, any possible benefits and risks of trial participation are identified. These are then reviewed before the trial begins by local and independent groups known as ethical review committees (ERC) or institutional review boards (IRB) and sponsors to ensure the list is complete. The ERC is committed to ensuring that the trials are run to the highest safety and ethical standards. All of the possible benefits and risks are also explained carefully to each interested volunteer during the informed consent process (see June 2005 Primer on Understanding Informed Consent).

## Benefits

There are several ways that clinical research, including AIDS vaccine trials, can benefit the countries and communities in which the trials take place even if the vaccine candidate being tested is eventually found to be not effective. Before AIDS vaccine trials are conducted, educational campaigns take place to raise awareness within the community about HIV transmission and prevention and these can benefit all community members, not just those who choose to volunteer for the trial. Many of these outreach programs also promote voluntary counseling and testing (VCT) for community members to find out if they are HIV infected, which can influence future decisions about their health and help reduce the stigma associated with HIV testing.

There are also several possible benefits for those who decide to participate in an AIDS vaccine clinical trial. They include the VCT services and risk-reduction counseling that the volunteers will receive regularly throughout the course of the trial (see August 2005 Primer on Understanding Risk-Reduction Counseling). Volunteers will

also have continuous access to the best available prevention measures in their community, including male and female condoms. Participants in AIDS vaccine trials also benefit from the rewarding feeling of being involved in medical research that may benefit others. Altruism, or concern for the welfare of others, is one of the most common reasons trial volunteers give for their participation.

Other possible benefits include the basic medical care that volunteers receive during the trial. People interested in volunteering for AIDS vaccine trials who are found to have malaria or tuberculosis can receive referrals to treatment programs in their community, therefore improving their overall health. This is also true for people who are found to be HIV infected or who become HIV infected during the course of the trial through exposure in their community. These individuals can be referred to treatment programs, as well as to support groups.

Volunteers in AIDS vaccine trials might also receive reimbursement for transportation to and from the trial site or for food if they are expected to be at the site during a mealtime. A reasonable amount is determined, with input from the community advisory board, before the trial begins and is reviewed and approved by the ERC.

Researchers and the ethics committees take these considerations seriously because they don't want the compensation or the health care provided at the trial sites to be the reason that people join the study. All trial organizers and approval bodies work carefully to avoid undue inducement. To prevent this, some trial sites may strive to provide a level of care that is consistent with what is available in the broader community. Other sites try to extend some basic healthcare services as much as possible to the wider community, which can be difficult at urban sites.

Volunteers should not feel pressured by the trial staff into enrolling in a trial but should make a decision only after weighing all of the potential benefits and risks. Ethicists are also studying how to ensure that adolescents fully understand the risks and benefits of participation in medical research before agreeing to enroll. This may be an important issue in the future

as researchers consider the possibility of testing AIDS vaccine candidates in this age group.


## Risks

It is equally important that all volunteers understand the potential risks of participating in AIDS vaccine clinical trials. All vaccine candidates are tested extensively before they enter human clinical trials, but there is still the possibility that there will be side effects or adverse reactions caused by the vaccine candidate. Often these are mild and can include headaches, fever, and inflammation at the injection site, but these effects should be explained to all volunteers clearly during the informed consent process. However, researchers can't predict each individual's response to the vaccine.

It is also critical for volunteers to understand that there is a possibility that the vaccine candidate will not be effective or that they will be randomly selected at the start of the trial to receive an inactive substance known as a placebo. Either way, the volunteers won't be protected against HIV infection by participating in the trial, emphasizing the need to practice risk-reduction behaviors.

Other potential risks include the possibility of receiving a false-positive HIV test result in the future (see November 2005 Primer on Understanding HIV Testing), being unable to donate blood after participation in the trial, and social risks such as facing possible stigma or discrimination.

Despite these inherent risks, researchers and trial staff are dedicated to making sure that AIDS vaccine trials are run safely and ethically and that these trials contribute to the overall health and welfare of the communities that participate in AIDS vaccine research, especially in developing countries.

The government trained 6500 healthcare workers to provide VCT services. Prior to this universal HIV testing initiative, it was estimated that only 1% of the population had accessed VCT 

*This article was reprinted from the September 2006 issue of Vax, published by the International AIDS Vaccine Initiative (IAVI) [www.iavi.org/iavireport](http://www.iavi.org/iavireport).*



## Did you know?

- Many of the reasons for the growing HIV burden on women are rooted in cultures that limit women's control over their bodies.
- People between the ages 13 and 25 account for about half of all new HIV infections worldwide. Unless adolescents are included in HIV vaccine trials, they may not have access to an effective vaccine as soon as one becomes available - preventing them from sharing in the benefits of vaccination right away and hindering efforts to curb the epidemic.
- In practice, there is no such thing as a vaccine that provides 100% protection, 100% of the time. In this sense, all vaccines are only "partially effective".
- Governments play an important role in mobilizing resources, determining how they are used and in creating an enabling environment for HIV vaccine development.

## THEY SAID IT...



CEO and President of IAVI, Dr. Seth Berkley, on the two recently ended National Institutes of Health (NIH) clinical trials of adult male circumcision in Uganda and Kenya - "We are enormously encouraged by these results. Any method of prevention which could reduce new HIV infections — now more than four million a year — should be supported as part of a comprehensive response to the HIV/AIDS pandemic."



Mitchell Warren, Executive Director of the AIDS Vaccine Advocacy Coalition (AVAC) - "No matter where we live, what our HIV status is, with whom (or whether) we have sex, we are all affected by HIV/AIDS - a fact that's often ignored. Not by those who live in communities where AIDS-related funerals are a daily reminder of the scourge. But in places where relatively few people are infected, the epidemic is more easily overlooked. Yet HIV/AIDS continues to change our collective global future by the devastation it wreaks to families, villages, cities and countries."

Emily Bass, on women's vulnerability to HIV infection - "Millions of women around the world exchange sex for money or food, often as their sole way of earning a living. It's an exchange that brings meager benefits and comes with staggering health risks."



Archbishop Desmond Tutu in a 15 January 2007 article in the Washington Post - "...The United States has the potential to be a global leader. Congress has the opportunity to remind the world of the good that can be done in the name of the American people, to help people around the world build better lives and restore our brotherhood and sisterhood. The promises made to poor countries are not just words on paper. They concern the lives of people who, in different circumstances, could be you or me."



Dr Emilio Emini, Former Senior Vice-President, IAVI - "Money can't buy a vaccine, but it should be able to buy answers to some of the questions that slow down rational vaccine design."

## 6 months at UVRI-IAVI

By Hedda Wold

### A Pfizer Global Health fellow - who is that?

A scientist working on a database to improve patient care at a refugee camp in northern Kenya. A research manager bringing her skills to bear on an AIDS vaccine clinical trial in Uganda. A doctor assessing training for medical colleagues in Russia. Me, Hedda Wold, a clinical research associate working with UVRI-IAVI assisting HIV/AIDS vaccine trials in Uganda. We are Pfizer's Global Health Fellows.

The Pfizer Global Health Fellows program is an innovative public-private partnership that leverages Pfizer Inc's most valuable

resource - people - to address systematic public health challenges in developing nations.

Now in its fifth year, the GHF program selects volunteers from among Pfizer employees to serve with non-profit organizations in developing countries. Our aim: transfer knowledge and skills to build capacity over a period of three to six months that will be helpful long after we have gone home. We are also manifestations of Pfizer's overarching



purpose: helping people live longer, healthier, lives.

IAVI is a trusted partner in this program. Two Pfizer fellows have previously worked for IAVI in Kenya and South-Africa, but I was the first to come to Uganda. I came to the UVRI-IAVI clinic in early August to spend six months working for IAVI at the UVRI/IAVI HIV Vaccine Program. This has been my first visit to Africa and it has been exciting.

Given my experience working on clinical trials for Pfizer in Norway, I was curious to see how a vaccine trial is conducted in Uganda to understand how the system compares to the one with which I am most familiar. I also had a desire to contribute to HIV prevention work broadly.

During these past six months, I supported IAVI in preparations for new and ongoing clinical trials. I have worked with quality

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# Involving Religious Leaders in HIV Vaccine Research

By Simon Sigirenda



Religious Leaders' support is important in the search for an HIV vaccine.

**H**IV/AIDS has devastated the world irrespective of age, gender, religious affiliation name it. Almost all Ugandans have a religious affiliation and have faith in their respective religious beliefs and leaders. With this in mind, the UVRI-IAVI HIV Vaccine Program organized a one-day religious leaders' sensitization seminar on 2nd November 2006 at Golf View Inn, Entebbe, to impart more knowledge among the religious leaders so that they will in turn relay the messages to their massive followers.

The seminar also aimed at discussing ways through which researchers can effectively work with Religious Leaders in involving communities in the search for an HIV Vaccine. Religious Leaders from Entebbe and surrounding communities like Kisubi, Kitubulu, Nkumba, Kajjansi and Bwebajja attended.

The religious leaders identified mechanisms for feedback or information flow in the communities. They recommended that researchers use mass media, posters and flyers, banners, films, sensitization seminars and workshops, internet and trained people of different ages and social status to communicate to communities. They also recommended that communities should communicate to the researchers through community gatherings/meetings, civic leaders, religious leaders, reports from the communities eg peer leaders and well-wishers in the communities like former volunteers.

They also identified ways through which religious leaders can support HIV Vaccine researchers and these include: getting involved in HIV Vaccine sensitization

programs; disseminating HIV Vaccine messages to their followers; informing people on the need for an HIV vaccine; whenever possible, participating in HIV Vaccine trials; and informing their followers of their institution's perception of HIV vaccine research and development. They received copies of the HIV vaccine awareness video to enable them sensitize their communities on vaccines. They also agreed to disseminate information on a one-to-one basis in the communities.

Since religious leaders are highly respected in their respective societies, they have a lot to contribute to the HIV Vaccine cause by being strong advocates among their brethren. At the end of the seminar, the religious leaders expressed their delight at having been invited to be part of the search for the HIV vaccine. □

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control of the feasibility Protocols B and C at the IAVI Cohort Entebbe (ICE) Project at Entebbe Hospital, and at the Medical Research Council (MRC) Clinic in Masaka. The UVRI-IAVI clinic in Entebbe has been preparing for a new vaccine trial, the V002 trial. The clinic staff and I worked closely to prepare the site for the full requirements of this new trial. It has been great to work with such a talented and dedicated staff at all of these locations.

I would like to offer a special thank you to all of the staff at the UVRI/IAVI clinic in Entebbe with whom I have had the privilege to work and to spend time with on a day-to-day basis. They have helped to make my six months in Uganda an enriching professional experience and a fantastic and rewarding personal experience. I even had the chance to visit Mt. Elgon as you can see me in the picture above. I will miss Uganda. □

## Vaccine Researchers meet News Editors



WE NEED EACH OTHER: New Vision's Hilary Bainemigisha (3rd R) shares his views with UVRI-IAVI's Dr Fiona Kalinda (in red), as Daily Monitor's Simon Kasyate (2nd L) and WBS's Moses Talemwa (2nd R) look on at a recent News Editors' Breakfast Meeting at Sheraton Hotel Kampala.

# Health reporting put at the center stage

By *Patience Atuhaire*



**PARTNERS IN VACCINE RESEARCH:** *Journalists and Researchers were all smiles after the media sensitization workshop, a sign of a noble partnership.*

Clarifying the mysteries around the search for the HIV vaccine to the public has been one of the hardest hurdles researchers charged with this task have had to contend with. Issues to do with AIDS being always as complicated as anything can be, it gets even worse when these medics and researchers try to explain to a lay person that the HIV/AIDS challenge could eventually find a prevention mechanism. Explaining to an ordinary Ugandan that your work is to search for a vaccine against HIV/AIDS would take a lot of convincing - at least in our UPE world.

To streamline issues surrounding health reporting and especially reporting on HIV/AIDS the UVRI-IAVI HIV Vaccine Program organized a Health Journalists' workshop at Grand Imperial Hotel on 5th and 6th October 2006

The workshop targeted wider and more informed coverage of health, specifically, HIV vaccine research. The researchers informed us that they look at the media as the society's watchdog, and that they [the media] are the public's main source of information. As such, involving

the media in their research will go a long way in helping researchers with the not-so-easy task of explaining the complications in HIV/AIDS vaccine research to the public.

The scientists took us through the not-so-exciting process of receiving updates on what the various partner projects in vaccine research are doing. The reporters, who represented various media houses, have been good couriers of this information. Since then it has been noticed country wide that health reporting, specifically on AIDS, has greatly improved.

News about HIV/AIDS no longer makes it to the main pages of our press. With many developments taking place in the battle against the pandemic, especially in vaccine research and accessibility to ARVs, we wondered why these stories are not on the front page.

AIDS may be depressing and seen as traumatizing and therefore the press find it easier putting it on the inside pages.. AIDS has no commercial meaning to media houses like politics and issues on economics. Maybe reporters no longer care to get involved in AIDS reporting. If we were to say that the AIDS story in Uganda is a story of success, why is the prevalence rate still high and increasing further? There were bitter, but convincing, revelations in a presentation by Simon Kasyate, a reporter with The Daily Monitor that health journalists fail to go beyond Press Releases and statistics. He urged reporters to find "the how and why side" to every story.

In the end, reporters went away determined to package their stories in a way that will always make the editor take a second look. And as if on cue, World AIDS Day 2006 received great media coverage. And it showed - for good reason!

Feedback was sent to us in appreciation of the better and wider coverage. The researchers confirmed that establishing a closer relationship with the media could greatly improve health reporting

## Staff Developments

### Out

Senior National Program Officer, Mr Emmanuel Mugisha left IAVI after five blissful years. He is now Country Manager of PATH (Program for Appropriate Technologies in Health), Uganda, an organization that primarily focuses on operations research to explore the most effective and acceptable strategies for vaccinating young people against HPV. He's been such a great part of the UVRI-IAVI Team and the Team, CAB, peer leaders and all partners will dearly miss him.

### In



The Program recruited a Pharmacist, Ms Victoria Nakiganda. She worked with AFFORD before joining IAVI. We welcome Victoria to the Team and look forward to working with her