



# ALLIANCE FOR MICROBICIDE DEVELOPMENT

14 September 2007, Volume 8, Number 36

The Alliance for Microbicide Development *News Digest* is an **unedited** compilation of:

- Media coverage of microbicides;
- Abstracts of articles on microbicides and relevant science in peer-reviewed journals;
- Material on other reproductive health and HIV prevention technologies, including HIV vaccines; and
- Matters of policy and politics with importance for microbicide research, development, and advocacy.

Its purpose is to:

- Raise awareness around the range of opinions and information about microbicides disseminated in the press and scientific journals; and
- Provide a neutral, objective basis for decision-making and evidence-based advocacy.

The *News Digest* is produced in a web-based format. Readers can view complete issues of the Digest or search by keyword for individual articles at <http://www.microbicide.org/publications/>. If you would like to be removed from the *Digest* distribution list, please send an email to [digest@microbicide.org](mailto:digest@microbicide.org). We welcome comments, questions, and ideas about other microbicide-relevant topics we might cover, services we might provide, and better ways of providing them!

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#### **1. MEDIA COVERAGE OF MICROBICIDES**

**"Kenya: how does country rate in the AIDS war"**

**Date:** 08 September 2007

**Source:** *The Nation*

<http://allafrica.com/stories/200709100423.html?viewall=1>

**EDITOR'S NOTE: Below is an excerpt of a question and answer session, with Professor Stephen Lewis, former UN envoy on AIDS in Africa, featured in Kenya, Nairobi's The Nation. The rest of the questions and answers can be found at the above website.**

Where are we likely to be in 10 years as far as vaccination and other initiatives against HIV/Aids are concerned? - Githuku Mungai, Nairobi.

You ask a vexing and frustrating question. There is a tremendous international effort to discover a vaccine, but many experts suggest that it's at least 10 years off. That's a clear tragedy because ultimately a vaccine is the only definitive answer to ending the pandemic. But alas, up to this point, the virus has outwitted the science. There is a similar effort being made to discover a **microbicide** for women to prevent transmission during sex. That may be a little closer, perhaps five or six years. It would make a tremendous difference, but it is not itself a cure. As a cause for optimism, however, it should be noted that there are many ongoing trials for both vaccines and **microbicides**, a reasonable number in Africa. No-one is giving up.

### **"Experts face tricky task in preventing HIV/AIDS in Africa"**

**Date:** 20 August 2007

**Source:** *Council on Foreign Relations*

**Author(s):** Interviewee: Laurie Garrett, Interviewer: Toni Johnson

[http://www.cfr.org/publication/14053/garrett.html?breadcrumb=%2Fpublication%2Fpublication\\_list%3Fgroupby%3D3%26page%3D1%26type%3Dinterview](http://www.cfr.org/publication/14053/garrett.html?breadcrumb=%2Fpublication%2Fpublication_list%3Fgroupby%3D3%26page%3D1%26type%3Dinterview)

**EDITOR'S NOTE: Below is an excerpt of the Council of Foreign Relations interview with Laurie Garrett, Senior Fellow for Global Health. Discussion preceding this portion focused on preventing mother-to-child HIV transmission through breastmilk. The AIDS vaccine and microbicide discussion is provided below. The full transcript, and a downloadable podcast audio, are available at the above website.**

*An AIDS vaccine is on the horizon and already a similar debate is ensuing over a differing role the vaccine would play in developing nations compared to developed ones, especially in Africa. Could you talk about what's going on in that debate?*

We have the potential that some time at the end of next year or early the following year, Merck Pharmaceuticals is going to unseal the blinded data on a study in which they've been comparing various groups receiving various doses of the Merck HIV vaccine to placebo recipients. We hope that vaccine is going to turn out to be effective at some level, though absolutely nobody thinks it will be effective at the level we traditionally expect of a vaccine, meaning near 100 percent ability to block the entry of the virus into your body. The company is really out on a limb on this one. If their vaccine is essentially blocked from use because it's not 100 percent effective, it will send a message to the entire vaccine industry to stay away from HIV/AIDS. On the other hand, it's going to be very difficult to figure out politically and socially how to use a partially effective vaccine.

We have a difficult situation here trying to understand how to walk the walk and talk the talk in terms of getting the kind of scientific answers we need to save millions of people from getting HIV, and at the same time showing the

appropriate sensitivity and concern for the needs of people in poor countries, particularly when there is a racial component to this, and those poor people are dark-skinned people and the researchers are light-skinned people.

Let's just say hypothetically that the Merck vaccine turns out to be 50 percent effective. That would mean that on a statistical basis if two people got vaccinated, one of them would be protected and one wouldn't, or it might mean on an individual basis that at any given time that you're exposed to HIV sexually or by other means, the odds are 50/50 you'll get infected with the virus. We're not sure which way it would be, but the point is, if you're in a situation where about a third of the population around you is already infected, every margin of protection is a help, is a good, is something you want, whether it's a condom, whether it's using any of a variety of different approaches to trying to protect yourself sexually, or whether it's a partially effective vaccine. But it doesn't make sense particularly to use a vaccine with that low of an efficacy for the general population in a country like the United States where well below 1 percent of the population is infected.

Instead of thinking of it in the context of how it would play out in Africa politically, ask yourself how it would play inside the United States if the Department of Health and Human Services announces that they're going to do targeted HIV vaccinations of only black-skinned people living in particular neighborhoods of the United States and homosexual men living in big, urban homosexual communities. You could see there would be a lot of tension around this because there would be a feeling that a given community is being targeted with a product that is less than perfect and that maybe they're being targeted with that product because they're considered less than perfect as well. If you take the same sort of tension that you could logically see arising and extrapolate it on an international basis, you can understand why some African countries in particular would look at this and say "Well, why is a product that you don't think is good enough to use on the general population in America good enough to use on the general population of, let's say, Botswana?" Something that's only a partially effective product would not be of utility to save a society if very, very few people in the society have that disease, but in a society or a community where the infection rate is extremely high, even a dismal product can have a benefit. It's going to be very, very tricky. It's going to require an enormous amount of political education and conversation, and it's going to require some serious diplomatic tact on the part of U.S. foreign aid experts.

*Overall, what lessons do you think global health experts and policymakers will take away from this infant formula policy?*

We're getting a number of sorry lessons piling on top of each other in the HIV-prevention arena all at once. The first one came related to a **microbicide** trial. A **microbicide** is a product that a woman could use in the form of a foam or a cream that she would insert in her vagina to protect her from HIV from her male sexual partner. There has been a whole lot of hope that an effective **microbicide** could basically accomplish the same deed as a vaccine, but we don't have a home run product, we have some sort of good products and we need to try them and see if they work. A clinical trial in South Africa of a particular **microbicide** product that some advocates were enthusiastic about backfired; it turned out that the group of women that received the **microbicide** had a higher HIV rate than those who received a harmless, useless placebo. This of course sparked huge outcry in South Africa, with many South Africans charging that it was a racist trial, that the United States and the Gates Foundation, which sponsored it, were using Africans as guinea pigs to test out crummy products.

So, we're now looking at one thing after another where [there's] this sensitivity in Africa about how these products are being tried out, who they're being tried on, and what the outcomes are of those trials. There's a tremendous amount

of conversation going on about this right now among all the HIV/AIDS community; it's not as if anybody's taking this lightly. Everybody's trying to figure out how to proceed.

But you can't get quick results on any product related to HIV unless you test it in a place where the AIDS rate is very high so that the likelihood of an individual being exposed is high. If we did all our trials on HIV products in, let's say, Des Moines, Iowa, it might take two or three decades to be able to tell a difference between something that looked to prevent HIV and something that looked like it wouldn't, just because the statistical odds of any given individual in Des Moines, Iowa, being exposed to HIV are tremendously low. If in contrast we do a trial like that in Gaborone, Botswana, where more than 35 percent of the population is infected in the adult sexually-active population, then we could get a result that tells us whether or not there's a prevention benefit in a matter of months. We have a difficult situation here trying to understand how to walk the walk and talk the talk in terms of getting the kind of scientific answers we need to save millions of people from getting HIV, and at the same time showing the appropriate sensitivity and concern for the needs of people in poor countries, particularly when there is a racial component to this, and those poor people are dark-skinned people and the researchers are light-skinned people.

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## 2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

### "Acceptability of hypothetical microbicides among women in sex establishments in rural areas in Southern China"

**Author(s):** Wang Y, Liao SS, Weeks MR, et al

**Reference:** N/A Epub ahead of print.

<http://highwire.stanford.edu/cgi/medline/pmid;17767093>

**Published Abstract:** *Objectives and Goal:* The objectives of this study were to measure the potential acceptability of a hypothetical **microbicide** among women in sex establishments in rural areas of Southern China and demographic, behavioral, and social context factors likely to affect **microbicide** acceptability. *Study Design:* This was a cross-sectional survey, using a quota sampling, among 300 women from sex establishments in 3 rural towns. An interviewer-administered standardized questionnaire was used to measure the acceptability score of hypothetical **microbicides'** characteristics, as well as sexual relationships and behaviors and other contextual factors. *Results:* Findings showed a generally positive response to **microbicides**, indicated by an acceptability index score of 2.89 (SD, 0.56, scale of 1-4) in the overall sample. Multivariate analysis shows that the acceptability score varied significantly by study sites, type of sex-work establishments, marital status, sex partner type, vaginal product experience, locus of control by partners, and locus of control by chance. *Conclusions:* **Microbicides** may be acceptable among sex workers in rural settings in China; however, contextual factors should be carefully considered in education and promotion of **microbicides** in the future.

### 3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

#### "A tough transition"

**Author(s):** Singer PA, Berndtson K, Tracy CS, et al

**Reference:** N/A 449(121):160-63.

<http://www.nature.com/nature/journal/v449/n7159/full/449160a.html>

**Published Abstract:** The path from basic scientific discovery to effective therapy is rarely rapid or simple, especially in the developing world. Making this transition easier is a sizeable and pressing problem. What is the best way to tackle such a complex issue?

One important step is to identify the factors that help and hinder the uptake of health-related biotechnology in developing countries. Although knowledge about these factors in developing regions is lacking(1), the spread of technologies and ideas across cultures has been studied extensively for several decades. The complex issues involved in the development of new technologies cover areas as diverse as science-capacity building(2), culture(3), economic analysis(4), foreign investment and imports(5), public-private product-development partnerships(6), intellectual property(7) and political policy(8). These issues, however, have mostly been explored in the context of the developed world and in isolation from one another, which means that the bigger picture remains unclear.

The diversity of factors involved in the developing world is illustrated by several recent events. Treatments for HIV infection are urgently needed in Africa, yet clinical trials of the anti-HIV drug tenofovir were halted in Cambodia, Cameroon and Nigeria because of claims that efforts to inform and involve local communities were inadequate(9). And, in the face of famine, the Zambian government rejected food donated by the United States because it was genetically modified(10). On a longer timescale, there was a large delay between the development of a vaccine against hepatitis B in the developed world and its widespread availability in the developing world.

At present, there is great interest in exploring such issues because of the unprecedented increase in financial resources for improving the health of individuals in the world's poorest countries. For example, since 2005, biomedical research projects focusing on the developing world have received US\$450 million from the Grand Challenges in Global Health initiative of the Bill and Melinda Gates Foundation. With the increase in resources comes added responsibility to ensure that optimal improvements are made.

We set out to identify the factors, or forces, that affect the uptake of health-related biotechnology in the developing world. To do so, we interviewed 70 key experts from various sectors - academia, industry, civil society (voluntary and civic organizations) and government - in developing countries (see Supplementary Information for full details and breakdown).

These interviews allowed us to identify eight key areas that affect the development and adoption of health-related biotechnology in resource-poor regions. These areas can be categorized into four main forces: scientific, social (including ethical and cultural), financial and political. As a result, we were able to generate a model that can be used to assess the likelihood of success of health-related biotechnologies (see graphic).

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**EDITOR'S NOTE:** *The full text of this article, including references, is available for public access at the above website.*

**"Grand challenges in global health: community engagement in research in developing countries"**

**Author(s):** Tindana PO, Singh JA, Tracy CS, et al

**Reference:** N/A 4(9):e273.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040273>

**Published Abstract:** The Bill and Melinda Gates Foundation (<http://www.grandchallengesgh.org>), the United States National Institutes of Health (<http://grants1.nih.gov/grants/index.cfm>), the United Kingdom Wellcome Trust (<http://www.wellcome.ac.uk/funding>), and others are increasing funding for research on diseases that affect the world's poor. The goal is to develop superior diagnostic tools, prevention strategies, and interventions to counter the debilitating impact of these diseases. Successful completion of this research and adoption of the resulting technologies will depend on successful engagement with the intended beneficiaries. Recent research in developing countries, such as the abandoned trials in Cameroon and Cambodia of tenofovir as pre-exposure prophylaxis against HIV infection [1], has shown that even in studies where ethical issues have been addressed, challenges related to community engagement (CE) can still undermine the research.

Various CE models exist in the fields of public health, community planning [2], governance, and community development. However, there have been few systematic attempts to determine the effectiveness of CE in research. As an advisory service on ethical, social, and cultural (ESC) issues for the Grand Challenges in Global Health (GCGH) initiative, discussed in the first article in this series [3], we are exploring a range of ESC issues identified by the GCGH investigators and developing world key informants, discussed in the second article in this series [4]. The investigators and key informants placed particular emphasis upon the importance of community engagement, and therefore we prepared a conceptual paper on this topic, which we distributed as a working paper to GCGH investigators and program staff at the 2nd Annual GCGH Meeting. In this article, we summarize this conceptual paper. We first examine the concept of CE in research in developing countries, then we describe published models of CE, and finally we discuss two relevant examples of CE in research from Africa.

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**EDITOR'S NOTE:** *The full text of this article is available at the PLoS Medicine website (see above). This is 1 of 4 articles on ethical, social and cultural issues in the Grand Challenges Program.*

**"Modelling the impact and cost-effectiveness of the HIV intervention programme amongst commercial sex workers in Ahmedabad, Gujarat, India"**

**Author(s):** Fung IC, Guinness L, Vickerman P, et al

**Reference:** N/A 7(195)

<http://www.biomedcentral.com/1471-2458/7/195>

**Published Abstract:** *Background* Ahmedabad is an industrial city in Gujarat, India. In 2003, the HIV prevalence among commercial sex workers (CSWs) in Ahmedabad reached 13.0%. In response, the Jyoti Sangh HIV prevention programme for CSWs was initiated, which involves outreach, peer education, condom distribution, and free STD clinics. Two surveys were performed among CSWs in 1999 and 2003. This study estimates the cost-effectiveness of the Jyoti Sangh HIV prevention programme. *Methods* A dynamic mathematical model was used with survey and intervention-specific data from Ahmedabad to estimate the HIV impact of the Jyoti Sangh project for the 51 months between the two CSW surveys. Uncertainty analysis was used to obtain different model fits to the HIV/STI epidemiological data, producing a range for the HIV impact of the project. Financial and economic costs of the intervention were estimated from the provider's perspective for the same time period. The cost per HIV-infection averted was estimated. *Results* Over 51 months, projections suggest that the intervention averted 624 and 5,131 HIV cases among the CSWs and their clients, respectively. This equates to a 54% and 51% decrease in the HIV infections that would have occurred among the CSWs and clients without the intervention. In the absence of intervention, the model predicts that the HIV prevalence amongst the CSWs in 2003 would have been 26%, almost twice that with the intervention. Cost per HIV infection averted, excluding and including peer educator economic costs, was USD 59 and USD 98 respectively. *Conclusions* This study demonstrated that targeted CSW interventions in India can be cost-effective, and highlights the importance of replicating this effort in other similar settings.

**EDITOR'S NOTE:** *The full article is available as a provisional PDF at the above website.*

### "Molecular characterization of HIV-1 and HIV-2 in Yaounde, Cameroon: evidence of major drug resistance mutations in newly diagnosed non-B infected patients"

**Author(s):** Ndembi N, Abraha A, Pilch H, et al

**Reference:** N/A Epub ahead of print.

<http://jcm.asm.org/cgi/content/abstract/JCM.00428-07v1?ct=ct>

**Published Abstract:** Prior to current studies on the emergence of drug resistance with the introduction of antiretroviral therapy (ART) in Cameroon, we performed genotypic analysis on samples from drug-naive, HIV-infected individuals in this country. Of the 79 HIV-1 pol sequences analyzed from these Cameroonian samples, 3 (3.8%) were identified as HIV-1 group O, one (1.2%) as HIV-2 intergroup B/A recombinant, and the remaining 75 (95.0%) as HIV-1 group M. Group M isolates were further classified as subtypes A1 (n = 4), D (n=4), F2 (n=6), G (n=12), H (n=2), K (n=1), circulating recombinant forms CRF02\_AG (n=41), CRF11\_cpx (n=1), and CRF13\_cpx (n=2). Two pol sequences were identified as unique recombinant forms of CRF02\_AG/F2 (n=2). M46L (n=2), a major resistance mutation associated with resistance to protease inhibitors (PIs), was observed in 2/75 (2.6%) group M samples. Single mutations associated with resistance to nucleoside reverse transcription inhibitors (NRTIs), T215Y/F (n=3), and non-nucleoside reverse transcriptase inhibitors (NNRTIs), V108I (n=1), L100I (n=1), and Y181C (n=2) were observed in 7 of 75 (9.3%) group M samples. None of these patients had any history of ART exposure. Population surveillance of transmitted HIV drug resistance is required and should be included to aid the development of appropriate guidelines.

## "Robust Gag-specific T cell responses characterize viremia control in HIV-2 infection"

**Author(s):** Leligdowicz A, Yindom LM, Onyango C, et al

**Reference:** N/A Epub ahead of print.

[http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list\\_uids=17823657&dopt=AbstractPlus](http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17823657&dopt=AbstractPlus)

**Published Abstract:** HIV-2 infection in the majority of infected subjects follows an attenuated disease course that distinguishes it from infection with HIV-1. Antigen-specific T cells are pivotal in the management of chronic viral infections but are not sufficient to control viral replication in HIV-1-positive subjects, and their function in HIV-2 infection is not fully established. In a community-based cohort of HIV-2 long-term nonprogressors in rural Guinea-Bissau, we performed what we believe is the first comprehensive analysis of HIV-2-specific immune responses. We demonstrate that Gag is the most immunogenic protein. The magnitude of the IFN-gamma immune response to the HIV-2 proteome was inversely correlated with HIV-2 viremia, and this relationship was specifically due to the targeting of Gag. Furthermore, patients with undetectable viremia had greater Gag-specific responses compared with patients with high viral replication. The most frequently recognized peptides clustered within a defined region of Gag, and responses to a single peptide in this region were associated with low viral burden. The consistent relationship between Gag-specific immune responses and viremia control suggests that T cell responses are vital in determining the superior outcome of HIV-2 infection. A better understanding of how HIV-2 infection is controlled may identify correlates of effective protective immunity essential for the design of HIV vaccines.

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## 4. EPIDEMIOLOGY

### "Indonesia faces rising tide of HIV"

**Date:** 12 September 2007

**Source:** *Voice of America News*

**Author(s):** Trish Anderton

<http://www.voanews.com/english/2007-09-12-voa6.cfm>

HIV, the virus that causes AIDS, is a growing threat in Asia. The United Nations says nearly a million Asians contract the virus each year. It is spreading fast in Indonesia, where prostitution is a major cause. Trish Anderton visited one organization in Surabaya, East Java, Indonesia, that is trying to slow the spread of HIV AIDS, and finds the work is slow and difficult.

In Indonesia's sex capital of Surabaya, clinic workers chat with a client as they usher her into a small, plain office. The 16 year old girl, who did not want her name to be used, is dressed in tight t-shirt and jeans. She has been a sex worker for more than a year. Talking with an outreach worker, she recounts the moment she got into the business -

when she caught her fiance having sex with another woman.

"I should have slapped him in the face, but he slapped me instead," she said. "I wanted to slap the girl he was with, but she slapped me instead. So the next morning I ran away." The girl says she has tried to find other work, but without success. Today she wants to be tested for HIV. She and the outreach worker review the basic facts about how HIV is transmitted. The girl knows she should always have her clients use a condom, but admits she cannot convince them. Even her current boyfriend will not wear a condom. She says she wants to, but her boyfriend does not, because he says it is less enjoyable.

This inability to dictate the terms of sex is a daily reality for prostitutes in Indonesia, says Esthi Susanti Hudiono, head of Hotline Surabaya - the organization that runs this office.

"Sex workers do not have bargaining power. That belongs to the customers," said Eshti. "It has proven almost impossible to give sex workers bargaining power in terms of condoms." Hotline Surabaya runs employment programs to provide alternatives to prostitution and a theater group to help women learn to express themselves. But Esthi says that peer pressure is stronger than individual rights, meaning stronger weapons are needed against HIV. She believes condoms have to be seen as mandatory, and that message has to come from the top down.

"If the elite don't support us, there won't be change," she said. "So the elite of government and the elite of society are important." Her group successfully lobbied for a local regulation in 2004 requiring that customers of sex workers use condoms. But this has so far remained a largely symbolic victory, because the law is not enforced.

An estimated seven to 10 million men visit commercial sex workers each year in Indonesia. Many have not been educated about the dangers of HIV. According to the United Nations, prevention efforts in 2004 reached about 18 percent of female sex workers and less than seven percent of their clients. There are some signs of progress, however. Data suggest the level of knowledge about HIV is improving among both prostitutes and their partners.

While it tries to combat the rising tide of infections, Hotline Surabaya is also working to prevent today's children from becoming tomorrow's sex workers. At a sparsely furnished office in one of Surabaya's red light districts, volunteers teach kids from the neighborhood, including children of sex workers. Prostitutes' children often dislike going to school because fellow students and even teachers ostracize them. Many are not allowed to enroll in school at all, because they do not have birth certificates.

Program manager Joris Lato and his staff talk to the parents and try to convince them to educate their children and respect their rights. Joris says many parents exploit their own children. They send them out to sing and beg in the streets. When they get older, the transition to prostitution is easy.

Indonesia's economy is improving, but its poverty level remains high, with nearly half the population living on \$2.00 a day or less. The poor have limited access to education, health care and shelter. Until that changes, groups such as Hotline Surabaya are not likely to have much influence on national statistics. But they may help individuals - such as the 16-year old prostitute - to improve their chances of survival.

## 5. OTHER PREVENTION APPROACHES

### "Time to address love and sexuality among teens born with HIV"

**Date:** 12 September 2007

**Source:** *PlusNews*

<http://www.plusnews.org/Report.aspx?ReportId=74259>

Paediatric HIV care is high on the agenda of most HIV programmes today, but less talked about are the social aspects of life as a child born with the virus, and later on, as an adolescent facing the challenges of relationships and sexuality.

"The focus has been on the medical aspects of sexuality, but it goes beyond the physical," said Dr Harriet Birungi, an associate with FRONTIERS, a reproductive health programme of the US-based Population Council. "Sexuality is emotional as well a source of happiness, person fulfilment and well being, and it's important for us to begin to address the needs of these adolescents as a whole."

Birungi has been part of an as yet unpublished study on the needs and desires of HIV-positive adolescents in Uganda. The study, co-funded by the Ford Foundation and the United States Agency for International Development, was conducted in partnership with 17 Ugandan groups, including The AIDS Support Organisation and the MildMay Centre. It involved 735 adolescents aged between 15 and 19.

According to the Population Council, with the advent of life-prolonging antiretroviral (ARV) medication, the proportion of children perinatally infected with HIV who are living on into adolescence is increasing, with many of them expecting to become sexually active and even have children."

#### *Looking for love*

"These children have gone through some hard times, with many of them losing their parents, and many on ARVs," Birungi told IRIN/PlusNews. "It is important to address their needs and ensure they have the right guidance as they go into adulthood. "About 67 percent of these children have no biological parents, so they are often taken in by extended family and in that process they are separated to spread out the cost of raising them," she noted. "So you find that the boyfriend-girlfriend relationship is, for many of them, the only concrete expression of love they have ever had." She added that many of them were excluded from education because the families that took them in expected them to die and therefore perceived education to be a waste of money.

"Outside the school environment, it is difficult to make friends, and they are also outside a protective environment and vulnerable to sexual advances from older men," Birungi said. "They often end up as married adolescents or single parents, which complicates their lives further." Despite these difficulties, the research found that these teens have the same desires and dreams as their HIV-negative counterparts.

"About 34 percent of them are sexually active, and among those who are not, the majority desire to have sex at some point," Birungi said. "Some want to have children, but others want to pursue careers before settling down." Discordance, she added, was common, and HIV-negative people often continued to push for a relationship even after

discovering the status of the teens.

"The study found that the teens desire to be responsible and are very afraid of infecting others," she said. "The possibility of this makes some of them very afraid of sex." She said the Population Council was currently developing interventions to address sexuality, love and desire among HIV-positive adolescents, which would include counselling on issues like disclosure of status and safe sex, as well as family planning.

"There is a need give them support and practical guidance so they can live full lives that are as normal as possible," Birungi said.

### **"Marriage not a barrier to catching HIV/AIDS"**

**Date:** 10 September 2007

**Source:** *The Monitor*

**Author(s):** Kakaire A Kirunda

<http://allafrica.com/stories/200709100704.html>

While marriage has highly been thought to greatly reduce the risk of catching HIV/Aids, it is increasingly emerging that this notion is proving otherwise. This emerged at the just concluded 1st regional forum on best health care practices. The forum, was organised by the East Central and Southern Africa Health Community in Arusha, Tanzania.

Debate ensured amongst delegates following a presentation by Dr Isaiah Tanui of the Global Aids Programme of the Centres for Disease Control in Kenya in which he cited Uganda as one of the countries in the region with a high incidence of HIV in married couples.

Dr Tanui's argument was based on Uganda's recent national HIV/Aids survey that appeared to indicate that over the last decade marriage did not protect couples from catching the deadly disease. The survey indicated that married couples accounted for the largest proportion of new HIV infections in the country. "Sixty five per cent occurred among married people, 26 percent among divorced or widowed women, and nine percent among never married," said Dr Tanui.

But last December, the press quoted the Director General of the Uganda Aids Commission as saying that research conducted from 1996 through 2005, showed that 42 per cent of the 130,000 new HIV infections in the country occurred within marriage. It emerged from the discussions that ensued after Dr Tanui's presentation that the problem was not only for Uganda but an emerging one for the entire region in all the 10 active East, Central and South African -Health Community countries.

Some delegates called for compulsory HIV testing for all couples intending to marry. Another group led by a Seychelles delegation called for an aggressive voluntary counseling and testing (VCT) for intending marriage partners. The called on religious organisations to join the campaign.

However, Dr Peter Toroitich of Kenya's National Aids Control Project cautioned the forum that compulsory testing would raise human rights questions. "What we need is to revisit our VCT policies and advise pre-tests every time there are new relationships," he added.

## "Challenge for AIDS fighters: circumcising Africans safely"

**Date:** 07 September 2007

**Source:** *The Wall Street Journal*

**Author(s):** Mark Schoofs

<http://online.wsj.com/public/us>

The recent finding that circumcision dramatically reduces the risk of contracting HIV has global health authorities mobilizing to offer the procedure broadly in Africa. But introducing mass circumcision presents challenges, epitomized by a young man in western Kenya.

Kennedy Sikuku went to the mud-and-wattle shack of Joseph Wanjala for a circumcision. Kennedy's father thought his son was getting treated by a doctor. In fact, Mr. Wanjala is a nurse and barred by Kenyan law from doing the operation. Over a dusty floor, Mr. Wanjala carried out the surgery to mark the passage of the teenager, then 17 years old, into manhood. Mr. Wanjala couldn't stanch Kennedy's bleeding. That set off a three-week ordeal in which Kennedy contracted a severe infection and escaped death "by a whisker," according to a medic who examined him at his lowest ebb. Fortunately, he was in a study evaluating the quality of locally performed circumcisions, and the study team took him to a district hospital for emergency intervention.

Circumcision offers one of the best ways to turn the tide against Africa's raging AIDS epidemic, but implementing the procedure is fraught with danger in a region with threadbare medical regulation, a shortage of doctors, and patients who often are minimally educated. In the "AIDS belt" of eastern and southern Africa, where the disease has taken the biggest toll, rates of circumcision are generally low. Zambia, Zimbabwe, Rwanda and Malawi all have circumcision rates below 20%. In South Africa, the largest ethnic group, the Zulus, generally do not circumcise. Kenya is an exception, with more than 80% of men circumcised. Complications from circumcision in this region of Kenya are common, showing the risks that may arise if health officials push circumcision throughout Africa.

The study in which the younger Mr. Sikuku took part assessed more than 1,000 boys and teenagers who received circumcisions in 2004. It found that 35% of those circumcised by ritual circumcisers, who have rudimentary medical training at best, suffered side effects such as infections, excessive bleeding and pain when urinating. Even among those who were circumcised in medical settings, a category that includes private clinics such as Mr. Wanjala's, 17% suffered adverse side effects. The rate is often under 2% when modern medical approaches and equipment are used. The results were published in 2006 in a report funded by the U.S. government. Robert Bailey of the University of Illinois and Moi University's Omar Egesah led the research.

The total number of sub-Saharan Africans with the AIDS virus reached 24.7 million last year, up from 23.6 million in 2004, estimates the Joint United Nations Program on HIV/AIDS, known as UNAIDS. Providing lifelong drug treatment for every AIDS patient is too costly for poor countries.

Technology to prevent sexual transmission of HIV has remained stalled for decades, with no new intervention since the condom. Attempts to develop an AIDS vaccine have foundered. Behavioral methods, such as abstinence, monogamy and condom use, have rarely worked well enough to reverse the trajectory of the epidemic. Circumcision is inexpensive and, according to recent studies, sharply reduces the chance of getting infected. Removing the penis's

foreskin causes the newly exposed skin to thicken, making it more resistant to microbes. Also, circumcision may improve hygiene and protect against other infections, such as syphilis and herpes, that can contribute to HIV infection.

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**EDITOR'S NOTE: The full text of this article is available at the above website. A subscription is required to view this article in its original location.**

## **"HIV loosens tribe's resistance to circumcision; many Kenyans see survival at stake"**

**Date:** 07 September 2007

**Source:** *The Washington Post*

**Author(s):** Craig Timberg

[http://www.washingtonpost.com/wp-dyn/content/article/2007/09/06/AR2007090602760.html?nav=rss\\_print/asection](http://www.washingtonpost.com/wp-dyn/content/article/2007/09/06/AR2007090602760.html?nav=rss_print/asection)

Family gatherings for Collins Omondi once were boisterous affairs here on the verdant shores of Lake Victoria. But in just 11 years, AIDS has killed seven of his uncles, six aunts, five cousins and both his parents. His extended family now consists of one surviving uncle, an aunt and their 2-year-old child -- all of whom have AIDS. Omondi, 28, a tall, broad-shouldered fish trader, has come to believe that a quirk of culture contributed to the decimation of his family. They were Luos, members of the only major tribe in Kenya that does not routinely circumcise boys. The absence of this ritual, Omondi said, helps explain why Luos are dying from AIDS at a rate unheard of among other Kenyans and rare in East Africa.

Twenty years after the first reports of a connection between HIV rates and circumcision, scientists are saying it is essential to understanding the path of the disease through Africa and possibly to reversing its course. President Bush's \$15 billion anti-AIDS program is pledging millions of dollars to Kenya and other countries so they can offer circumcision services in communities long defined, in part, by their reluctance to perform the procedure. The unprecedented effort already has provoked a backlash from the Council of Luo Tribal Elders, which decided last year to officially oppose it. But along the beaches of Lake Victoria, where fishermen push their colorful sailboats into the waves before dawn each day, many express a willingness to leave this tradition behind if it means surviving an epidemic that seems to have no end.

"We are the people who are sick," said Omondi, who recalled the haunting feeling of walking through his father's empty home on a nearby beach. "We are the ones who lose people every day."

Most African tribes traditionally circumcise boys in rituals marking the onset of manhood. But the Luos and some other Nilotic tribes, whose ancestors migrated south from Sudan, used to mark the end of childhood in a different but also painful way -- removing six bottom front teeth. AIDS emanated from the jungles of Cameroon or Gabon but hit massive epidemic levels after reaching the uncircumcised tribes around Lake Victoria and, later, southern African tribes that had abandoned their own traditional circumcision rites. These differences help explain why West Africa, where circumcision is routine, has HIV rates much lower than in southern or East Africa. Within Kenya, roughly one in

17 adults has HIV. Yet among Luo adults, the virus has infected one in five.

Scientists say the cells in a man's foreskin are unusually easy for HIV to penetrate. Removing it through circumcision also makes the skin on the penis head grow thicker and more resistant to infection. Trials in Kenya, Uganda and South Africa have shown that circumcised men are 60 percent less likely to contract HIV. The World Health Organization endorsed it as a key prevention strategy in March.

"It's now the most proven, effective HIV prevention strategy we have for male heterosexuals, so it's really important that we make this widely available," said Robert C. Bailey, an epidemiologist at the University of Illinois at Chicago who oversaw the Kenyan trial in nearby Kisumu. Bailey has calculated that a well-run program could lower the HIV rate among Luo men from 18 percent to 8 percent over 20 years, averting tens of thousands of infections. Women would also be less vulnerable to HIV because of the decreasing infection rates of their sexual partners. Across Africa, widespread circumcision programs could save 5.7 million lives -- far more than any prevention strategy yet tried, U.N. officials have estimated.

Several countries, including Zambia and Swaziland, are exploring how to expand circumcision services, but none is further along than Kenya. Peter Cherutich, a top health official overseeing the issue, said a policy on making circumcision "available in a safe and voluntary manner" probably will be completed in the next month or two.

Officials for the Bill and Melinda Gates Foundation have expressed interest in helping expand circumcision services in Africa but said no final decisions have been made. Several Kenyan health experts said a multimillion-dollar grant from the foundation supporting the effort is expected to be announced soon after Kenya's policy is adopted. The U.S. contribution, worth \$5 million to Kenya this year, also is due after the government policy is released. The program initially would focus here in western Kenya's Luoland. Existing clinics and youth centers could begin offering services as soon as early next year, and mobile teams would use vans to visit churches, markets and beaches where fishermen work, offering free circumcisions with sterile surgical kits they would bring along.

Kawango Agot, a circumcision researcher and herself a Luo, said the effort is likely to be popular. In a survey she and Bailey conducted, 60 percent of Luo men said they would like to be circumcised because they believed it was cleaner and healthier. The percentage was highest among those younger than 25. She called the cultural concerns overblown. "Sincerely, I just don't care," Agot said. "What I care about is people are dying."

### *Fear and Education*

Luos long have faced discrimination for not circumcising their sons. Members of other Kenyan tribes sometimes refused to vote for Luo politicians on the grounds that they had not become adults. Luos who traveled far from their homeland were mocked with a variety of cruel nicknames, such as "Kehe," which translates literally as "uncircumcised" but to Kenyan ears means "boy."

Meshack Riaga Ogalo, the 73-year-old leader of the Council of Luo Tribal Elders, said the true source of high rates of HIV in the tribe, which is one of Kenya's largest with a population of about 4.5 million, is not the lack of circumcision but the abandonment of traditional culture, especially by fishing communities. "Nowadays, because of Christianity and all kinds of civilization, you introduce something like love affairs. The world is now horrible," said Ogalo, who favors a walking stick and black cowboy hat. "We don't want foreigners to interfere with our culture. It is absolutely wrong."

Lake Victoria's fishermen, following the winds, often kept girlfriends at several different beaches. The men generally were among the few in villages with steady supplies of cash, arriving home each day with \$10 or \$20 -- sometimes much more -- in areas where many earn less than \$1 a day.

"With the fishermen, you can't trust them," said Mary Achieng Bunde, 41, a former fish trader and an AIDS activist whose husband died of the disease. Of the women who trade in fish, she said, sexual favors were expected and generally granted. "Most of them, they are ready to do because maybe your husband has died, your children have school fees. . . . What can you do?" She said attitudes are changing on the beaches because of fear and aggressive education programs. More fishermen are living in family houses, with their wives and children, rather than in communal dorms. The carousing has quieted as the toll of AIDS has grown. Yet she suspected that circumcision would require a degree of change beyond what most fishermen would accept. "It will not be easy for them, because it is not our culture," she said.

### *Abandoning Tradition*

Less than a mile away, down on the soggy, grass-covered beach where Bunde once bought fish, a new generation of fishermen has taken over. Erick Onyango Otieno, 21, called circumcision "a good idea" and said younger fishermen did not want to make the mistakes of the previous generation. "The older ones are almost all dead," he said. "I do not want to die at this early age."

Otieno and other fishermen expressed concern about the procedure itself, the amount of pain involved and the possibility of side effects. They worried about losing profits during the days -- and in some cases weeks -- that men may miss work while healing from the procedure. A few, including some women who worked the beach, echoed the concerns of tribal elders about abandoning culture. Yet more said a Luo man who is circumcised is no less a Luo. A substantial minority of Luos, especially those who have lived in other parts of Kenya, already have been circumcised. That includes Omondi, whose father had him circumcised when he was a child to prevent him from being teased when he bathed with boys from other tribes.

On another nearby beach, Erick Okoth, 31, a fisherman and father of two, said he has grown weary of the shifting AIDS-prevention strategies -- condoms, abstinence, monogamy, testing -- brought to Luoland. He would rather see the Luos solve their problems themselves. "Removing the skin is like taking my rights away," Okoth said. "If you are telling me to get circumcised at this age, it's like telling another tribe to remove the teeth."

Some also wondered whether circumcision would affect their fertility, though scientists say it does not. Luos traditionally have large families, and pressures to have several children have grown along with the death toll of AIDS.

"We are going to lose our strength," warned George Okoyo Mawere, 48, a part-time fisherman, politician and local tribal elder. "When you are circumcised, the hormones are lower. That's why within the Luos, we have a very small area, but we have a very big population." Yet Mawere said that despite his misgivings, he would support making the procedure available if it curbs AIDS. "Obviously we shall, because it's a disaster," he said.

On the beaches closer to the town center of Mbita, where lifestyles are less traditional, few fishermen expressed opposition to circumcision. On the beach worked by Omondi, there was wide consensus about the need for expanding services.

"I'll do it, plus my three sons," said Arthur Odipo, 33, a lean but fit-looking fisherman. "If circumcision can reduce the risk, we will do it."

Fishermen have been dying in Luoland so quickly and for so long that several said they were eager for any solution, regardless of culture. One respected fisherman died just last month, and his wife appears sick as well, other fishermen said. His picture hangs on the wall of the fishermen's association office, and they were preparing to go, as a group, to the funeral.

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## 6. POLITICS AND POLICY

### "China needs to speed up AIDS fight: U.N."

**Date:** 09 September 2007

**Source:** *Reuters*

**Author(s):** Jason Subler

<http://www.reuters.com/article/reutersEdge/idUSPEK424320070909?sp=true>

China needs to speed up efforts to combat the spread of HIV/AIDS by giving freer rein to civil society organizations and enrolling the help of companies, a U.N. official said. Peter Piot, head of the United Nations AIDS agency UNAIDS, gave Beijing high marks for opening up official policy towards AIDS, once stigmatized as a disease of the West. But a gap between centrally-made rules and implementation by local authorities was impeding prevention efforts, threatening China with an even bigger human and financial toll, Piot said in an interview.

"It's act now, or pay later," Piot said. "Given the fantastic economic development and the social transformation that is going on ..., delaying or being slow in terms of implementing the policies will result in the spread of HIV."

Side-effects of economic growth, including swelling populations, have helped feed high-risk activities like the sex trade and presented authorities with new challenges, Piot said. Armies of men have moved from their villages to the cities to help build roads, office blocks and factories that serve as the backbone of the world's fastest-growing major economy. That economic engine is also being greased by roving businessmen, who are widely known to be another major client source for sex workers.

#### *Sexual Entrepreneurs*

"This whole, let's say, sexual entrepreneurship is a side-effect of rapid economic growth and new wealth," Piot said. "(It's about) mobile men with money or without money." Piot, attending a meeting of the World Economic Forum, said it was especially important that authorities gave more freedom to civil society organizations more quickly, as they are best placed to reach out to marginalized groups. "I don't know of any society that has dealt successfully with AIDS where civil society groups ... do not have the space to do their work," he said. "It's hard for government to do. Just think of gay men, or men who have sex with men -- how could the government do that, organize that?"

China keeps a tight grip on non-governmental organizations. Rights groups say local officials, particularly in Henan province, have banned some activists from holding meetings and shut down other groups. Henan was one of China's first areas hit by AIDS, with many people contracting the virus through contaminated blood in the 1990s. An estimated 650,000 people are now living with HIV/AIDS in China.

Piot said China needed to start letting activists speak out. "A voice from those who have no voice is very important," he said. While he sensed readiness among central officials to allow AIDS activists to speak out more freely, Piot said many local officials were worried that greater openness about AIDS could hurt the local economy. "I say: 'That's exactly the opposite. If people have a suspicion that you're covering up, not dealing with that, ... that decreases the confidence of investors,'" Piot said. Piot hoped companies could get more involved in prevention efforts -- especially those employing migrant workers on building sites, at home or abroad. Piot urged Chinese firms to overcome a reluctance to be associated with HIV/AIDS and set up education and prevention programs for workers and populations they are in contact with.

### **"Mayor calls for condoms in public toilets"**

**Date:** 09 September 2007

**Source:** *New Vision*

**Author(s):** Ali Mambule

<http://allafrica.com/stories/200709100475.html>

Mbarara mayor, Wilson Tumwine, has advised political leaders and counsellors to keep condoms in public toilets to save more people from contracting HIV/Aids and other sexually transmitted diseases. Tumwine said many people, especially the youth were afraid of picking condoms from public places and in hospitals where they are given out freely.

"Put a box of condoms in a public toilet. In only a few hours, the box will be empty." He was addressing politicians and counsellors from various towns countrywide at Bwala Social Centre during the launch of the Alliance of Mayors' Initiative for Community Action of HIV/Aids at the Local Level activities in Masaka last week.

Tumwine said it was surprising that condoms expire in hospitals yet they are given out freely. He advised counsellors not to over rely on the abstinence campaign, saying many of their clients and the youth, who are their main target, were not willing to comply. "Tell them about abstinence but do not waste so much time on that because they will not comply. Teach them how to use condoms and make them available where they can easily be accessed."

Masaka Archdeacon Canon Nkambo Mugerwa said although the Church was against the use of condoms, the idea of placing them in public toilets was good. "We need to keep the people alive so if they do not respond to the abstinence call, maybe in future they will listen. Tumwine's suggestion is not bad." The municipal council speaker, Denis Lukanga Majwala, represented Masaka mayor John Tebyasa Matovu.

## "Borysiewicz to head UK medical council"

**Source:** *Hopkin, M. Borysiewicz to head UK medical council. Nature. 13 Sept 2007; 449(121).*

<http://www.nature.com/nature/journal/v449/n7159/full/449121a.html>

The next head of the UK Medical Research Council (MRC) has been chosen, potentially bringing to a close a period of significant unrest within the organization. Nature has learned that the government's biomedical research organization will appoint Leszek Borysiewicz as successor to its current chief executive Colin Blakemore when he steps down at the end of this month.

Borysiewicz, who is currently deputy rector at Imperial College London, has a clinical-sciences background and is currently co-chair of the MRC's advisory group on stem-cell research. He will take charge of the MRC's £460-million (US\$933-million) annual research budget - perhaps more, if a government decision to increase the MRC's spending power is announced as expected later this year. "I hope that there will be a substantial increase in the MRC's budget," says Blakemore. "It is important for the MRC to sustain its investment in fundamental research, as well as having funds to expand."

Borysiewicz will inherit an organization whose scientists are beset with doubts about their future. Last year's government-commissioned review of the MRC's goals by venture capitalist and former Wellcome Trust governor David Cooksey called for the council to pursue an agenda of 'translational research' - biomedical research more strongly focused on health benefits and the economic bottom line. The review voiced economists' and executives' fears that, despite the MRC's impressive track record of medical discoveries such as cancer drugs and monoclonal antibodies, it has failed in the past to maximize the clinical impact and reap the cash rewards its innovations deserve. But the new agenda has left MRC-funded scientists worried that basic research will be left out in the cold.

"I'm a lot more confident than I was six months ago that the MRC will not have to reduce its commitment to fundamental research or the breadth of its portfolio, and, in addition, that it will be given the ability to transform discoveries into valuable applications more efficiently," Blakemore told Nature.

Critics of the translational research agenda are anxious that the new appointee should not stifle basic research. "We need someone committed to making sure that 'blue sky' research funding is maintained," says Hilary Leever, acting director of the Campaign for Science and Engineering in the UK. "We need to make sure science is balanced." With a strong basic research background that has also yielded clinical benefits such as vaccines, Borysiewicz looks well placed to deliver on this balancing act.

The process of selecting a new chief executive has also suffered controversy, with doubts about the suitability of MRC chairman John Chisholm - appointed last year to lead the search for a new chief executive - to select the right candidate. In July, the Commons Science and Technology Committee said that it had "serious reservations as to whether Sir John is the right person to guide the MRC executive through the coming period of change". Chisholm previously presided over the spin-out of the government's defence research agency to form a profit-making company called QinetiQ. At the MRC, he was appointed as a non-executive chairman with no involvement in the council's decision on where to direct funds, but rumours have persisted that more than one well-qualified candidate has been discouraged from applying for the role of chief executive owing to fears of interference in such decisions. Blakemore

says he was not aware of candidates declining to apply, adding that "I am very confident that the next chief executive will be expected to be a strong scientific leader of the MRC". Although Blakemore claims that he has no certain knowledge of who will replace him, he says "I hope that we will have a new chief executive in post shortly after my departure. " He adds that selecting a chief executive from a clinical background would potentially be a good strategic move.

"The most important thing is that the MRC should, and I think will, maintain its quality of judgement in supporting the very best biomedical research in the UK," Blakemore says.

Most observers of British science agree that the translational research agenda is a necessary and pragmatic new direction, providing that basic science does not suffer unduly. This was a widespread fear when Blakemore announced his intention to leave earlier this year. "We hope the agenda can be implemented without losing research quality," says Royal Society president Martin Rees. "The appointment of someone of high standing and professional reputation is crucial."

Borysiewicz, described by Rees as a "distinguished figure", has a research background focused on viruses and immunology. In 2001 he received a knighthood for his work on developing a range of vaccines, including the vaccine against human papilloma virus aimed at preventing cervical cancer. A popular figure among students and researchers at Imperial College, Borysiewicz is responsible for the college's overall scientific and academic direction. He has embraced applied research, particularly in establishing the Schistosomiasis Control Initiative, which was funded by the Bill and Melinda Gates Foundation.

Another influential British science policy job also looks to have been given to a candidate from Imperial College. John Beddington, a biological economist and political adviser on fisheries, is to be asked to become the British government's new chief science adviser, replacing David King when he finishes his eight-year tenure at the end of this year. The Department of Innovation, Universities and Skills is expected to make a formal announcement shortly.

With a background in environmental and fisheries research, Beddington is well-versed in the issues that look set to dominate government science policy during the next few years. "We at the Royal Society feel he's an excellent choice," says Rees.

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## 7. HIV/AIDS FUNDING

### "U.S. donates fund to UNHCR's HIV/AIDS programmes"

**Date:** 08 September 2007

**Source:** *Daily Monitor (Uganda)*

<http://allafrica.com/stories/200709100058.html>

The United States Government has made a cash contribution of USD 981,700 to the United Nations High Commissioner for Refugees (UNHCR) to support of the agency's HIV/AIDS programmes in refugee camps in Ethiopia. The funding is provided under the United States Leadership against HIV/AIDS, Tuberculosis and Malaria

Act of 2003 and is part of the President's Emergency Plan for AIDS Relief (PEPFAR), the UN agency said in a statement.

UNHCR programmes in Botswana, Kenya, Rwanda and Zambia have also benefited a share of the total of USD 2,119,120 made available under PEPFAR, the statement indicated.

"UNHCR, the global refugee agency, is grateful for the continuous support of the Government and people of the USA in favour of refugee care and protection world wide; this latest contribution is yet another expression of their commitment to support UNHCR's humanitarian activities in this part of the world," the statement quoted, UNHCR's Addis Ababa-based Regional Liaison Representative as saying. "On behalf of the refugees under our care, I express my gratitude to the government and people of the USA for this important humanitarian gesture," he added. Ethiopia currently hosts more than 86,000 refugees in seven camps.

The UN refugee agency continues to protect and support the refugees while it helps the government of Ethiopia in the rehabilitation of infrastructure and the environment in and around the refugee camps, the statement indicated. The majority of the refugees in Ethiopia are Sudanese who fled their country due to the 21-year-old north-south conflict there. There are also a significant number of Somali and Eritrean refugees as well.

The signing of the Comprehensive Peace Agreement between the Sudanese warring factions in January 2005 has ended the conflict in south Sudan, paving the way for thousands of refugees to return. More than 20,000 have already gone home from Ethiopia between March 2006 and May 2007 through a joint operation of the government of Ethiopia, UNHCR, IOM and WFP.

The Refugee agency in the statement also thanked its top ten donors in its global program who in 2007 alone contributed almost 700,000,000 USD as at 30 June. These, the statement listed, are USA, Sweden, Japan, European Commission, the Netherlands, Denmark, Norway, CERF, Canada and Germany in that order.

### **"Australian aid to combat AIDS in northeast India"**

**Date:** 05 September 2007

**Source:** *Indo-Asian News Service*

<http://www.calcuttanews.net/story/279566>

Australia has committed 10 million Australian dollars to curb spread of HIV/AIDS in four states of northeast India. Minister of State for Health and Family Welfare Panabaka Lakshmi informed the Lok Sabha Wednesday that these funds are for Manipur, Nagaland, Mizoram and Meghalaya. However, she said: 'The funds are yet to be received.'

According to a revised estimate, the National AIDS Control Organisation (NACO) has reduced the AIDS population in India from 5.2 million to 2.5 million. As per data with the health ministry, HIV/AIDS adult prevalence rate in Manipur is as high as 1.68 percent as against the national rate of 0.36 percent. The adult (15-49 age group) prevalence rate in Nagaland is 1.27 percent, 0.74 percent in Mizoram and 0.06 percent in Meghalaya.

## 8. PHARMACEUTICAL INDUSTRY

### "New body to streamline drug licensing, imports"

**Date:** 07 September 2007

**Source:** *The Hindu*

**Author(s):** Sarah Hiddleston

<http://www.hindu.com/2007/09/07/stories/2007090755021500.htm>

The Central government is set to introduce a bill in the monsoon session of Parliament to bring about changes to the body that regulates the manufacture, import, storage, promotion and use of medicines, cosmetics and other pharmaceuticals.

The new structure is designed to centralise drug approvals and tighten the lax manufacturing practices that have led to a proliferation of poor ethical practices and substandard drugs, endangered lives and given the pharmaceutical industry a bad name.

According to a Cabinet note, a new independent Central Drugs Authority of India (CDAI) will replace the Central Drugs Standard Control Organisation, along the lines suggested by the former CSIR Director, Dr. R.A. Mashelkar's expert committee in 2003. The CDAI is to "be responsible for the development and definition of basic standards," "provide technical vision" and ensure that "for every activity there [is] a clear policy framework and efficient supervision to ensure a uniform legislation."

#### *New divisions*

Ten new divisions headquartered in Delhi are to take up specific roles, including regulation, enforcement, legal and consumer affairs; biotechnology products; pharmacovigilance/drugs safety; medical devices/diagnostics; imports; quality control; and Indian systems of medicine. The States will continue to grant drugs sales licenses, but responsibility for the manufacturing licenses is to move over a five-year period to the CDAI. Additionally, the penalty for conducting clinical trials without permission is to be raised to 10 years' imprisonment with a fine of Rs.20 lakh.

The Drugs Controller General (DCG) is to become Additional Secretary, and two Additional Drugs Controllers will work under him, one on Indian systems of medicine and the other on the remaining issues. Two new zonal offices are to be set up in Hyderabad and Chandigarh, and 114 posts created on top of the 82 currently sanctioned, of which 29 lie vacant. The extra cost of expansion, estimated at Rs.3 crore, is to be met through new fees for inspection and registration, and licenses for manufacturers, new products and clinical trials.

#### *"More efficiency"*

Both pharmaceutical stakeholders and public health groups feel that having a Central authority with greater manpower will streamline licensing and improve quality control monitoring. "The authority on drugs control today is overloaded," said D.G. Shah of the Indian Pharmaceutical Alliance. "If the DCG is away or attending parliamentary questions, the

drug approval process comes to a standstill. The changes should bring in more efficiency and allow time for in-depth study of applications."

"Across the world, there is one central drugs authority. I would go for it," Ranjit Shahani said on behalf of the Organisation of Pharmaceutical Producers of India.

"At present, there are a lot of gaps, especially when it comes to registering drugs for clinical trials. Companies slip through the net easily," said Kajal Bhardwaj from the Lawyers Collective, a non-governmental organisation that provides public interest legal services.

"Greater centralising of drug approvals will help. Almost all approvals for combination drugs over the past few years should not have been allowed," said Dr. Amit Sengupta of the People's Health Movement.

The DCG on Tuesday banned 12 combination drugs, and the State regulators are to act on 34 others. The lack of adequate staff is another reason for the absence of quality control, Dr. Sengupta said. Since many large companies, both domestic and multinational, subcontract their manufacturing to small dispersed units, determining quality without enough inspectors is difficult. The new legislation will address these concerns.

### **"Traditional medicine for HIV to go on trial"**

**Date:** 04 September 2007

**Source:** *SciDev.Net*

**Author(s):** Carol Campbell

<http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=3870&language=1>

Clinical trials to test a traditional medicine's effectiveness in delaying the onset of AIDS in HIV-positive patients will begin in South Africa within weeks, according to researchers. Approximately 125 HIV-positive patients at Edendale Hospital in Pietermaritzburg in KwaZulu-Natal province will take part in trials of the herb *Sutherlandia frutescens*, a well-known South African traditional medicine. The purpose of the trial will be to test the safety and effectiveness of capsules of *Sutherlandia* in patients newly diagnosed with HIV.

The scientists announced their plans last week (28 August), saying the project will most likely begin this month, once the South African Medicines Control Council completes its final regulatory check. They expect to have results by August 2009. The research will be conducted by the South African universities of KwaZulu-Natal and the Western Cape, along with the Traditional Healers' Association of South Africa and the US-based University of Missouri.

Traditional healers use *Sutherlandia frutescens*, sometimes known as 'cancer bush', to treat a host of ailments from weight loss to aches and pains. *Sutherlandia* has several active ingredients, said Quinton Johnson, one of the study researchers and director of the International Centre for Indigenous Phytotherapy Studies at the University of the Western Cape. The plant contains pinitol (a compound with anti-diabetic properties), canavine (used by traditional healers to treat wasting diseases like tuberculosis) and the amino acid GABA, which produces a feeling of wellbeing.

Nceba Gqaleni, deputy dean of the University of KwaZulu-Natal's Nelson R. Mandela School of Medicine, said this was the first collaboration between scientists and traditional healers to assess the effectiveness of indigenous

practices in treating such a serious health issue. "This research will further the cause of traditional medicine, as well as assist scientific study," he told SciDev.Net.

Sazi Mhlongo, chairman of the Traditional Healers' Association of South Africa, told SciDev.Net that the plant is "the most powerful of our herbs, which we mix with other herbs to treat a lot of different problems". Mhlongo, who has practised as a traditional healer in KwaZulu-Natal for 34 years, said traditional healers have become increasingly aware of the herb's success in treating HIV-positive patients. Patients who took it "felt better", he said.

## "Pharmacovigilance in developing countries"

**Source:** *Pirmohamed M, Atuah KN, Dodoo AN, et al. BMJ. 2007 Sep 08;335(7618):462. Editorial.*

<http://www.bmj.com/cgi/content/full/335/7618/462>

Efforts are increasing to ensure that resource poor countries, which bear almost 90% of the global disease burden, have access to effective medicines.<sup>1</sup> As a result, drug companies are facing increased pressure from governments, the World Health Organization, and patient lobby groups to remove legal and financial barriers to access.<sup>2</sup> However, although these campaigns are necessary and clearly laudable, they are not accompanied by the development or upscaling of processes for monitoring drug safety. Although many drugs have been extensively used and studied in developed countries (thus informing global practice), their safety profile cannot necessarily be generalised to developing countries, where the incidence, pattern, and severity of adverse reactions may differ markedly because of local environmental and genetic influences.<sup>3</sup>

After the thalidomide disaster in the 1960s, most Western countries developed national pharmacovigilance systems.<sup>4</sup> These systems use spontaneous reporting or other pharmacoepidemiological methods to systematically collect and analyse adverse events associated with the use of drugs, identify signals or emerging problems, and communicate how to minimise or prevent harm. Although these processes are not perfect, as exemplified by recent problems,<sup>5</sup> they do provide evidence that can be used to institute regulatory action to protect public health.

At the global level, the WHO programme for international drug monitoring at the Uppsala Monitoring Centre collates adverse drug reaction reports via the national pharmacovigilance centres of the 81 member countries ([www.who-umc.org](http://www.who-umc.org)). However, currently only six sub-Saharan African countries (South Africa, Zimbabwe, Tanzania, Mozambique, Nigeria, and Ghana) are full members of the programme. In fact, less than 27% of lower middle income and low income economies have national pharmacovigilance systems registered with the WHO programme, compared with 96% of the high income countries in the Organisation for Economic Co-operation and Development. The main reasons for this are lack of resources, infrastructure, and expertise. Thus, although access to medicines is increasing in developing countries, there is a danger that their risk benefit profiles in indigenous populations will not be fully monitored and acted upon.

So what can be done to improve drug safety monitoring in developing countries? In the short term, we need to make better use of ongoing or planned studies. The ability to detect an adverse drug reaction depends on its frequency and the total number of people exposed to the drug.<sup>6</sup> A logical approach would be to encourage collaboration between academic investigators, drug companies, and governments undertaking clinical studies to develop common adverse

reaction reporting forms and to deposit the data into a single database.

Similar partnerships could also be established with organisers of public health and drug access campaigns and with regional surveillance systems, such as the East African network for monitoring antimalarial treatment<sup>7</sup> and the network for assessing health and demography in developing countries.<sup>8</sup> The operational advantages of this approach are that data can be obtained from a range of studies and that pre-existing manual and technical infrastructures can be used to acquire the data. This would provide demographically relevant data from large (and less homogeneous) populations in a structured and systematic fashion, and these data could then be used to identify warning signals.

Individual investigators would still own their data and publish results of their trials, but the pooling of data on adverse drug reactions would add value to ongoing studies. This has already happened on a small scale. For example, an increased risk of serious neurological reactions was identified in people taking ivermectin who were infected with *Loa loa* before treatment started.<sup>9</sup> Such pooling of data needs to be increased and considered for all drug classes within a formulary.

What role should the drug industry have in promoting pharmacovigilance? The current model for drug development in resource poor settings depends on public-private partnerships, such as the Medicines for Malaria Venture. These partnerships should be encouraged to continue beyond the point of obtaining a drug licence to developing a proactive phase IV programme. Such a programme could be designed to show the effectiveness of the drug in a real world situation, and through this obtain safety data in much larger cohorts of patients. A few examples of this approach already exist in Africa,<sup>10</sup> but these need to become the norm rather than the exception.

In the long term, every country should develop its own national pharmacovigilance system, which contributes to a global database such as that held by the Uppsala Monitoring Centre. This will need an extensive infrastructure, however, which would be costly. In a climate where health resources are limited, funding a pharmacovigilance system will come second to other competing priorities such as implementing a new vaccine programme. The funding model for pharmacovigilance activities in the United States recently advocated by the Institute of Medicine<sup>11</sup> is unlikely to work in developing countries if it increases drug costs, as this defeats the aim of increasing access to medicines. No easy answers are available, but WHO needs to lead a dialogue between the major stakeholders with the aim of developing a novel funding model that supports pharmacovigilance activities in developing countries. The lack of local expertise in pharmacovigilance could be tackled through developing exchange programmes with the major drug regulatory agencies and sharing of best practices.

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## **9. ANNOUNCEMENTS**

### **LEGAL ASPECTS OF HIV/AIDS: A GUIDE FOR POLICY AND LAW REFORM**

[http://www.yppf.org/legal\\_aspects\\_of\\_hiv\\_aids\\_a\\_guide\\_for\\_policy\\_and\\_law\\_reform\\_book\\_launch\\_world\\_bank](http://www.yppf.org/legal_aspects_of_hiv_aids_a_guide_for_policy_and_law_reform_book_launch_world_bank)

Written by a team of eminent legal scholars and practitioners, this book summarizes key legal and policy issues for 65 wide-ranging topics related to HIV/AIDS. The concise format will be useful for policy makers, HIV/AIDS practitioners, lawyers, the media and others seeking clear, precise information. The Guide shows how laws and regulations can either underpin or undermine good public health programs and responsible personal behaviors. It provides relevant "practice examples" (citing from actual laws and regulations) and offers selective lists of references.

## **MAC AIDS FUND LEADERSHIP INITIATIVE**

[http://www.hivcenternyc.org/training/leadership\\_initiative.html](http://www.hivcenternyc.org/training/leadership_initiative.html)

Great challenges demand great leadership. Combating HIV/AIDS is one of the greatest challenges facing the world - and South Africa in particular. Recognizing the critical need to catalyze and encourage new and emerging leadership in HIV/AIDS prevention within countries hard hit by the epidemic, the M-A-C AIDS Fund has launched the Leadership Initiative in collaboration with Columbia University and UCLA. If you have the initiative, the vision, and the determination to become a leader in the fight against HIV/AIDS in South Africa, we would like to help you take the next step.

What is the Leadership Initiative?

The Leadership Initiative is a one-year training program designed to help cultivate emerging leaders in South Africa who will make a major contribution to HIV/AIDS prevention advocacy at the local, regional, or national levels. The focus of the program is on reducing the spread of HIV and the impact of AIDS by addressing the role of gender inequality.

The Leadership Initiative provides a structured, supportive program to enable participants to learn about and engage in the exchange of successful approaches to HIV/AIDS prevention that can be modified to meet local needs. This program is underwritten by the M-A-C AIDS Fund and directed by the HIV Center for Clinical and Behavioral Studies (Columbia University, New York City) and the UCLA Program in Global Health (University of California, Los Angeles).

***EDITOR'S NOTE: For more information and to apply, please visit the above website.***

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