



ALLIANCE FOR MICROBICIDE DEVELOPMENT

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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 individual articles or complete issues at <http://www.microbicide.org/publications/> and may also search by keyword for articles included in issues of the *Digest* created after 27 January 2006, at <http://www.microbicide.org/publications/search.html>. Should you wish to be removed from the *Digest* distribution list, please advise us at 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

"AIDS study in mice may yield hope"

Date: 27 March 2007

Source: *Dallas Morning News*

Author(s): Sue Goetinck Ambrose

http://www.dallasnews.com/sharedcontent/dws/news/localnews/tv/stories/DN-nuhivmice_27met.ART.State.Edition2.4442153.html

Dallas researchers have successfully infected mice with the virus that causes AIDS, a major advance in researchers' ability to test preventive medications, treatments and vaccines. HIV attacks immune cells, and the mice have a humanized immune system to allow infection.

The virus is known to infect only people, and researchers trying to figure out how to stop HIV's spread have relied mainly on monkeys infected with a monkey version of the virus. Mice are cheaper and easier to house than monkeys. "If you want to figure out how to stop the spread of the virus, you have to have something like this," said J. Victor Garcia, a professor of medicine at UT Southwestern Medical Center who led the new research. "This is the very first model where you can demonstrate transmission of HIV via a normal route."

A report describing the mice and their susceptibility to HIV appeared online Monday in the *Journal of Experimental Medicine*. **[EDITORS' NOTE: The abstract of the article is included in this issue of the Digest, under the category, "New Published Research: Microbicide-Specific."]**

Transmission of HIV

HIV can enter the body through the bloodstream, through contaminated needles shared by intravenous drug users, for

example. But it is most commonly transmitted through sexual contact, with the virus entering the body through the surfaces that line the oral cavity, the vagina or the rectum. The mice were infected through rectal transmission, the most common way HIV is spread between men.

In the new study, six of seven inoculated mice showed evidence of infection after the researchers introduced HIV particles into the mice's rectums. Three of four mice tested made human antibodies to the virus, just like people do. Autopsies of the mice showed they were producing HIV in lymph nodes, spleen and other immune tissues. The virus also was being produced in the lungs, intestines, and male and female reproductive tracts. "The pathology we observe in animals remarkably resembles what you observe in people," Dr. Garcia said. Other researchers have infected mice with HIV, Dr. Garcia said, but those animals had a less complete humanized immune system. Also, he said, in those cases the virus was transmitted by injection, not rectally.

Dr. Garcia starts with mice born with no immune system. A transplant of human fetal liver and thymus tissue, as well as special cells that give rise to immune system cells, kicks off a human immune system. After the immune system takes hold, the mice can be infected with HIV.

Dr. Garcia's mice should allow researchers to search for topical antiviral medications known as **microbicides** that could be applied in the vagina or rectum. That the mice exhibit an immune response to HIV also suggests they could be used to test vaccines against the virus. New therapies for established infections could be studied using the mice, Dr. Garcia said.

'Significant advance'

Other researchers praised the work. "For people trying to prevent the epidemic from spreading, this is a significant advance," said Dr. Ian McGowan, an associate professor of medicine at the University of California, Los Angeles. Dr. McGowan said he believed the biggest application of the mice would be in testing preventive medications such as **microbicides**.

The mice should allow researchers to get a glimpse of an infection as it's occurring, said Dr. Martin Markowitz, an AIDS researcher at the Aaron Diamond AIDS Research Center. "The exact time of infection is hard to pinpoint in people," Dr. Markowitz said. "Even if you can, most people come in after they've been infected for several weeks."

The biggest advantage to having HIV-susceptible mice is cost and ease of care, said molecular biologist Janet Young, program officer with the division of AIDS at the National Institute of Allergy and Infectious Diseases in Rockville, Md. "They are a very easy animal to work with," Dr. Young said. "We've been forced to use rhesus [monkeys] and other nonhuman primate models."

An estimated 1 million people in the U.S. are infected with HIV. Men who have sex with men represent the largest group living with HIV - 45 percent. While no official statistics exist on the precise route of transmission, experts say unprotected anal sex is the most common way men contract HIV.

Other UT Southwestern researchers who participated in the study were Zhifeng Sun, Paul Denton, Florence Othieno, Bangdong Wei, Anja Wege, Michael Melkus and Angela Padgett-Thomas. Also contributing were Minnesota researchers Jacob Estes, Mary Zupancic and Ashley Haase.

"Fighting HIV's relentless march"

Date: 26 March 2007

Source: *Canberra Times*

Human behaviour and drug resistance are contributing to the increasing risk of contracting HIV and scientists are uniting in their efforts to fill the gaps in knowledge that could help to control the global epidemic.

Last year approximately 4.3 million people were newly infected with HIV and the death toll from AIDS reached approximately 2.9 million. Most deaths occurred in sub-Saharan Africa, where life expectancy at birth is now just 47 years, 30 years less than in most high-income countries. In some areas, infection rates have risen by more than 50 per cent since 2004. Although the magnitude of Australia's problem is much less, the number of new HIV infections has begun to rise and the increased frequency of unprotected sex, notably among Sydney men who have sex with men, suggests that the preventive practices adopted in the 1980s and '90s may be declining. Annual infection rates peaked at over 1000 at that time and then declined to around 500 but the number of new infections rose to 899 in 2004 and 954 in 2005.

A range of interventions have already been proven to reduce the spread of HIV. Among the most effective are abstinence, the consistent and correct use of condoms, sterile drug injecting equipment and male circumcision. But these measures have limitations, predominantly related to human behaviour. For example, some men refuse or forget to wear condoms or don't put them on properly. Researchers from the Forum for Collaborative HIV Research met late in 2006 to foster international cooperation on research into different preventive measures to combat HIV. The forum comprises international experts from academia, government agencies, pharmaceutical companies, community organisations and private foundations.

Problems and issues that limit the progress of research were identified and gaps in existing knowledge were documented during the meeting. Forum director Dr Veronica Miller hopes this will pave the way for prioritising and accelerating future research effort. Although condoms offer a high level of security, Miller believes a range of options must still be developed. "The additional interventions have a role in filling the gap that the imperfect use of condoms leaves open," she said.

Not all interventions currently under development are likely to be widely acceptable, no matter how much scientific validation they receive. Miller cites as an example the development of genetically engineered varieties of vaginal bacteria that release anti-HIV compounds.

"We need to think about something like that. Would it be feasible to implement in the developing world? Are we really saying people from the West are going to come and distribute bacteria to African women? It just doesn't sound politically feasible. That doesn't mean the science should not be worked on but it is not something that would be the first priority." In contrast, the ongoing development of antiretroviral (ARV) drugs is the subject of much promising research. These drugs act to inhibit the reproduction of the HIV virus in the body. Various ARVs have improved the health outcomes for HIV-positive people over the past few decades and they can also be given to non-infected people to reduce the likelihood of the virus taking hold in the body should they become exposed to it. As a preventive measure, ARVs can be included in **microbicide** gels, creams or lubricants during intercourse or used in slow-release form through vaginal rings or diaphragms. Another option, suited to the risks of intravenous drug use as well as sexual

transmission, is to take ARVs as an oral prophylaxis.

Currently people given ARVs after infection have between 5 and 20 per cent chance of developing a drug-resistant strain that could then be passed on to others. Using the same ARVs as a preventive treatment would render them effective in this situation.

"Drug resistance is just one of the facts of life," says Miller. "I am one of the optimistic ones. I think that in the prevention setting, other than mother to child transmission, it won't be such a huge problem. When a person who is not yet HIV-infected is being exposed to a virus population at the portal of entry you have these drugs which stop the virus from actually seeding. It is a completely different dynamic because you don't have the virus replicating in the presence of drugs so much at that point." Miller accepts that her optimism is speculative because the research has not yet been done to provide an understanding of the processes involved but hopes that, by clearly defining what still needs to be done, the group can direct the focus of future research. Little is known about the infectiousness or resistance properties of the HIV virus at a genetic level and little is known about how well measures of virus levels in the bloodstream correlate to those in semen or cervical mucosa where the virus is likely to be transmitted.

Trials into **microbicides** that incorporate ARVs are due for completion in the next couple of years but none so far are assessing their efficacy for rectal use. The long-term safety of oral prophylaxis drugs has not been confirmed beyond 18 months and they have yet to be shown conclusively to be safe and effective for women. The effectiveness of irregular doses is not known, nor is the impact of combining them with other drugs such as those used for the treatment of tuberculosis, although serious negative interactions have been encountered.

ARV agents can be used singly or in combination and researchers are still debating whether the search for new ARVs should focus on potency or drug resistance. Combination treatments add to the complexity of research and trials required before a treatment can be released for public use and to the purchase cost once they are available. Some researchers are concerned that they will lead to the development of an "Andromeda strain" which could mutate so rapidly that it could not be controlled.

The number of people already carrying drug-resistant forms of HIV is unknown because tracking programs in many countries have not been comprehensive. The World Health Organisation has recently begun setting up the infrastructure required to document resistance among people in developing nations. Their goal, agreed by United Nations member states in June 2006, is to achieve "universal access to comprehensive prevention programs, treatment, care and support" by 2010.

Miller hopes the forum will provide an objective means of prioritizing and focusing research to help achieve this goal.

"Microbicides: a long and bumpy road to success?"

Date: 28 February 2007

Source: *AIDS Reviews Hot News*

Author(s): Vicky Jespers, Marie Laga, Yven Van Herrewege, and Guido Vanham, et al

http://www.aidsreviews.com/files/2007_9_1_61_63.pdf

The need to develop additional HIV prevention tools, under the control of women, is urgent [1]. The search for an effective vaginal **microbicide** started in the early 1990s [2] and has been accelerated in recent years [3]. On January 31, 2007, CONRAD announced the discontinuation of their Cellulose Sulphate (CS) **microbicide** phase III effectiveness trial because "preliminary data indicated that cellulose sulphate could lead to an increased risk in HIV infection". This press announcement was received with disappointment and shock. It is yet another reminder that the road to success may be longer and more complex than anticipated. In the 1990s, high hopes were based on N-9 based spermicides. These cheap products were readily available on the market, approved as vaginal contraceptives, and data on anti-HIV activity from *in vitro* and animal models were promising. In 1996, after extensive safety studies [4-7], an HIV prevention phase III trial was launched, showing an increased risk of HIV among the N-9 users versus the placebo [8,9]. Important lessons were learned about local toxicity of vaginal detergents when used frequently and for a longer period of time [9]. Newer *in vitro* models confirmed that the "therapeutic window" between toxicity and anti-HIV efficacy was very narrow for N-9 [10].

Screening of products, development of new *in vitro* and animal models more relevant for vaginal transmission of HIV, and multiple consultations between experts led to the identification and evaluation of potentially more effective and less toxic candidate products. The polyanions CS, Carraguard[®], PRO 2000 and the acidifying agent Buffergel[®] entered phase III trials in 2004/2005 and investments in **microbicides** of the newer generations including the nonnucleoside reverse transcriptase inhibitors and newer versions of small molecular HIV-specific entry inhibitors strengthened [11]. As said, the CS trial was prematurely interrupted and the results of the other nonspecific entry inhibitors trials are eagerly awaited. What are the lessons learned? The negative effect of CS was a surprise. Expectations on the efficacy of CS varied from "promising" to "no effect", depending on which *in vitro* studies were referred to, but the increase in HIV risk was not expected, and no immediate explanation can be given.

This surprising result nevertheless brings us to a central issue in **microbicide** research: how can we best predict efficacy and toxicity of new candidate products and what is the relevance of the different *in vitro*, *ex vivo* and *in vivo* models in this context? The models can provide us with a good idea of the relative potency and toxicity of various candidates, but none of the present *in vitro* models is truly able to mimic completely transmission *in vivo* and many basic questions on vaginal transmission remain to be solved. It is a matter of proof of concept to allow for the various *in vitro* models to be validated.

Given the complexity of a phase III trial (cost, ethics, organization), only the very best products should move to this development stage. Therefore we need to invest in research on all levels:

- In the lab, to improve *in vitro* models for efficacy and toxicity, to be able to select the best possible candidates for future phase III trials.
- In the clinic, to rethink safety evaluations.
- In epidemiologic methods, to better understand the data on sexual transmission, and to maximize the phase III trial methodology for HIV prevention trials.

Probably most important is that there is fertilizing cross-discipline exchange! The challenges are enormous, but doing nothing would be the worst for the millions of vulnerable women and men in the world!

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2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Intrarectal transmission, systemic infection, and CD4+ T cell depletion in humanized mice infected with HIV-1"

Author(s): Sun Z, Denton PW, Estes JD, et al

Reference: N/A Epub ahead of print.

Published Abstract: Intrarectal infection between men who have sex with men represents a predominant form of human immunodeficiency virus (HIV) transmission in developed countries. Currently there are no adequate small animal models that recapitulate intrarectal HIV transmission. Here we demonstrate that human lymphocytes

generated *in situ* from hematopoietic stem cells reconstitute the gastrointestinal tract of humanized mice with human CD4+ T cells rendering them susceptible to intrarectal HIV transmission. HIV infection after a single intrarectal inoculation results in systemic infection with depletion of CD4+ T cells in gut-associated lymphoid tissue and other pathologic sequela that closely mimics those observed in HIV infected humans. This novel model provides the basis for the development and evaluation of novel approaches aimed at immune reconstitution of human gut-associated lymphoid tissue and for the development, testing, and implementation of **microbicides** to prevent intrarectal HIV-1 transmission.

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3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Fine-touch pressure thresholds in the adult penis"

Author(s): Sorrells ML, Snyder JL, Reiss MD, et al

Reference: N/A 99(4):864-9.

Published Abstract: OBJECTIVE: To map the fine-touch pressure thresholds of the adult penis in circumcised and uncircumcised men, and to compare the two populations. SUBJECTS AND METHODS: Adult male volunteers with no history of penile pathology or diabetes were evaluated with a Semmes-Weinstein monofilament touch-test to map the fine-touch pressure thresholds of the penis. Circumcised and uncircumcised men were compared using mixed models for repeated data, controlling for age, type of underwear worn, time since last ejaculation, ethnicity, country of birth, and level of education. RESULTS: The glans of the uncircumcised men had significantly lower mean (sem) pressure thresholds than that of the circumcised men, at 0.161 (0.078) g ($P = 0.040$) when controlled for age, location of measurement, type of underwear worn, and ethnicity. There were significant differences in pressure thresholds by location on the penis ($P < 0.001$). The most sensitive location on the circumcised penis was the circumcision scar on the ventral surface. Five locations on the uncircumcised penis that are routinely removed at circumcision had lower pressure thresholds than the ventral scar of the circumcised penis. CONCLUSIONS: The glans of the circumcised penis is less sensitive to fine touch than the glans of the uncircumcised penis. The transitional region from the external to the internal prepuce is the most sensitive region of the uncircumcised penis and more sensitive than the most sensitive region of the circumcised penis. Circumcision ablates the most sensitive parts of the penis.

"Impact and process evaluation of integrated community and clinic-based HIV-1 control: a cluster-randomised trial in Eastern Zimbabwe"

Author(s): Gregson S, Adamson S, Papaya S, et al

Reference: N/A 4(3):e102.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0040102>

Published Abstract: Background: HIV-1 control in sub-Saharan Africa requires cost-effective and sustainable programmes that promote behaviour change and reduce cofactor sexually transmitted infections (STIs) at the

population and individual levels. **Methods and Findings:** We measured the feasibility of community-based peer education, free condom distribution, income-generating projects, and clinic-based STI treatment and counselling services and evaluated their impact on the incidence of HIV-1 measured over a 3-y period in a cluster-randomised controlled trial in eastern Zimbabwe. Analysis of primary outcomes was on an intention-to-treat basis. The income-generating projects proved impossible to implement in the prevailing economic climate. Despite greater programme activity and knowledge in the intervention communities, the incidence rate ratio of HIV-1 was 1.27 (95% confidence interval [CI] 0.92-1.75) compared to the control communities. No evidence was found for reduced incidence of self-reported STI symptoms or high-risk sexual behaviour in the intervention communities. Males who attended programme meetings had lower HIV-1 incidence (incidence rate ratio 0.48, 95% CI 0.24-0.98), and fewer men who attended programme meetings reported unprotected sex with casual partners (odds ratio 0.45, 95% CI 0.28-0.75). More male STI patients in the intervention communities reported cessation of symptoms (odds ratio 2.49, 95% CI 1.21-5.12). **Conclusions:** Integrated peer education, condom distribution, and syndromic STI management did not reduce population-level HIV-1 incidence in a declining epidemic, despite reducing HIV-1 incidence in the immediate male target group. Our results highlight the need to assess the community-level impact of interventions that are effective amongst targeted population sub-groups.

"Langerin is a natural barrier to HIV-1 transmission by Langerhans cells"

Author(s): de Witte L, Nabatov A, Pion M, et al

Reference: N/A 13(3):367-71.

Published Abstract: Human immunodeficiency virus-1 (HIV-1) is primarily transmitted sexually. Dendritic cells (DCs) in the subepithelium transmit HIV-1 to T cells through the C-type lectin DC-specific intercellular adhesion molecule (ICAM)-3-grabbing nonintegrin (DC-SIGN). However, the epithelial Langerhans cells (LCs) are the first DC subset to encounter HIV-1. It has generally been assumed that LCs mediate the transmission of HIV-1 to T cells through the C-type lectin Langerin, similarly to transmission by DC-SIGN on dendritic cells (DCs). Here we show that in stark contrast to DC-SIGN, Langerin prevents HIV-1 transmission by LCs. HIV-1 captured by Langerin was internalized into Birbeck granules and degraded. Langerin inhibited LC infection and this mechanism kept LCs refractory to HIV-1 transmission; inhibition of Langerin allowed LC infection and subsequent HIV-1 transmission. Notably, LCs also inhibited T-cell infection by viral clearance through Langerin. Thus Langerin is a natural barrier to HIV-1 infection, and strategies to combat infection must enhance, preserve or, at the very least, not interfere with Langerin expression and function.

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4. EPIDEMIOLOGY

"Uganda's early gains against HIV eroding"

Date: 29 March 2007

Source: *Washington Post*

Author(s): Craig Timberg

<http://www.washingtonpost.com/wp-dyn/content/article/2007/03/28/AR2007032802510.html>

Students packed a grassy field at Makerere University in April 1989 for a farewell concert by singer Philly Lutaaya. This symbol of swaggering virility had grown gaunt, with splotchy skin and the fine, sparse hair of a baby. He sang hauntingly, "Today it's me, tomorrow it's somebody else." Between songs, he warned the stunned crowd that having several sex partners was a sure way to die in the age of AIDS, echoing pleas also made by political and religious leaders of the time. When Lutaaya died that December, at age 38, the country already had begun its historic reversal of the epidemic, researchers say, because of the power of that single, terrifying message.

Despite this success story, unmatched elsewhere on this AIDS-ridden continent, no country has entirely replicated Uganda's approach. Most instead have followed a diffuse palette of other remedies pushed by Western donors -- condom promotion, abstinence training, HIV testing, drug treatment and stigma reduction -- while forgoing what research shows worked here: fear and a relentless focus on sexual fidelity.

Even in Uganda, these key ingredients have been lost as a new generation coming of age years after Lutaaya's death indulges in the same reckless behavior that first spread the disease so widely. "We saw him. We saw him die. We abandoned the girlfriends," said Swizen Kyomuhendo, a social scientist at Makerere, who was an undergraduate when Lutaaya spoke there. "When you look at the university students now, they are not as terrified as we were then."

The percentage of sexually active men with multiple partners has more than doubled in recent years, undoing earlier declines, surveys show. Reports of sexually transmitted diseases among women, another indicator of dangerous behavior, have risen sharply as well.

A glimpse of changing attitudes can be seen every Friday night as cars stream onto Makerere's campus and pull into darkened parking lots outside women's dormitories. The glow of cellphones briefly illuminates the drivers, most 10 or 20 years older than the average student, as they call their girlfriends to come out for dates. Cathy Katumba, 22, a student with a heart-shaped face and long braids looped into a knot at her neck, said many of these college women have on-campus boyfriends their age plus older, often-married ones with the means to provide dinners out and nice clothes. Many young women, Katumba said, arrive with few possessions but finish their studies with refrigerators, DVD players and closets full of the latest fashions. As for AIDS, she said, most women at Makerere are more worried about getting pregnant. "They don't look at it as a deadly disease now," she said.

Yet even in an era of improved treatment, AIDS remains Uganda's leading killer of adults. The HIV rate has risen again at some urban hospitals. And a 2004 study put the adult infection rate at 7 percent -- several times lower than its estimated peak in the 1990s but higher than estimates just a few years earlier. Ugandans are contracting HIV five times faster than doctors are able to put new patients on the antiretroviral drugs that offer the only hope of long-term survival.

The country's once lean, focused programs, meanwhile, have grown complacent, Ugandans say. Even President Yoweri Museveni, praised for his leadership in early years, "has gotten a bit bored with the AIDS story," said his spokesman, John Nagenda. "The whole thing is too big now, too heavy," said Sam Okware, a top Ugandan health official who designed early, frightening anti-AIDS campaigns. "It has adapted too much to international guidelines instead of sticking to our own methods, which were very controversial at first but which worked."

'Fear Is Stronger Than Love'

Scientists identified Uganda's first case of AIDS, a mysterious new disease beginning to appear across Africa, in 1982. But a government response in this mostly rural country of 28 million came only after Museveni, a blunt, charismatic rebel leader, ended years of civil war by taking control in 1986. That year, he sent 60 military officers to train in Cuba. Eighteen tested positive for HIV in routine screenings there, according to Museveni's advisers. At a conference that year in the Zimbabwean capital of Harare, Cuban President Fidel Castro told Museveni, "Hey, brother, you have a problem."

Museveni soon huddled with his top doctors and focused on what they knew: A fatal, incurable, sexually transmitted disease was on the rampage. The only solution, they decided, was to urge Ugandans to stay faithful to one sexual partner or, if in polygamous marriages, to those spouses. The dominant message was, in Museveni's simple but evocative phrasing, "zero grazing," an agricultural term inspired by the zero-shaped patch created when livestock were tied to a post and allowed to eat only from a single section of grass.

Billboards went up. Songs were sung. The national radio broadcaster, which in that era dominated public airwaves, started each day at 6 a.m. with the rumble of war drums followed by the soft voice of a schoolgirl pleading, "Father, I'm still too young. Please don't die. Be faithful." AIDS programs of the time had rough edges. In a documentary on Lutaaya chronicling his decline from energetic Afro-pop superstar to a man barely able to walk, he is shown wincing as a group of village women sing sweetly, "AIDS was inflicted upon the rebellious, the promiscuous and the criminals."

While warning against stigmatizing those with the disease, Lutaaya didn't flinch from his core message. "Changes must be made in our sexual behavior," he tells one group shown in the film. "If we don't work hard, the human race is going to die." This message worked because of the passion of the delivery and the dynamics of HIV, which spreads most easily among networks of men and women with several ongoing sexual relationships, researchers say.

Such arrangements declined sharply in the years after Lutaaya's campaign. The number of Ugandan men reporting three or more non-marital sexual partners fell from 15 percent to 3 percent between 1989 and 1995, according to World Health Organization reports. The HIV rate in Kampala, once estimated at as high as 30 percent, fell dramatically. Some of that resulted from an estimated 1 million AIDS deaths, but Uganda -- a rarity among African countries -- also experienced a steep and sustained drop in new infections. "You change because of fear. And you change because of love," said Jesse Kagimba, a longtime AIDS adviser to Museveni. "Fear is stronger than love."

Fewer Casual Sex Partners

During the zero-grazing era, Museveni resisted promoting condoms on the grounds that they offered false hope that the epidemic could be stopped without curbing multiple sexual partnerships. In 1991, his government banned condom advertising. And at the International AIDS Conference that year in Florence, he told delegates, "We are being told that only a thin piece of rubber stands between our people and the death of the continent, but condoms cannot be the main means of stemming the tide of AIDS."

So rare were condoms in those years that Westerners working in Uganda had trouble getting them for their own programs. A clinic that the University of California at San Francisco had set up to treat sexually transmitted diseases resorted to ordering boxes of them in rainbow colors -- lemon yellow, cherry red, lime green -- that their Ugandan clients found odd, said Nick Hellmann, a doctor who ran the clinic from 1989 to 1991. Few knew how to use them. "It clearly at the time was not a commonly utilized product," Hellmann said from Seattle, where he is a senior AIDS

program official at the Bill & Melinda Gates Foundation.

Museveni gradually relented. The number of condoms delivered and promoted by international groups rose from just 1.5 million in 1992 to nearly 10 million in 1996, most paid for by the U.S. Agency for International Development. Uganda eventually adopted a national plan to distribute condoms whose packages featured pictures of healthy, amorous young couples. But their role in curbing the epidemic is unclear.

Kampala's decline in new infections began in 1990 and ended by 1994, according to an analysis by U.S. researchers Rand L. Stoneburner and Daniel Low-Beer, meaning the change happened before massive condom imports began. The key factor in this reversal, they concluded based on models of the epidemic and surveys from the time, was the decision by Ugandans to have fewer casual sex partners.

One national survey in 1995 found that more than half of Ugandans said they were sticking to one sexual partner to protect themselves from AIDS. Only 11 percent of men and 2 percent of women said they were using condoms for that reason.

The major push on abstinence began even later, several years after Uganda had its dramatic decline in new infections. And though surveys have shown a gradual decrease in the age when youths here begin having sex, the connection to infection rates remains unproved. A 2005 journal article by national health officials here reported that among adult Ugandans, those who started having sex at 16 are no more likely to have HIV than those who started at 19.

Despite the uncertain science behind both condom promotion and abstinence training, AIDS activists worldwide hotly debated them after President Bush created his \$15 billion anti-AIDS program in 2003. The program endorsed a prevention strategy called "ABC," for "Abstain, Be Faithful and Condomize," with \$1 billion set aside for abstinence programs alone. In the international debate that followed, conservatives rallied for abstinence, liberals for condoms. Each side bashed the other's strategy. And attention to the one element that clearly worked -- fidelity -- dwindled, even in Uganda.

Fueling confusion were the dynamics of AIDS itself. A decade often separates the date of HIV infection and death. So Ugandan health officials did not know they had made great strides against the epidemic until recently, when researchers identified those early years of zero grazing as decisive. By then, the initiative had been overtaken by big-budget, bureaucratic programs that resembled those in most African countries. Persuading Ugandans to stay faithful to their partners was no longer the focus. "It was a mistake," Okware said. "That message was loud and clear."

Nearly 18 years after Lutaaya's dramatic crusade, billboards warning against the dangers of reckless sex are hard to find in today's Kampala, the graceful, hilly capital. Far more common are photocopied fliers brazenly saying "Get a Lover" and listing a cellphone number.

Using Condoms Sporadically

As Uganda's AIDS programs lost their focus, Raymond Kwesiga, a quietly charismatic altar boy with gentle eyes behind gold-rimmed glasses, contracted HIV. It wasn't for lack of available condoms or familiarity with abstinence messages. Ugandan high school students receive AIDS education focused heavily on abstinence. And in a 2004 survey, 92 percent of young, urban Ugandan men said they knew where to find condoms. What gave Kwesiga HIV, he said, was the behavior Lutaaya once warned against.

Kwesiga, 24, had a girlfriend, several occasional partners and a knack for seducing others so reliable that his friends dubbed him "Raymond the Great," he said. Many nights, too lazy to call a girlfriend after downing a bottle of Uganda's bitter national liquor, Waragi, he spent 75 cents to hire a prostitute. Sometimes he used condoms, sometimes not -- a common but uneven approach that research shows almost entirely undermines their value. "I was enjoying my life, and I thought I wouldn't get the virus," Kwesiga said, speaking with the deliberate cadence of one trying to live up to newly learned ideals. "I wasn't very scared. . . . During the night, you don't get scared."

Now many of Kwesiga's nights are filled with fear. He fears dying. He fears he may not be able to marry or have children. And with the painful clarity that has come with sobriety, he fears he may have given HIV to somebody else. With his voice filled with regret, Kwesiga said darkly, "I'm like a murderer."

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5. POLITICS AND POLICY

"WHO, UNAIDS recommend male circumcision to help reduce spread of HIV/AIDS"

Date: 29 March 2007

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=43916

The World Health Organization and UNAIDS on Wednesday recommended that male circumcision be made available in countries highly affected by HIV/AIDS to help reduce transmission of the virus through heterosexual sex, the *Washington Post* reports. According to the *Post*, the recommendations were released in response to growing evidence that routine male circumcision could reduce a man's risk of contracting HIV (Timberg, *Washington Post*, 3/29). According to final data from two NIH-funded studies conducted in Uganda and Kenya published in the Feb. 23 issue of the journal *Lancet*, routine male circumcision could reduce a man's risk of HIV infection through heterosexual sex by 65% (*Kaiser Daily HIV/AIDS Report*, 3/7). The agencies on Wednesday recommended that circumcision be offered in addition to other prevention programs, including HIV testing and counseling, treatment for other sexually transmitted infections, promotion of safer-sex practices and condom distribution. The agencies said that the procedure only should be performed by trained, certified providers in "sanitary settings with adequate equipment and with appropriate counseling and other services." In addition, male circumcision should be offered at no cost or at the lowest possible price, the agencies said (UNAIDS/WHO release, 3/28). Officials also said that men who have sex before the circumcision wounds have healed, which generally takes several weeks, might increase the risk of contracting HIV or transmitting the virus to their partner (*Washington Post*, 3/29). Preliminary results from a study being conducted in Uganda and presented earlier this month to UNAIDS and WHO officials found that HIV-positive men undergoing circumcision might be more likely to transmit the virus to their female partners if they have sex before the circumcision wounds have healed (*Kaiser Daily HIV/AIDS Report*, 3/7).

Cost, Donor Funding

UNAIDS did not set a goal for the number of circumcisions that should be performed in the next several years, and the agency did not estimate costs associated with male circumcision programs, the *San Francisco Chronicle* reports. Officials said that countries will need to determine "whether and how" to implement the recommendations, while larger

donor organizations -- including the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the U.S. government -- are prepared to fund them, the Chronicle reports (Russell, *San Francisco Chronicle*, 3/29). Several donor organizations -- including the Global Fund and the President's Emergency Plan for AIDS Relief -- "have already indicated" that they are willing to cover the cost of male circumcisions if countries ask for money and can show that the procedures will be performed safely and with appropriate counseling, the *New York Times* reports (McNeil, *New York Times*, 3/29). Advocates say expanding circumcision programs "would be logistically daunting but possible and affordable" because they would reduce the need for some future treatments, the *Post* reports. The cost of performing male circumcision -- including training, personnel, facilities and supplies -- is about \$50 to \$100 per procedure. Ambassador Mark Dybul, who serves as the U.S. global AIDS coordinator and administers PEPFAR, said that the U.S. would "support safe male circumcision services ... as a part of an expanded approach to reduce HIV infections."

Implementation, Next Steps

According to the *Post*, focus on the implementation of male circumcision programs has been centered on sub-Saharan Africa, where public health infrastructures largely are underdeveloped. Health officials in Africa generally have said that they are waiting for guidance from WHO before expanding access to male circumcision (*Washington Post*, 3/29). According to WHO, implementing circumcision programs in sub-Saharan Africa could prevent about 5.7 million new HIV cases and three million deaths during the next two decades. "If you combine this with other modalities -- condom usage, responsible behavior, knowing the HIV status of your partner -- this is a big addition to that armamentarium," Anthony Fauci, director of NIH's National Institute of Allergy and Infectious Diseases, said. According to the *Los Angeles Times*, WHO is encouraging countries to provide access to no-cost male circumcision and initially to target adults (Chong, *Los Angeles Times*, 3/29). Countries in Southern and East Africa, where HIV rates are high and circumcision rates are low, should consider adopting male circumcision as "an important and urgent" health priority, with the target group being boys and men ages 13 to 30, Kevin De Cock, director of WHO's HIV/AIDS Department, said (*San Francisco Chronicle*, 3/29). In addition, the agencies said it is critical for men to know that even if they are circumcised, they can still contract HIV and transmit it to their partners. Therefore, circumcised men should continue to practice abstinence, have fewer sex partners and use condoms, the agencies said (*New York Times*, 3/29). UNAIDS and WHO experts said additional research is required to assess the impact of male circumcision on sexual HIV transmission from men to women; the risks and benefits of the procedure for HIV-positive men; the protective benefit of the procedure for men who have sex with men; and the resources needed and the most effective means to expand such services. In addition, they said that research to determine whether "there are modifications in perceptions and HIV risk behavior over the longer term" in men who are circumcised and in their communities "will also be essential" (UNAIDS/WHO release, 3/28).

The recommendations are available at http://data.unaids.org/pub/Report/2007/mc_recommendations_en.pdf

NPR's "All Things Considered" on Wednesday reported on the recommendations. The segment includes comments from De Cock and Ron Gray, a professor of reproductive epidemiology at the Johns Hopkins Bloomberg School of Public Health (Wilson, "All Things Considered," NPR, 3/28). Audio of the segment is available at <http://www.npr.org/templates/story/story.php?storyId=9190027>

"FDA moves to try to reduce conflicts of interest on boards"

Date: 22 March 2007

Source: *Washington Post*

Author(s): Shankar Vedantam

<http://www.washingtonpost.com/wp-dyn/content/article/2007/03/21/AR2007032102068.html?nav=hcmodule>

The Food and Drug Administration said yesterday that it plans to make extensive changes in how it selects medical experts to serve on its advisory panels after years of complaints that many of them have financial ties to the companies whose products they evaluate. The proposal would eliminate many experts who serve on the panels despite having such financial conflicts, FDA officials said. Experts with limited conflicts of interest would be allowed to participate in the discussions but not to vote on the recommendations made to the agency.

The advisory committees play a central role in regulating drugs, medical devices and diagnostic tests. Their decisions largely determine what drugs and medical products can be marketed to Americans -- because the agency nearly always follows the panels' guidance. In recent years, concern about the composition of the panels has reached a crescendo. The FDA and others have argued that overly strict rules might eliminate many -- in some cases all -- of the panel candidates with the needed expertise. Yesterday, officials maintained that the agency's procedures have not been biased in favor of industry, but the new guidelines implicitly acknowledge what critics have long said -- that it is possible to find enough qualified experts who do not have ties to drug and device manufacturers.

The new rules come as Congress has become increasingly vocal about its displeasure with how the FDA is run and follow a stinging federal Institute of Medicine report last year, which called on the agency to address the concerns over conflicts of interest. "This is one of several announcements the FDA has made in recent months whose timing suggests they are reactions both to the IOM report and the bills moving through Congress," said R. Alta Charo, a University of Wisconsin bioethicist who served on the institute's FDA review panel. "The FDA is intent on getting out ahead of some of its critics as effectively as possible -- and that is a good thing," she said. Although the changes have not gone as far as urged -- capping the number of members with conflicts on any given panel -- Charo said: "The last thing I want to do is discourage incremental progress."

Under the new rules, any scientist or physician who has had \$50,000 or more in financial ties to a company over the past 12 months, including stock or consulting arrangements, would be barred from panels evaluating that company's products. Those who have received less than \$50,000 in the previous year might be allowed to participate in the discussion but could not vote.

In general, the FDA said, it will try to limit the participation of experts who are perceived to have a conflict of interest. If the FDA commissioner thinks an expert with financial conflicts is needed on a given panel, an exception can be made, but this will be rare, said Randall Lutter, the agency's acting deputy commissioner for policy. Lutter and Jill Hartzler Warner, senior policy adviser and counselor in the FDA's Office of Policy and Planning, said it is not possible to say precisely how many experts who currently serve on advisory panels would be affected by the new rule, but they said it would have a significant impact. Agency officials did calculations to measure the impact of various cutoff points before deciding on \$50,000. "We are very interested in ensuring we have the best possible access to scientific experts," Lutter said. "At the same time, we seek to ensure we have the fullest public confidence in the integrity of our advisory committee process."

Lutter denied that the proposal, which will be open for public comment for 60 days, reflects FDA unease about the panels. Rather, he said, the step was being taken to ensure that the public's perception about the advisory panels' quality is in line with the agency's perception. "We think we have done a very good job of ensuring the process deserves the respect of the American public," he said. "We are not aware of any instances where decisions have been unfairly or adversely affected by conflicts."

Lutter and Warner said the \$50,000 figure would not apply to research grants made by pharmaceutical companies to universities where the scientists work, only to grants given directly to experts.

Diana Zuckerman, president of the advocacy group National Research Center for Women & Families, said the FDA guidelines will not do enough. Companies wield influence, she said, with sums far smaller than \$50,000. "A drug rep who takes someone to a memorable restaurant twice a year to chat about their research is spending relatively little money but is building a relationship that is likely to be more influential than giving a \$2,000 honorarium -- perhaps even more than a \$50,000 grant for a study funded by several companies," she said.

Zuckerman's center analyzed the votes of 11 FDA advisory committees from 1998 through 2005. She said the idea that experts with conflicts could serve on committees but not vote was not well thought out -- because nonvoting members play a substantial role in pushing the committees in one direction or another. "Our study of advisory committee deliberations showed the collegial, consensus-building nature of these decisions," she said. "The votes are often unanimous because the group comes to a consensus, almost always to approve a product."

"The denialists"

Date: 12 March 2007

Source: *The New Yorker*

Author(s): Michael Specter

EDITORS' NOTE: *The 12 March 2007 issue of The New Yorker included a feature on AIDS denialism in South Africa. An abstract of the article follows; the full text is available to subscribers at*

http://www.newyorker.com/reporting/2007/03/12/070312fa_fact_specter

Annals of Science about the AIDS denial movement in South Africa. Zeblon Gwala is a 50-year-old South African who sells ubhejane, an untested herbal remedy he claims will cure AIDS. On a typical day, as many as 100 people come to his clinic. Ubhejane has been endorsed by South African President Thabo Mbeki's health minister, Manto Tshabalala-Msimang, and by Herbert Vilakazi, the head of Mbeki's Presidential Task Team on African Traditional Medicine. Vilakaze believes that the toxicity of antiretroviral drugs, or ARVs-the only successful treatment for millions infected with H.I.V.-causes more harm than good. Like Mbeki himself, he's convinced that a cure for AIDS is more likely to be found in traditional African medicine rather than Western pharmaceuticals. AIDS denial plays a corrosive role in the health policies of many countries, but South Africa provides the most extreme and enduring example. Five and a half million of the country's 48 million people are infected by H.I.V. Today, only 200,000 receive AIDS drugs. In 2003, the South African government issued a comprehensive AIDS policy, but it wasn't implemented. Mbeki has never disavowed his view that H.I.V. medicines are aimed at maiming Africans, and he's never publicly acknowledged that H.I.V. causes AIDS. With government approval, clinics like Gwala's are thriving. In 1987, molecular biologist Peter Duesberg published a paper challenging the consensus that H.I.V. causes AIDS. Describes the history of retrovirus

research and how H.I.V. was linked to AIDS. Duesberg argues that recreational drugs, not a retrovirus, destroy the immune system. To prevent or even cure AIDS, he recommends eating properly and abstaining from drug use. Through the force of his will, he essentially invented the AIDS dissident movement. Lists the three basic versions of the H.I.V.-denial credo. The most pernicious one is that Sub-Saharan Africa simply has no AIDS epidemic; instead, the problem is blamed on the absence of proper nutrition or clean water. Duesberg's influence gained new momentum when Mbeki discovered him. Mbeki usually focuses on politics, not science, when discussing AIDS. Describes the racist tone of Mbeki and Vilakazi's arguments. "The situation in America is one of intolerance," Vilakazi says. "Only one approach to treating this deadly illness is permitted...Who benefits from ARVs? Hundreds of millions of U.S. dollars have been spent on research and you have to get a return on your investment..." Mentions Marta Darder, who works in Khayelitsha with Medecins Sans Frontieres. Describes the activities of German entrepreneur Mathias Rath, who promotes vitamins to cure AIDS. Mentions Thami Mseleku, South Africa's director general of health, and **Quarraisha Abdool Karim, former head of South Africa's AIDS program**. Writer spoke with Nozizwe Madlala-Routledge, South Africa's deputy health minister, who disagrees with Tshabalala-Msimang's position on H.I.V. and AIDS.

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6. PHARMACEUTICAL INDUSTRY

"Biomarkers versus blockbusters"

Date: 27 March 2007

Source: *Cambridge Healthtech Institute Weekly Update*

Author(s): Malorye Allison

http://www.biomarkerbts.com/articles/07/mar21/Editorial/Biomarkers_or_blockbusters.asp

Is the blockbuster finally doomed? Proponents have been sounding the call for an alternative approach - 'personalized medicine' - for several years already. Meanwhile, the rise in biomarker research is indisputable. But are the two trends connected, and are companies really changing their strategies and using biomarkers to target smaller, better-defined patient sets with their new drugs? Or, is the vast majority of pharma biomarker studies just aimed at culling bad drugs from their pipelines? At CHI's recent Translational Medicine meeting, some panelists debated the future of the blockbuster. The discussion showed just how much controversy and uncertainty surrounds this question.

"I'm not sure the age of the blockbuster is dead," said Hugo Stephenson, president of strategic research and safety at Quintiles, one of the world's largest CROs. Stephenson sees lots of unmet need and opportunity in areas such as hyperlipidemia and hypertension. "These are major areas for industry growth," he said. "We've been treating LDL levels and blood pressure, but we know there have to be better mechanisms we can target."

"I do not buy that the biomarker alone is the answer," Stephenson added. "If you have a family history of Alzheimer's, and someone launches a product that will delay onset of the disease if taken from age 40 onward, well, that is a product that will sell \$5 billion, at least."

But others are not so sure those mega markets still exist. "Our position is that those 'big' diseases like Alzheimer's are really driven by many different factors that will respond to different drugs," said Bob Sch mouder, executive director of Exploratory Clinical Development at Novartis. "If you are giving people a drug that works on a different factor than what is driving their disease, you might as well be giving them bottled water."

During his presentation, Sch mouder described how Novartis has shifted to the type of "learn and confirm" model of drug discovery and development that Wyeth is also using. The old model, he said, "Was not very parallel, it was stepwise instead." The new model puts an emphasis on early proof of concept and the intelligent use of biomarkers throughout the process. According to what Peter Kim described at last year's BIO CEO, Merck is taking almost exactly the same approach of greatly increasing the biological evidence around any project, and looking more closely at how individual differences affect response to drugs.

It is increasingly evident that there is a new way of doing things in large pharmaceutical R&D.

One of the most striking aspects of this is a greatly reduced emphasis on the traditional phases of drug development. "The FDA is not hung up on seeing exactly Phase I, II, III, IV," Sch mouder said. "Now, we often dovetail the Phase I and proof of concept by using adaptive trial design." To do this wisely, he counseled, requires a lot of interaction with the FDA, but "They are reasonably receptive." As the number of subjects in a trial increases, the agency will demand more evidence that the drug actually works.

While this strategy can deliver earlier proof of concept, it doesn't necessarily protect companies from the other big challenge in this field - drug safety. And there are still huge problems deciding which drugs to bring from preclinical development into trials. "We've made a lot of progress, but first in man is still the great unknown," Sch mouder said.

Still, it is encouraging that pharmaceutical companies are really changing their strategy, and it seems to be based on a very logical premise. "The greatest incremental value of any compound is accrued during the translational phase," Sch mouder said.

Ironically, big pharma's place at the blockbuster banquet may be taken by biotechnology instead. "It's true that most pharmaceutical companies are shifting that way, toward targeting specialized segments," said Stephenson. "But personally, I'm optimistic that there will be more blockbusters, given some of the programs I have seen at a biotech level."

Sch mouder remained pessimistic though. "I sure hope I'm wrong," he said. "But personally, I'm afraid the blockbuster era is behind us. We expect to see about ten more years worth of blockbuster markets, then the companies who evolved into using more focused approaches will succeed or fail based on that strategy."

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7. ANNOUNCEMENTS

Microbicides Medical Officer (closing date 9 April 2007)

The WHO Department of Reproductive Health and Research (RHR) is the focal point within the United Nations system for research, development, advocacy and promotion of **microbicides** for the prevention of sexually transmitted infections, especially HIV. The Department aims to build capacity in developing country institutions to design, implement and complete clinical safety and effectiveness studies of promising candidate **microbicides**, and develop strategies for acceptable and sustainable product introduction; to sponsor and coordinate selected **microbicide** research projects in collaboration with partners; to strengthen national capacity to oversee **microbicide** research in the context of best practices for HIV prevention research; and, to strengthen developing-country national regulatory authority capacity to oversee clinical trials, review licensure applications and implement appropriate post-licensure monitoring procedures.

RHR is looking for a qualified person to lead WHO's work in this exciting area. For more information, please follow this link: <http://www.who.int/employment/vacancies/en/> and look for vacancy notice HQ/07/RHR/FT237.

New Publication: Improving the Reproductive Health of Married and Unmarried Youth in India

<http://www.icrw.org/html/workinaction/rockefeller-adolescenthealth-10-06.htm>

The International Center for Research on Women (ICRW) distributed two new publications about adolescent reproductive health at a March 20th dissemination meeting. The publications, a final report and the accompanying toolkit, are the culmination of a 10-year research program in India.

Funded by the Rockefeller Foundation, the program found that one of the best - and fastest - ways to improve adolescents' reproductive health is to involve parents, in-laws and the communities where adolescents live. The program focused on developing and evaluating interventions tailored to the context of adolescents' lives, including their families and their communities. The research was done in partnership with:

- The Christian Medical College, Vellore (CMC);
- The Foundation for Research in Health Systems (FRHS);
- The Institute for Health Management, Pachod (IHMP);
- KEM Hospital Research Centre; and
- Swaasthya.

Additional information about the program is available at <http://www.icrw.org/html/workinaction/rockefeller-adolescenthealth-10-06.htm>

PSI HIV/AIDS Director

PSI seeks candidates for the position of Director, HIV/AIDS. The HIV/AIDS Director will provide global leadership in HIV prevention, care and service delivery to PSI programs in over 60 developing countries. PSI seeks a technically qualified expert, recognized by the global public health community, with advanced experience and education in this critical health area.

PSI's strategy through 2011 assumes piloting and bringing to scale a range of HIV/AIDS related products, services and communications interventions. The HIV/AIDS director leads that effort by setting PSI strategy in HIV/AIDS, designing interventions, providing technical review of funding proposals, managing stakeholder relations, and building capacity. PSI's interventions include condom social marketing, communications to influence abstinence, fidelity, condom use, needle sharing, prevention of mother to child transmission, male circumcision, voluntary counseling and testing, treatments for sexually transmitted infections, and a package of health products and care for HIV positive persons.

This full-time position is based in Washington, D.C., and reports to the Chief Technical Officer.

For more information, visit <http://sh.webhire.com/servlet/av/jd?ai=624&ji=1932011&sn=1>

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