



ALLIANCE FOR MICROBICIDE DEVELOPMENT

18 April 2008, Volume 9, Number 16

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. 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. ALLIANCE UPDATES AND COMMUNITY NEWS

News Digest Publication

The Alliance will not publish the *News Digest* on Friday, 25 April 2008. The next issue of the *Digest* will be published on Friday, 2 May 2008. Alliance *Alerts* will continue to be sent as those become necessary in the periods 21-25 April and 28 April-2 May.

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2. MEDIA COVERAGE OF MICROBICIDES

"NGOs advocate use of microbicide for HIV prevention"

Date: 15 April 2008

Source: *The Tide Online (Nigeria)*

<http://www.thetidenews.com/article.aspx?qrDate=04/15/2008&qrTitle=NGOs%20advocate%20use%20of%20microbicide%20for%20HIV%20prevention&qrColumn=HEALTH>

Some NGOs have advocated the use of **microbicide** by women to prevent the transmission of HIV and AIDS as well as other Sexually Transmitted Infections (STIs).

Microbicide is a substance which can substantially reduce the transmission of STIs when applied either in the vagina or the rectum.

The NGOs, Global Alert for Defence of the Youth and Less Privileged, Ngo-Hygie Enwerem Health Foundation and Didi Oparaku Health Foundation, made the call at a meeting in Lagos.

The NGOs met with the other members of the Ikeja Local Action Committee on AIDS.

Their spokesperson, Mrs Patsy Oparaku, said **microbicide** currently undergoing trials and researches, would soon be available to the public.

Oparaku, also the Project Director of Didi Oparaku Health Foundation, said a recent international conference on the substance resolved that it would be in gels, creams, suppositories and lubricants.

"**Microbicide** will kill inactivate STI pathogens, block the entry of pathogens in the vagina or rectum, and prevent infections from proceeding further. While the use of condom will remain as the first preference, **microbicide** could help those women, whose partners refuse condom," she said.

Oparaku said **microbicide** would bridge the gap in the range of STI prevention tools for women.

"It will empower women sexually; men will also benefit from it. **Microbicide** is free to use; it does not need the permission of one's partner before usage," she said.

Also speaking, the AIDS Action Manager, Ikeja Local Government Area, Mrs Bolanle Faleke, said the manufacture of **microbicide** was in the interest of women who, she said, were most vulnerable to HIV and AIDS.

Faleke urged Nigerian women to embrace the substance.

"Obama, Clinton call for allocating more resources to fight spread of HIV/AIDS"

Date: 14 April 2008

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/health2008dr.cfm?DR_ID=51499

Sens. Barack Obama (D-Ill.) and Hillary Rodham Clinton (D-N.Y.) on Sunday both called for allocating more resources to fight the spread of HIV/AIDS, AFP/Google.com reports (AFP/Google.com, 4/14). The Democratic presidential candidates' comments came during a forum at Messiah College that was sponsored by Faith in Public Life, the Hartford Courant reports (Buck, Hartford Courant, 4/14).

In response to a question concerning potential policies on providing access to antiretroviral drugs in developing countries, Clinton said, "I believe that our government must do so much more to get generic drugs and low-cost drugs to people suffering. Not only from HIV/AIDS, but the range of diseases that affect disproportionately the poor." Clinton added that "our great pharmaceutical companies ... do a lot of good. Because, after all, they invent the compounds and put them together that the generics then are able to copy. But we need to do much more to get our pharmaceutical companies to work with us to get the drug costs down and to open the pathway for generic drugs." Clinton also said, "I commend President Bush" for the President's Emergency Plan for AIDS Relief. "It was a very bold and important commitment, but it didn't go far enough in opening up the door to generics and getting the costs down" (Forum transcript, 4/13).

Obama, when asked if faith and abstinence education should have a role in the fight against HIV/AIDS, said, "Part of the battle against AIDS should be abstinence" (Hartford Courant, 4/14). Obama added, "I also think that contraception is important; I also think that treatment is important; I also think that we have to do more to make antiviral drugs available to people who are in extreme poverty." Obama also discussed his efforts to encourage HIV testing in Kenya, lauded President Bush for PEPFAR and said prevention efforts focusing on women are important (Forum transcript, 4/13).

The CNN forum was televised nationwide and was moderated by Newsweek editor Jon Meacham and Campbell Brown of CNN, the New York Times reports (Stanley, New York Times, 4/14). The candidates answered questions from journalists and audience members, including several faith leaders (Murray/Bacon, Washington Post, 4/14). Sen. John McCain (Ariz.), the presumptive Republican presidential nominee, declined an invitation to participate in the forum, citing a scheduling conflict, the Philadelphia Inquirer reports (Worden, Philadelphia Inquirer, 4/14).

Excerpt from CNN transcript:

OBAMA: I do think that -- and I've said this when I was in Kenya -- that there is a behavioral element to AIDS that has to be addressed. And if there is -- if there's promiscuity and we are pretending that that's not an issue in spreading AIDS, then we're missing part of the answer.

But I also think that -- keep in mind, women are far more likely to be infected now between the ages of 18 and 25 than are men. And that's why focusing, for example, on the status of women, empowering women, giving them **microbicides**, or other strategies that would allow them to protect themselves when they sometimes in certain situations may not be able to protect themselves from having unprotected sex, all those things are going to be just as important, as well.

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EDITOR'S NOTE: The full CNN transcript is available for public access at <http://transcripts.cnn.com/TRANSCRIPTS/0804/13/se.01.html>

"Nerenberg Lecture"

Date: 10 April 2008

Source: *Western News (The University of Western Ontario)*

Author(s): Mitchell Zimmer

http://communications.uwo.ca/com/western_news/stories/nerenberg_lecture__20080410442036/

Sally Blower has made a career of constructing mathematical models to study the evolutionary dynamics of drug resistance. Her research at the David Geffen School of Medicine at UCLA has spanned studies into syphilis, genital herpes, smallpox, tuberculosis, MRSA, leprosy, trachoma and influenza but her main focus is on HIV.

In countries where AIDS infection rates continue to grow, public health organizations remain on the lookout for new intervention strategies to halt the spread. One area of research is the use of vaginal **microbicides** to prevent infection in women.

A lot of hope is being invested in **microbicides** and, as Blower says, "they are being designed for women to be used by women with the goal of empowering women" particularly in a cultural climate that may offer little choice. Women who are beaten for merely suggesting using a condom may be afforded some protection through **microbicides**. Currently, these treatments are in randomized drug trials and not expected to reach the market until 2013.

What Blower and her colleagues have been doing for the last few years is evaluating the benefits of **microbicides** "which is quite obviously to prevent infections, but also evaluate the minuses. It might cause decreased condom use, because people might think 'OK there is a new invention, I can use that, I won't use condoms anymore,' or they can generate drug resistance."

To answer questions raised by these positive and negative factors, Blower constructed mathematical models reflecting real world situations: the transmissibility of HIV per sex act, the number of sex acts a female sex worker has with a client, the number of clients per day, how well condoms work, how well **microbicides** work, the number of sex acts in which each type of protection is used, and prevalence of HIV in the client population. Different probabilities for each parameter were chosen at random and run through a mathematical model 10,000 times.

The models contained a few surprises; Blower showed that in certain cases replacing condoms with **microbicide** "could have a high chance of increasing the infections" if the treatment has an efficacy of only 30 per cent. If the treatment has at least 80 per cent efficacy and the application becomes routine, the real benefits of preventing infection can be seen.

Blower's next step was to construct models of clinical trials. In this analysis there is the added factor of acquired resistance, "if you take someone who is infected with HIV and you give them antiretroviral drugs".

"What can happen is that the viral load is reduced because of the drug but there is still some virus and the virus becomes resistant... Over time the drug sensitive virus, the wild type, disappears but the drug resistant virus wins out. The treatment is actually selecting for drug-resistant virus."

Blower also investigated high-risk and low-risk **microbicides**. The high-risk anti-retroviral **microbicides**, Blower says are "the ones that are systemically absorbed in the blood will have a high chance of becoming resistant."

As drug trials continue, it is difficult to determine which treatments are high-risk or low-risk because of ethical considerations. In this scenario high-risk **microbicides** could pass clinical testing and be used as interventions making it impossible to predict the population-level consequences beforehand.

To account for the both high-risk and low-risk **microbicides**, Blower constructed two population-level models. Here she found a paradox, in both cases. Even though the new treatments will be used by women to protect themselves from infection, it will be men who realize the greater benefit. The advantage decreases as the "fitness of the drug-resistant strains and **microbicide** efficacy (for women) increases."

The Nerenberg Lecture is named after the late Morton (Paddy) Nerenberg, a much-loved professor and researcher born on March 17 -- hence his nickname. He was a professor for more than a quarter century, and founding member of the Department of Applied Mathematics. Nerenberg regretted that scientific and mathematical ideas had become inaccessible to so many. The series honors his appreciation for the democracy of ideas. He died in 1993 and is survived by his children Albert, Ben and Simone.

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3. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Cervicovaginal evaluation in macaques used as a model for topical microbicide safety studies"

Author(s): Scorpio DG, Ruben DS, Liao Z, et al

Reference: N/A 37(Suppl 1):65-73.

<http://highwire.stanford.edu/cgi/medline/pmid;18269532>

Published Abstract: INTRODUCTION: Macaques are a commonly used non-human primate (NHP) model to evaluate safety and efficacy of topically applied vaginal **microbicides**. Cervicovaginal evaluation for topical **microbicide** safety studies requires proper technique, equipment, supplies, and sequence of sample collection. MATERIALS AND METHODS: Eleven rhesus macaques received a comprehensive sequential cervicovaginal examination under sedation before treatment and 24 hours post-instillation of test material. Examination was initiated with colposcopy, followed by diagnostics including vaginal culture, pH determination, cervicovaginal lavage, and cervicovaginal biopsy. RESULTS: Overall, the methods performed yielded samples that were appropriate for diagnostic evaluation and interpretation, and the macaques experienced minimal discomfort and complications. DISCUSSION: This paper provides a descriptive summary of compiled techniques required to conduct a safety evaluation for topically applied vaginal **microbicides**. This novel method-based approach should be methodically executed when evaluating a vaginally-applied, topical **microbicide** candidate.

"Susceptibility of Chlamydia trachomatis to the excipient hydroxy-ethylcellulose: pH and concentration dependence of antimicrobial activity"

Author(s): Abdul Sater AA, Ojcius DM, Meyer MP

Reference: N/A Epub ahead of print.

<http://aac.asm.org/cgi/content/abstract/AAC.00785-07v1?maxtoshow=&HITS=1&hits=1&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct>

Published Abstract: Hydroxyethyl cellulose (HEC) is used as a neutral excipient in **microbicides** against sexually-transmitted pathogens. However, HEC inhibits infection of cervical epithelial cells by Chlamydia trachomatis at pH 5 in a concentration-dependent manner. At pH 7, infection is inversely dependent on the concentration of HEC, possibly due to pH-dependent calcium sequestration.

"The Brazilian treatment model: a new course for global AIDS policy"

Author(s): Rey PJ

Reference: N/A 25(1):51-72.

<http://itc.gsw.edu/ATWS/volumes/vol25.htm>

Published Abstract: CONCLUSION Technology continually provides new tools in reducing the spread of HIV, while improving the quality of life of those burdened with it. The traditional methods of prevention, education programs, testing, condom distribution, and needle exchanges, have produced significant results globally, but alone these methods cannot curtail the most severe AIDS crises with sufficient haste, given the enormity of the disease. Brazil's example of both the traditional and modern methods of prevention coupled with active and aggressive treatment proved effective in reducing the spread of HIV, while improving the quality of life for its victims. Through state activism on an international scale, Brazil proved it possible to force the hand of the patent holding pharmaceutical corporations and purchase treatment medications at a rate that makes the treatment model financially viable. Even with the resources available, the success of the model elsewhere will then hinge on the implementation of a successful distribution scheme. Nations must dedicate themselves to the basic idea that treatment ought to be available to all without judgment; otherwise, members of certain vulnerable groups may be discouraged from participation. For nations who lack a solid infrastructure for distributing healthcare services, Brazil's localization scheme provides an alternative framework for AIDS related services. The model, though a fundamentally domestic project set forth by the Brazilian government following their human rights platform, is itself now a truly international force. To achieve its domestic goals, the government was required to systematically affirm that same humanitarian platform on the international stage over and above other regulations, and particularly, in opposition to the market forces of the world-system; in pursuing this course through the internal development of new resources, Brazil found a fulcrum on which to leverage itself from relative marginalization. Furthermore, Brazil, as a global activist, has sought to export this platform (and its subsequent empowerment) to other nations, developing their internal technological resources or sharing its own, so that the breadth of possibilities for all afflicted states may be expanded to new horizons. If these countries are capable of

establishing the necessary infrastructure, use all resources at hand to leverage global efficacy for themselves, and have enough fortitude to treat all citizens-placing special emphasis on target populations, despite social stigmas that may be associated with them-then the Brazilian model provides hope to the 40 million people currently living with AIDS and all those who may otherwise fall victim to its proliferation.

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RECENT DISCOVERIES

Current medical research has provided AIDS policy-makers with a new set of tools in reducing global HIV infection rates while expanding the length and quality of life experienced by those already infected. Studies show that antiretroviral medicines decrease the transmission rates of infected partners by 50% (while an 80% reduction was recorded in conjunction with condom use).¹⁶ The concentration of HIV present in semen correlates with a man's level of infectiousness. Antiretroviral treatments control HIV by reducing the probability that the virus will successfully replicate within the body and subsequently reduce the overall viral load. Recent studies indicate that HIV becomes undetectable in the semen of most men who receive highly active retroviral treatment.¹⁷ Women also experience a decreased probability of transmission if they are receiving antiretroviral treatment as the antiretroviral medicines decrease the viral load in their mucus and vaginal secretions.¹⁸ Emerging studies illustrate a substantial pre-exposure and postexposure prophylactic effect with antiretroviral medicine if taken by HIV negative partners in discordant relationships. "Additionally, antiretroviral treatments have been found to diminish the rate of HIV transfer from pregnant women to their children. A clinical trial showed a possible reduction in the control transfer rate of 25.5% to 8.3%. Even one dose during labor can reduce the transfer rate by 13.6%.²⁰ Circumcision is another recently proven prevention method, which decreases the susceptibility of HIV negative males to transmission from HIV positive females.²¹ Finally, medical researchers have developed **microbicides** that are applied before intercourse to reduce susceptibility to HIV.²²

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EDITOR'S NOTE: This article's abstract and an excerpt discussing microbicides are listed above. The full text of the article, including references, is available at the above website with a subscription.

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4. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Hormonal contraception and HIV prevalence in four African countries"

Author(s): Leclerc PM, Dubois-Colas N, Garenne M

Reference: N/A 77(5):371-76.

<http://www.contraceptionjournal.org/article/S0010-7824%2808%2900061-9/abstract>

Published Abstract: *Background* The HIV seroprevalence among women aged 15-24 years was compared according to their pattern of contraceptive use in four African countries: Kenya, Lesotho, Malawi and Zimbabwe. *Study Design* Data were derived from Demographic and Health Surveys (DHS) conducted between 2003 and 2006 on representative samples, totaling 4549 women. *Results* It is indicated that users of depo-medroxyprogesterone acetate (DMPA) have a significantly higher seroprevalence than nonusers [odds ratio (OR)=1.82, 95% CI=1.63-2.03] and higher than users of oral contraceptives and users of traditional methods. The results were confirmed in a multivariate analysis including as controls, age, duration since first intercourse, urban residence, education, number of sexual partners in the last 12 months and marital status. A somewhat smaller net effect (OR=1.34, 95% CI=1.10-1.63) was found. In contrast, oral contraceptives and traditional methods did not show any risk for HIV (OR=0.96 and 0.92, respectively). *Conclusion* The increased risk of DMPA was present in three of the four countries investigated, and significant in Zimbabwe and Lesotho, the countries with the highest HIV seroprevalence. The HIV risk attributable to DMPA remained small altogether and was estimated as 6% in the four countries combined.

"Inhibition of herpes simplex virus type 1 infection by cationic {beta}-peptides"

Author(s): Akkarawongsa R, Potocky TB, English E, et al

Reference: N/A Epub ahead of print.

<http://www.ncbi.nlm.nih.gov/pubmed/18391029>

Published Abstract: Previously, it was shown that cationic alpha-peptides derived from the HIV TAT protein transduction domain blocked HSV entry. We now show that cationic oligomers of beta-amino acid residues ("beta-peptides") inhibit herpes simplex virus type 1 (HSV-1) infection. Among three cationic beta-peptides tested, the most effective inhibition was observed for the one with a strong propensity to adopt a helical conformation in which cationic and hydrophobic residues are segregated from one another ("globally amphiphilic helix"). The antiviral effect was not cell-specific. Inhibition of virus infection by the beta-peptides occurred at the post-attachment penetration step with an EC50 of 3 microM for the most effective beta-peptide. The beta-peptides did not inactivate virions in solution nor did they induce resistance to infection when cells were pre-treated with the beta-peptides. The beta-peptides showed little if any toxicity toward Vero cells. These results raise the possibility that cationic beta-peptides may be useful antiviral agents for HSV-1 and demonstrate the potential of beta-peptides as novel antiviral drugs.

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5. HIV/AIDS VACCINES

"Researchers join forces for AIDS vaccine"

Date: 16 April 2008

Source: *The News and Observer*

Author(s): Sarah Avery

<http://www.newsobserver.com/news/story/1038771.html>

AIDS researchers, frustrated by the failure of efforts to develop a vaccine against the human immunodeficiency virus, announced Tuesday they would join forces in a worldwide collaboration that merges the International AIDS Vaccine Initiative and the Center for HIV/AIDS Vaccine Immunology at Duke University.

The groups would work to answer basic biological questions that have puzzled scientists in the more than three decades since AIDS was identified, thwarting an effective vaccine. Last year, according to the United Nations, 33 million people worldwide were living with HIV/AIDS, and the virus killed 2.1 million people.

Despite huge investments in research from governments, private foundations, corporations and international aid organizations, a vaccine to guard against infection has remained elusive. Last month, a vaccine being tested by the pharmaceutical company Merck and Co. was pulled from use because it did not protect against the virus and, instead, tended to increase the risk of infection.

Other experimental drugs have also shown little or no benefit in preventing the illness or reducing the virus in people who are already infected.

By joining forces, researchers hope to pool their expertise, resources and know-how.

"Solving the HIV vaccine puzzle is a scientific challenge that can only be solved through fundamental and applied research, collaboration and transparency. The work that will be done by IAVI, CHAVI and their networks of partners will rapidly enhance our understanding of HIV and help lay the groundwork for new vaccine approaches," Dr. Barton Haynes, CHAVI director and professor of medicine at Duke University Medical Center, said in a prepared statement.

The collaboration will focus on four key areas, including the virus' genetic sequence, how other genetic factors control infection and why some people who are exposed to the virus don't get sick. In addition, the groups will work to develop standard ways of sampling body tissue where HIV gains entry.

CHAVI, established in 2005 by the National Institute of Allergy and Infectious Diseases, is based at Duke University, but includes a consortium of 70 investigators at 37 institutions, including UNC-Chapel Hill. Its mission was to bring leading AIDS researchers under a single organization, to share research findings and focus on specific areas of inquiry.

The global, not-for-profit IAVI works to develop a vaccine for use throughout the world. It was founded in 1996 and is funded by foundations, individual countries, corporate donors, world aid groups and private donors.

"Keep funding the AIDS vaccine"

Date: 14 April 2008

Source: *The Los Angeles Times (Op-Ed)*

Author(s): David Baltimore, Seth Berkley

<http://www.latimes.com/news/opinion/la-oe-w-baltimore14apr14,0,2709040.story>

In his Blowback, "Stop AIDS vaccine research," Michael Weinstein suggested that U.S. government funding for AIDS vaccine research should stop and the money now being used to this end be redeployed to treatment. This very pessimistic view of the possibility of success in the vaccine quest is a misreading of the situation.

Yes, the Merck trial of an experimental vaccine failed to show efficacy. But it was not a failure as a trial. It had a hugely important outcome: We now know one preparation that will not work as a vaccine. Before this trial we knew only one other direction that had failed, so our knowledge has doubled.

Knowing what not to do is useful because it informs further research. Of course, we would rather have successful trials that tell us we are going in the right direction, but AIDS vaccine development is hard, and negative trials are not a surprise. Because the trial was so professionally accomplished, we can trust its results.

Now what we need are more such trials of materials different enough from the Merck materials that we can learn something from them. The job of the research community is to make the judgment of what materials fit this criterion. But to give up at this point would be criminal. Luckily, the cool heads in the AIDS research community are not giving up -- they are searching for new directions. There is a healthy debate about what those directions should be. But to our minds, we need more human clinical research, not less, if we are to find the magic formula that will protect people against AIDS.

David Baltimore is president emeritus and Robert Andrews Millikan professor of biology at the California Institute of Technology. Seth Berkley is president and CEO of the International AIDS Vaccine Initiative.

EDITOR'S NOTE: Micheal Weinstein's article "Stop AIDS vaccine research" is available for public access at <http://www.latimes.com/news/opinion/la-oe-w-weinstein4apr04,0,7369027.story>.

"The HVTN Protocol 903 Vaccine Preparedness Study: Lessons learned in preparation for HIV vaccine efficacy trials"

Author(s): Djomand G, Metch B, Zorrilla CD, et al

Reference: N/A Epub ahead of print.

<http://www.ncbi.nlm.nih.gov/pubmed/18391750>

Published Abstract: Successful recruitment and retention of HIV-uninfected at-risk participants are essential for HIV vaccine efficacy trials. A multicountry vaccine preparedness study was started in 2003 to assess enrollment and retention of HIV-negative high-risk participants and to assess their willingness to participate in future vaccine efficacy trials. HIV-negative high-risk adults were recruited in the Caribbean, in Southern Africa, and in Latin America, and were followed for 1 year. Participants included men who have sex with men, heterosexual men and women, and female sex workers. History of sexually transmitted infections and sexual risk behaviors were recorded with HIV testing at 0, 6, and 12 months, and willingness to participate in future vaccine trials was recorded at 0 and 12 months. Recruitment, retention, and willingness to participate in future trials were excellent at 3 of the 6 sites, with consistent declines in risk behaviors across cohorts over time. Although not powered to measure seroincidence, HIV

seroincidence rates per 100 person-years (95% confidence interval [CI]) were as follows: 2.3 (95% CI: 0.3 to 8.2) in Botswana, 0.5 (95% CI: 0 to 2.9) in the Dominican Republic, and 3.1 (95% CI: 1.1 to 6.8) in Peru. The HIV Vaccine Trials Network 903 study helped to develop clinical trial site capacity, with a focus on recruitment and retention of high-risk women in the Americas, and improved network and site expertise about large-scale HIV vaccine efficacy trials.

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6. OTHER PREVENTION APPROACHES

"Kenya: When there's no excuse not to use a condom"

Date: 15 April 2008

Source: *IRINNews.org*

<http://www.alertnet.org/thenews/newsdesk/IRIN/713c824a609f04c614b193f6e4d77f47.htm>

When the music's pumping, drinks are flowing and hormones are raging, condoms don't often spring to mind, until it's too late. By then, the shops are closed and a packet of three is hard to come by.

That's where enterprising vendors outside the busy bars and nightclubs in Nairobi, the Kenyan capital, are now selling them, and so are some bars. Steve Kielu, a street trader with a spot outside The Wallet, a club in downtown Nairobi, has added condoms to the usual cigarettes, chewing gum, batteries and assorted handy items.

"Some people come around and pretend - they first buy sweets and then a while later they ask if I have any condoms as well," he said. "This is how I came to stock condoms."

"I target both men and women, but men are my customers more often than women. I know that I have helped them instead of them going away without," Kielu told IRIN/PlusNews.

Psys, another popular club in the Nairobi suburb of Lang'ata, keeps condoms behind the bar. "This is a highly social place where two consenting adults will walk in together, or meet, and chemistry is all over the place," said Martin, a Psys bartender.

"We have a variety of condoms on display for sale. As much as it is important to carry condoms around, not everyone carries condoms in their wallets or handbags, so usually you will find them at our counter," he added. "What is worse, contracting HIV or the embarrassment of asking for a condom over the counter?"

Various NGOs are also working to make condoms more accessible. "What we encourage is the availability of condoms in high-risk areas, such as the highway bars, lodgings, casinos and clubs," said Chris Wainaina, brand manager of "Trust" condoms at Population Services International (PSI), a global non-profit social marketing organisation.

Wainaina said PSI was conducting training sessions for bar owners, club bartenders and hotel lobby staff to make condoms more widely available and help them deal with requests for condoms sensitively.

"Condoms are even being sold by taxi drivers at night to their clientele. They work very late at night and are parked strategically in high-risk areas," he noted.

Jude Musyoka* a student at the United States International University in Nairobi, appreciates the convenience of it all. "Usually I carry my own stash [of condoms], but the problem is you don't always plan these things, so when you have met a nice girl outside school, the bartender or the street vendor will always come in handy," he said. "I just don't want to wake up in the morning and have to worry about what I should have done."

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

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7. POLITICS AND POLICY

"In U.S., few alternatives to testing on animals"

Date: 12 April 2008

Source: *Washington Post*

Author(s): Gilbert M Gaul

<http://www.washingtonpost.com/wp-dyn/content/article/2008/04/11/AR2008041103733.html>

Each year, American doctors inject more than 3 million doses of Botox to temporarily smooth their patients' wrinkles and frown lines. But before each batch is shipped, the manufacturer puts it through one of the oldest and most controversial animal tests available.

To check the potency of its product under federal safety rules, Allergan Inc. injects mice with Botox until it finds a dose at which half of the animals die -- a rough gauge of potential harm to humans.

Animal protection groups consider "lethal dose 50," as the test is known, to be "the poster child for everything that's wrong with animal testing," said Martin Stephens, vice president for animal research issues at the Humane Society of the United States. "It's as bad as it gets, poisoning animals to death."

Allergan officials say they have no choice. Without a federally approved safety test that does not use animals, a company spokeswoman says, lethal dose 50 "is by default the required test."

The controversy over the Botox test highlights the slow pace of government efforts to replace or reduce the large numbers of animals used by pharmaceutical companies, chemical manufacturers and consumer firms to ensure that their products are safe for people. A decade after Congress created a panel to spur the development of non-animal tests, only four such tests have been approved out of 185 reviews, according to the panel's records.

Several of the panel's original backers now consider the system broken. As a result, critics say, hundreds of thousands of mice, rabbits, hamsters and dogs continue to suffer and die unnecessarily in tests for pesticides, household cleaners, sunscreens and other products.

"We were thrilled when the legislation was passed," said Sara Amundson, a former official with the Doris Day Animal League who was involved in creating the panel. "It's shocking to look back and see how little we have accomplished."

The federal panel is known as the Interagency Coordinating Committee on the Validation of Alternative Methods, or ICCVAM. Representatives of 15 federal agencies make up the committee.

Instead of acting as an advocate for companies and nonprofits proposing non-animal tests, the panel has become an obstacle, animal welfare groups say. They point to Europe, where a similar panel has approved 34 alternatives to animal tests and has another 170 in its pipeline. Critics say the U.S. panel is slow and favors older animal tests that have never gone through the same rigorous scientific review.

The executive director of the U.S. panel, William S. Stokes, said in a statement that his group "has successfully reviewed over 185 test methods" and that the four alternatives it has endorsed "have significantly reduced the number of animals required for safety assessments, and provided for improved welfare of animals used in safety evaluations." One alternative has saved "at least 36,000 animals annually," Stokes said.

Members of the panel also contend that it is unfair to compare Europe and the United States because the laws, rules and expectations are different. Europe has legislation mandating the use of non-animal tests. The United States only recommends their use.

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

"Government adopts male cut as strategy in fight against HIV"

Date: 10 April 2008

Source: *The Nation*

Author(s): Arthur Okwemba

http://www.nationmedia.com/dailynation/nmgcontententry.asp?premiumid=0&category_id=39&newsid=120839

It is now official. A new circumcision policy for men aimed at reducing HIV infection rates has been published by the Government. The policy, stipulating how all willing Kenyan men, irrespective of their age, will undergo circumcision, sets into motion the use of the surgical procedure as a standard HIV prevention strategy for the country.

Health personnel from Government health facilities at various levels are to undergo in-service training to hone their skills on the new procedure. A Male Circumcision Task Force that will guide male circumcision in Kenya will be set up soon.

Titled Policy on Male Circumcision in Kenya 2008, the document also wants circumcision to be promoted and delivered to males of all ages in a manner that is culturally sensitive to minimise the stigma that may be associated with an uncircumcised person.

In the past, fears been raised over the possible conflict between this policy and the traditions of some of Kenya's communities, which, as a custom, do not practise circumcision. While some Kenyan communities invoke religious, cultural or social reasons for circumcision, others like the Teso, Luo, Turkana, and a few groups in the Coast undertake other rites of passage, which do not include circumcision.

Circumcision involves the removal of the foreskin of the male member. Studies have shown the skin's inner mucosal surface to be the breeding ground for the virus. This is because compared to the external surface, more of its cells are vulnerable to HIV infection. Circumcisers will, therefore be required to counsel males and use techniques that reduce or eliminate the pain associated with such a surgical procedure so as to encourage more men to opt for circumcision.

Says the policy: "Ensure that male circumcision is performed by well-trained practitioners in antiseptic settings under conditions of informed consent, confidentiality, risk reduction counselling and safety."

Health facilities from the dispensary to the district hospital levels are to be strengthened to ensure that they cope with the expected demand from men seeking to be circumcised. Those implementing the policy will be required to put in place appropriate laws, regulations and supervisory mechanisms that are going to ensure that circumcision services are accessible and provided safely without any discrimination.

The Government's move to adopt the policy comes at time when results from HIV vaccine trials indicate that circumcised volunteers had a lower risk of HIV infection compared to their uncircumcised counterparts. Scientists are trying to investigate this development further to see if there is any correlation between the HIV vaccine and circumcision. Likewise, the policy is also being implemented at time when there are fears that the number of males being circumcised may be reducing.

According to the 2003 Kenya Demographic and Health Survey, close to 72 per cent of men aged between 15 and 19 years were circumcised compared to 84 per cent above this age. However, the survey does not analyse HIV prevalence in regions that predominantly circumcise compared to those which don't.

The new policy has generated excitement and disquiet among members of the public who talked to Nation, with some praising it and others saying it will worsen the vulnerability of women to HIV infection as men are likely to refuse to have protected sex.

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

"Drug-safety agency names its first chief scientist"

Source: *Nature*. 2008 Apr 16; Epub ahead of print.

<http://www.nature.com/news/2008/080416/full/452796d.html>

The 102-year-old US Food and Drug Administration (FDA) appointed its first chief scientist last week, acting at the behest of Congress, which mandated the position last September.

Frank Torti, a clinician and molecular oncologist who chairs the department of cancer biology at Wake Forest University in Winston-Salem, North Carolina, will begin the job next month. He will also serve as principal deputy commissioner, effectively the agency's second-in-command.

An expert on prostate and bladder cancer who has run many clinical trials, Torti will be charged with ensuring the quality of the agency's intramural research in response to a recent dire assessment of its scientific capabilities (see Nature 450, 1143; 2007). He will also launch a high-profile, two-year FDA fellowship programme aimed at recruiting, training and retaining scientists and administrators in an effort to combat attrition at the agency.

"Indian journals push for clinical-trial registration"

Source: *Nature*. 2008 Apr 16; Epub ahead of print.

<http://www.nature.com/news/2008/080416/full/452797a.html>

Eleven of India's leading medical journals will now consider publishing the results of clinical trials only if the trial in question has been registered with the Indian Council of Medical Research (ICMR) in New Delhi or any primary clinical-trial register.

The move follows the 2005 decision by the International Committee of Medical Journal Editors to publish only the results of registered trials. According to Kanikaram Satyanarayana, deputy chief of the ICMR, the delay was partly due to reluctance by the journal editors and pressure from industry. In addition, the ICMR had hoped that a bill it drafted in 2006 to regulate human trials would become law.

Trials that start in or after June of this year must be registered before enrolling their first participant; those beginning before this must register retrospectively. The ICMR says mandatory registration will ensure transparency and honesty, and discourage unethical trials.

An estimated 250 drug trials are under way in India, with applications for 30 more received on average each month.

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8. PHARMACEUTICAL INDUSTRY

"HIV drug sales boost Gilead profits"

Date: 16 April 2008

Source: *TheStreet.com*

Author(s): Elizabeth Trotta

http://www.thestreet.com/s/hiv-drug-sales-boost-gilead-profits/newsanalysis/biotech/10412362.html?puc=_tscrss

Gilead Sciences GILD trounced Wall Street targets with its first-quarter financial numbers after the market close Wednesday.

Shares of the Foster City, Calif.-based biotech company climbed more than 3% after the earnings release. But the stock settled in recent after-hours trading, down 80 cents, or 1.5%, at \$51 after the company's earnings call, which included reaffirmation of previous 2008 guidance.

The HIV drug specialist reported earning \$522.1 million, or 54 cents a share, before items, compared to \$447.6 million, or 46 cents a share, in the year-ago quarter. On a GAAP basis, the company earned 51 cents a share. Revenue rose 22% to \$1.26 billion.

Results beat estimates of analysts surveyed by Thomson Financial who'd expected earnings of 48 cents a share on \$1.2 billion in revenue.

Sales totaled \$1.14 billion for the quarter, with \$946.7 million of that from the HIV franchise. HIV drug Truvada brought in \$479.4 million, beating the Wall Street consensus target of \$468 million. Atripla sales totaled \$324.2 million, beating the consensus target of \$311 million.

Viread sales decreased 5% to \$152.7 million, in light of lower sales volumes in the U.S. and Europe, according to the company. But it still beat Wall Street's target of \$146 million.

On its earnings conference call, Gilead executives said recent study data had no impact on revenue from its HIV drug franchise in the first quarter.

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

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9. ANNOUNCEMENTS

Population Council selects Louise Pedneault as Clinical Director, Microbicides, HIV and AIDS Program

<http://www.popcouncil.org/mediacenter/newsreleases/LouisePedneault.html>

The Population Council appointed Louise Pedneault, M.D., clinical director of **microbicides** for the organization's HIV and AIDS program. In addition to managing clinical trials, Pedneault will work on strategic planning for next-generation **microbicide** candidates as part of the Council's continued commitment to develop products that provide women with the means for protecting themselves from HIV infection.

A physician with a specialization in infectious diseases and medical microbiology, Pedneault brings to the Council a decade of experience in the clinical development of HIV and AIDS medications and vaccines through her work in the pharmaceutical industry (at Bristol-Myers Squibb Company, Glaxo Wellcome, and GlaxoSmithKline). She also worked in the academic setting as an assistant professor, Department of Microbiology and Immunology, University of Montreal.

Pedneault received an M.Sc. in microbiology and immunology and an M.D. from the University of Montreal. She earned a second master's degree in international administration at the University of Miami, where she participated in a medical mission to provide care to the Mayan population in Guatemala. She speaks English, French, and Spanish.

In 2007, the Council completed a Phase 3 clinical trial of its candidate **microbicide**, Carraguard(R), the first to reach this advanced phase of clinical research. Building on this work, the Council is developing next-generation **microbicides** with new formulations and mechanisms of action.

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