



ALLIANCE FOR MICROBICIDE DEVELOPMENT

14 March 2008, Volume 9, Number 11

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. MONTHLY MICROBICIDE PIPELINE UPDATE

March 2008

<http://www.microbicide.org>

The most recent summaries of Ongoing and Planned and Funded Clinical trials are now available on the Alliance homepage.

- **Microbicide** Candidates in Ongoing Clinical Trials: Summary as of March 2008 <http://www.microbicide.org/microbicideinfo/reference/Microbicide.Ongoing.Clinical.Trials.Summary14Mar08.pdf>
- **Microbicide** Candidates and Ancillary Devices in Planned and Funded Clinical Trials: Summary as of March 2008 <http://www.microbicide.org/microbicideinfo/reference/Microbicides.Planned.Funded.Clinical.Trials14Mar08.pdf>

Currently, there are 10 **microbicide** candidates in clinical development and over 40 confirmed products in preclinical development. As a continued effort to maintain the most up-to-date information, we urge you to visit the Alliance website at www.microbicide.org or contact Stephanie Tillman, Alliance Writer/Research Associate, by email (stillman@microbicide.org) or by phone (301-587-3302) with any updates, questions, or comments.

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2. MEDIA COVERAGE OF MICROBICIDES

"Scientists still wary, but HIV research vital"

Date: 13 March 2008

Source: *Sydney Star Observer*

Author(s): Ani Lamont

<http://www.ssonet.com.au/display.asp?ArticleID=7992>

American HIV researcher Dr David Baltimore's statement that we are no closer to finding a vaccine is being questioned by local HIV/AIDS organisations, as the need for more **microbicide** research is highlighted.

In a speech to the American Association for the Advancement of Science, Baltimore, a Nobel Prize Laureate for his discovery of the enzyme which allows the HIV virus to reproduce, said; "We've been working on a vaccine [since the 1980s] and we are no closer to a vaccine now than we were then.

"You are quite within bounds to ask, if it's been 10 years away for 20 years, does that mean it's really never going to happen? There are people who are saying it will never happen."

Positive Life spokesperson Rob Lake said more research was vital.

"While it would be unwise of us to put all our faith in a reliable, affordable vaccine being found, that research must continue," he said.

ACON community health director Nick Corrigan disagreed with the American research.

"I don't really agree with Baltimore that we are no closer, because any research, even studies that have a negative result, help us to know what doesn't work and what direction we should be heading in," he said.

Continued research into preventative measures is of particular concern in the developing world, where increased funds are being allocated to **microbicide** research.

The development of **microbicide** creams, gels or rings it is hoped would dramatically cut the number of new infections, particularly in women who make up 50 percent of the HIV population worldwide.

"Realistically speaking it is going to be a long time until a vaccine or effective preventative measures are found, but we are all looking to the future when there will be effective **microbicides**, which would have a particular impact in the third world," Corrigan said.

"Merck licenses fusion inhibitor to International Partnership for Microbicides"

Date: 12 March 2008

Source: *AIDSmap.com News*

Author(s): Keith Alcorn

<http://www.aidsmap.com/en/news/D5EF9B3A-C75F-4553-804A-035C3C69F33C.asp>

Merck and Co said yesterday it has licensed an experimental fusion inhibitor, code-named L'644, to the International Partnership for **Microbicides** to develop a potential vaginal **microbicide**.

Microbicides are gels which can be applied prior to sexual intercourse, containing agents which block HIV from infecting vulnerable cells in the genital area. It is hoped that women will be able to adopt **microbicides** without having to negotiate their use with male partners, one of the big disadvantages of condoms.

There is increasing interest in the use of antiretroviral drugs within **microbicides**, following disappointing results from trials of first-generation vaginal **microbicides** such as cellulose sulphate (UsherCell) and Carraguard.

There is some concern that the incorporation of antiretroviral drugs into **microbicides** could lead to the development of drug resistance in HIV-positive women, if the compound passed through the vaginal wall into the bloodstream.

Fusion or entry inhibitors such as L'644 may be particularly attractive as a **microbicide** ingredient because this class of antiretroviral drug is not likely to be widely used in treatment, particularly in developing countries.

Merck's compound is the sixth antiretroviral agent licensed to the IPM, and follows a similar agreement with Merck that granted IPM a royalty-free license in 2005 to develop another compound, L'167/CMPD167, which belongs to the class of molecules known as CCR5 blockers.

"Merck deserves recognition for its exemplary commitment to HIV prevention research," says Dr. Zeda Rosenberg, CEO of the International Partnership for **Microbicides**. "This arrangement for L'644 helps IPM pursue development of compounds that target HIV at many points in the virus's lifecycle. We're working toward the day when millions of women around the world will have access to safe and effective **microbicides** - and partnerships like this will help us get there."

In addition to Merck, IPM's pharmaceutical partners include Pfizer, which in January 2008 agreed to allow IPM to develop the CCR5 blocker maraviroc as a **microbicide**. In December 2006, IPM and CONRAD reached independent agreements with Gilead Sciences to develop tenofovir (PMPA), a nucleoside reverse transcriptase inhibitor.

In October 2005, IPM entered agreements with Merck and Bristol-Myers Squibb to develop CCR5 blocker and entry inhibitor compounds early in development. In March 2004, IPM signed an agreement with Johnson and Johnson subsidiary Tibotec Pharmaceuticals to develop the company's non-nucleoside reverse transcriptase inhibitor, dapivirine, as a **microbicide**; IPM expects to put that compound into a Phase III clinical trial late in 2009.

"New hope for anti-HIV gels"

Date: 10 March 2008

Source: *Royal Society of Chemistry*

Author(s): Victoria Gill

<http://www.rsc.org/chemistryworld/News/2008/March/10030802.asp>

Early data from a clinical trial has rekindled hope of an effective topical gel to prevent HIV infection. Barrier and **microbicide** gels were originally sought to give women the ability to protect themselves against HIV without having to persuade their partner to use a condom. But development of the gels has been blighted by failure in human tests.

The new gel will enter the second stage of phase II trials this year, and is the first in a new generation of treatments to contain an ingredient specifically active against HIV. The active ingredient, tenofovir, developed by US pharmaceutical company Gilead Sciences, is a nucleotide that binds to a reverse transcriptase enzyme - via which the virus replicates within cells.

'It's already available as a pill, and it's a popularly prescribed antiretroviral,' says Craig Hoseley from the University of Alabama, US, one of the centres at which the trial was carried out.

The development of **microbicides** against HIV was sparked by the discovery that a long-used spermicide gel called nonoxynol-9, still used in many brands of condom, destroyed the HIV virus in a test tube. But subsequent clinical studies found that rather than protect against infection, the gel made it worse. 'It caused local inflammation, which recruited HIV host cells [immune cells] to the area and exacerbated transmission of the virus,' explains Hoseley.

Trial rethink

At the end of last year, the FDA went as far as adding a warning to the packaging of spermicides sold over the counter that contain nonoxynol-9, pointing out the increased risk of HIV infection caused by the gel. The nonoxynol-9 horror story stimulated a rethink about the clinical study of anti-HIV gels. Researchers have since made the search for markers of inflammation an integral part of safety studies.

Even so, that move has not stopped the list of failures from growing. The latest phase III flop, Ushercell, had passed safety trials with flying colours. Trials of the cellulose sulfate gel compound developed by Canadian pharmaceutical firm Polydex were halted after women in one trial who were using Ushercell became infected at a higher rate than those not using it.

However, the new generation of gel treatments containing tenofovir has spurred fresh optimism. 'I truly believe we are turning a corner,' says Sharon Hillier from the US-based **Microbicide** Trials Network (MTN) that organised the tenofovir trials.

Lisa Rossi, a spokesperson for MTN added that if the new generation of locally applied prophylactics are successful, other HIV drugs could find new uses in gel treatments.

'One new drug called maraviroc [developed by Pfizer] is very effective at preventing HIV uptake by immune cells, but the drug itself doesn't absorb well - its effect is very localised,' she says. 'This could make an ideal ingredient for a topical **microbicide**.' Hoseley points out that the 'jury is still out' on why Ushercell and other cellulose-based polymer compounds had failed to provide protection, and that they might still prove useful in the future. 'Only one of the Ushercell trials showed this slight increase in HIV transmission, and none of the data showed signs of inflammation - we're still waiting for the data on why these gels didn't work,' he says. If this data shows that the gels are safe and well tolerated, they could provide useful carriers to make active ingredients into topical treatments.

Resistance concerns

Two more gels are currently being tested in phase III trials in Africa. Buffergel, made by US-based Reprotect maintains a slightly acidic and protective vaginal pH. And Pro2000 is a barrier gel that blocks initial infection.

But already, the high dose arm of the trial of Pro2000 trial has been halted by the organiser - the UK's Medical Research Council (MRC) - after an interim analysis showed that the highest dose was unlikely to protect against HIV infection compared to placebo. But trials of both gels will continue and results are expected later this year.

Michael Lederman is director of the Center for AIDS Research at Case Western Reserve University in the US. His group's lead molecule, PSC-RANTES has been developed specifically for local application. It blocks a receptor called CCR5 which HIV uses to gain access to immune cells.

Lederman points out that there are additional clinical complexities plaguing the **microbicide** field, particularly drug resistance.

'Tenofovir and other agents that share resistance patterns with tenofovir are already in use as therapeutics, so there is the risk that it may not work against viruses that already have key resistance mutations,' he says. 'Also, if [these gels] are used by persons who are infected and do not know it, there is the possibility of inducing resistance mutations in that person, limiting future treatment options.'

Hillier admits that drug resistance is an issue. 'We build many layers of protective measures into our clinical trial, and people are not exposed to the gel if they are infected,' she says. 'But we will have a long wait before these gels can be widely distributed.'

But Hoseley is optimistic, and thinks that an effective anti-HIV gel could be available within five years. 'Eventually, as we progress with these studies, we may find that it's a combination of these treatments that's required for an effective gel - many people in the field advocate that type of combination therapy especially to combat resistance,' he says. 'But I'm excited about these new **microbicides**. And the best news we could hope for is that we have developed an effective gel already.'

"Statement of Anthony S. Fauci, M.D."

Date: 10 March 2008

Source: *NIH News*

Author(s): Anthony S. Fauci

http://www3.niaid.nih.gov/about/directors/news/women_girls08.htm

Today, we pause to commemorate the third annual National Women and Girls HIV/AIDS Awareness Day and to recognize the female face of HIV/AIDS in America. Since the epidemic began in the early 1980s, more than 181,000 women and girls in the United States have been diagnosed with AIDS, and an estimated 86,000 have died with the disease.¹

In some parts of the world, HIV/AIDS predominately strikes women; globally, approximately half of all people living with HIV are female.² Although that is not the case in the United States, women represent more than a quarter of all new annual HIV/AIDS diagnoses in this country. In 2005, nearly 10,000 U.S. women and adolescent girls (13 years of age and older) were diagnosed with HIV/AIDS.³

HIV/AIDS disproportionately affects women of color in the United States. For example, in 2004 AIDS was the leading cause of death for black women ages 25 to 34.¹ The following year, African-Americans accounted for roughly two-thirds of the nearly 127,000 U.S. women living with HIV/AIDS, even though only 13 percent of U.S. women are African-American.¹ For Hispanic women living in the United States, HIV/AIDS is also a significant health issue. In 2005, Hispanic women were diagnosed with AIDS at more than five times the rate of white women in the United States.³

Sex with an HIV-infected male partner is the leading mode of HIV transmission to women and adolescent girls. Approximately 80 percent of new female HIV/AIDS cases diagnosed in 2005 in the United States arose through heterosexual sex,³ and surveys suggest that many of the men involved did not know they were infected with HIV. It is crucial for women to know both their own HIV status and the HIV status of their sexual partners. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), strongly endorses testing for HIV during routine medical care for adolescents, adults and pregnant women, as recommended by the U.S. Centers for Disease Control and Prevention.⁴ The early diagnosis of HIV not only has the potential to help prevent transmission by motivating infected people to modify their behavior, but also creates the opportunity to start treatment promptly, control the virus, make informed choices about childbearing and prolong life.

Sharing syringes and other equipment for injecting illegal drugs is the second most common mode of HIV transmission to American women, directly accounting for approximately one in every five new female HIV/AIDS cases in 2005.³ Injection drug use indirectly promotes HIV transmission as well: Since the AIDS epidemic began, at least 50 percent of all AIDS cases among women have been attributed to either injection drug use or sex with partners who inject drugs.³

Tragically, some women find themselves in situations in which they lack the power to protect themselves from sexual transmission of HIV. They may be forced into sex, their male partners may refuse to wear condoms, or their partners may prevent them from using female condoms. NIAID supports a variety of research designed to develop new HIV

prevention tools specifically for women. One priority research area is the development of safe, effective and acceptable **microbicides**--gels, creams or other substances that women could utilize before sexual intercourse to prevent the transmission of HIV and other sexually transmitted infections.

NIAID also funds research investigating gender-specific differences in HIV/AIDS progression, complications and treatment, as well as research to prevent HIV transmission from an infected mother to her baby - an area in which scientists have made great strides.

Still, there is much work to be done to protect women and girls from becoming infected with HIV. As a global community, we must correct the gender-based inequality that places many women at increased risk. Nationally, we must dramatically lower the rates of HIV/AIDS among racial and ethnical minorities. Women can take control of their health by getting routine HIV testing, avoiding illicit drug use and, when possible, learning their partners' HIV status and using protection during sex. These behavioral changes combined with scientific and socioeconomic advances will help reduce the vulnerability of all women and girls to this terrible disease.

Dr. Fauci is director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health in Bethesda, Maryland.

"Next generation microbicides offer new hope for women's sexual health, UK"

Date: 07 March 2008

Source: *MedicalNewsToday.com*

<http://www.medicalnewstoday.com/articles/99890.php>

On International Women's Day, 8 March 2008 the National AIDS Trust calls on Government and pharmaceutical companies to support trials of a new class of **microbicides** that could offer the greatest hope for women's sexual health in the 21st century. Existing methods of HIV prevention are failing millions of women, particularly in developing countries, where women often cannot negotiate condom use.

While trials of some early day **microbicide** candidates have ended without showing effectiveness, next generation **microbicides** offer new hope in 2008. These new compounds, currently in trials, differ from earlier options as they specifically target HIV, use different delivery methods (such as a gel, cream, or vaginal ring), can protect for longer periods, and - most importantly - are based on proven antiretroviral therapies commonly used to treat HIV.

Deborah Jack, Chief Executive of the National AIDS Trust, comments:

"Women are disproportionately affected by HIV globally, yet we still do not have a widely accepted female controlled option for women to protect themselves against HIV. Next generation **microbicides** offer a real hope to empower women and reduce HIV as part of a comprehensive prevention package.

"Government and pharmaceutical companies must make HIV prevention a priority and ensure that every necessary resource is harnessed to give next generation **microbicides** the greatest chance of success."

"Advocating for rectal microbicides"

Date: 06 March 2008

Source: *Bay Area Reporter*

Author(s): Bob Roehr

<http://www.ebar.com/news/article.php?sec=news&article=2773>

The quest to develop a **microbicide** that protects against HIV infection is proving daunting. Such a compound would be part of a lube or other product used during sex, or perhaps before it, such as a douche.

But a couple of candidates have fallen by the wayside and that was in trials of vaginal sex, not anal sex where transmission of the virus is far more efficient and the challenges of protection presumably far greater.

International Rectal **Microbicides** Advocates is one of the few groups pushing for development of **microbicides** that can be used in the rectum. It issued a report on February 24 in New Delhi, India, at the start of the biennial confab of **microbicides** researchers. The title of that report said it all: "Less Silence, More Science."

A paltry \$7 million a year is being spent on research into rectal **microbicides**, only about 3 percent of the total **microbicide** portfolio. Almost all of the rectal funding is coming from the National Institutes of Health. IRMA is calling for a five-fold increase to \$35 million by 2010, and a diversification of funding from multiple sources.

Common misconceptions are that only gay men are interested in a rectal **microbicide** and that heterosexuals don't engage in anal sex. But research shows otherwise. Studies in the United States and the United Kingdom have found that anywhere from 10 percent to 35 percent of heterosexual women have engaged in anal sex.

"In absolute numbers, seven times more heterosexual women than gay men in the U.S. practice receptive anal intercourse," the IRMA report noted.

Given the biology of the vagina and rectum, transmission of HIV through the latter tissue is many-fold more efficient. And heterosexuals almost never use condoms when they practice anal sex. This could be an important but hidden source of HIV transmission among heterosexual couples.

Jim Pickett, chairman of IRMA and director of advocacy at the AIDS Foundation of Chicago, said, "This could be a sizable amount of the epidemic. Anal sex is a highly stigmatized behavior - people who are doing it don't want to talk about it, they lie about it, policymakers don't want to say it, funders don't want to talk about it - so we just don't know" the full extent of the role anal sex is playing in heterosexual transmission.

The 48-page IRMA report is a primer on the history of development of rectal **microbicides** and where the field is today. It also lays out research priorities for the coming years.

Surveys

Last year IRMA conducted an Internet survey on use of lubricants during anal sex.

"We were going to be happy if a couple of hundred people did this; our wildest dream was 500. We thought, no one was going to take some dusty survey, it is going to be like pulling teeth," said Pickett. "But it took on a life of its own; people were posting it, writing about it. It took on a bit of a viral quality, we were seeing periods where 100-150 people a day were taking it, and we kept extending it."

They finally called it quits after 8,945 people had completed the survey. Some 88 percent were men across a broad range of ages, and most (64 percent) lived in North America. The main survey was in English but volunteers translated it into a handful of languages, and the surprising star turned out to be Turkish. Almost 20 percent of the surveys were taken in Turkish.

One of the surprising findings from the survey was how many people use saliva in doing the act, regardless of whether they were using or not using condoms or lube. And that adds the research question of just what effect spit might have on any **microbicide**.

An earlier Internet survey found that more than a quarter of HIV-negative gay men, and almost half of HIV-positive gay men, douche before and/or after engaging in anal sex. A major reason was simple hygiene, and many thought that a post-sexual douche might protect them from infection with HIV.

Those findings came as a revelation to researchers who hadn't thought about the role that douching might play in making a person more vulnerable to or protected from infection. Now researchers are scurrying to find out just what effect douching might have on the lower reaches of the gut. They also are considering whether douching might be an effective way to deliver a **microbicide**.

Optimism

Pickett said that the recent failures of vaginal **microbicides** trials have had no effect on the rectal area because, "We're in such a different place, we just started safety trials, so the thought of efficacy trials is a long ways away."

He acknowledged that there has been "some tension" within the field of **microbicide** development. Some advocates have focused solely on a vaginal product and tried to ignore any possible rectal use, and even safety issues associated with that likely use. They wanted to minimize controversy that might delay development of a product that could "empower women."

But that has started to change, said Pickett. "I think there is much more willingness to talk about it, there is a much greater acknowledgment of the need."

He believes the Food and Drug Administration has come around to the need for rectal safety data on any **microbicides** that might be submitted for its approval.

"Less Silence, More Science" is available online at <http://www.aidschicago.org/rectalmicrobicides>.

"Q&A: 'Science and ethics can be served in clinical trials'"

Date: 06 March 2008

Source: *The Times of India*

Author(s): Editorial

http://timesofindia.indiatimes.com/Editorial/QA_Science_and_ethics_can_be_served_in_clinical_trials/articleshow/2843441.cms

Preventive technologies remain the only way to slow down AIDS which claims five million new infections every year. **Microbicides** will put prevention in the hands of women, more vulnerable both biologically and socially. Zeda Rosenberg, founder-president of the International Partnership for **Microbicides** (IPM), spoke to Bachi Karkaria of the hope that can be wrested from the persistent failures of clinical trials:

What is the basis for your optimism when all we have are controversies and failures?

We are trying to find the first vaginal **microbicide**, and against the most devious virus. There are bound to be many failures. But these have helped us arrive at the next generation of products. The early chemicals did not have higher longevity in the body. Today's new stronger, longer-lasting anti-retrovirals (ARVs) used for treatment do. We had to get pharma companies to give us access to these drugs so that we could develop and license them for use as preventives.

What will ensure greater adherence, the sticking point in earlier trials?

We can have a more acceptable product delivery system since these new ARVs can stay potent in the body much longer - once-a-day gels or even once-a-month rings. These are coitally independent. Women found the earlier products inconvenient, or impossible, because they had to be used around the time of intercourse. The IPM's contribution has been to expand the number of drugs that can be developed into **microbicide** products, and to make the intravaginal ring into a feasible drug delivery system.

*Will trials of GenNext **microbicides** also be designed differently?*

Yes. Women will be contacted every day, not once a month or every three months. The empty gel applicator will be collected. The new smart applicators can tell us the time the gel was expelled as well as the body temperature at the time, a more reliable indicator of actual use. We always hope to maximise our ability to show that **microbicides** work against HIV, proof of concept. Then we can look at many more products and formulations, and pick the best products, and try them in the best-designed trials to give the product the greatest chance of working. We have to understand the exact degree of both safety and efficacy. After that, the community, that is women, will assess the risks and make a cost-benefit decision.

What are the lessons learnt?

That complicated trials involving very large numbers of women can be conducted, and that both science and ethics can be served. Indeed trials create the ideal HIV prevention because all participants get access to the highest standards of STD prevention, counselling, and free condoms. Then we see the difference between the groups using the active product and the one getting the placebo. Those found HIV+ at the start are referred to appropriate care. Those infected during the trial (not from the product), get good medical care.

"South Africa: HIV prevention trials 'hindered by obstacles'"

Date: 05 March 2008

Source: *SciDev.Net*

Author(s): T V Padma

<http://allafrica.com/stories/200803060632.html>

Developing countries face several challenges to conducting clinical trials on HIV prevention strategies, scientists have cautioned.

Africa is particularly vulnerable to political pressure to halt trials, unpaid and over-burdened ethics committees and delays in obtaining ethical approval, Salim Abdool Karim, director of the Centre for the AIDS Programme of Research in South Africa (CAPRISA), told a plenary session at an international **microbicides** conference in Delhi last week (25 February).

Karim cited South Africa's health minister calling for a halt to all HIV prevention trials in the country in November 2007 - following the drug company Merck's decision to stop further phase II trials on an anti-HIV vaccine that was found to be ineffective - as an example of political interference.

"It should not be a political issue, but one of good science and good ethics," he said.

Karim added that while many women enroll in trials for **microbicides** - vaginal anti-HIV gels or creams to prevent infection - for altruistic reasons, others enroll for reimbursements, often causing them to drop out or not adhere to the study guidelines.

He also pointed out that in African multicentre trials, researchers often have to deal with inconsistent research standards, and trial regulators are often "inadequately equipped to address technical aspects of complex trials".

Nirmal Kumar Ganguly, advisor for the newly-announced Indian Translational Health Science and Technology Institute, cautioned that India also faces several challenges in anti-HIV clinical trials, despite the recent hype surrounding the country's emergence as a hub of clinical trials research (see Vaginal anti-HIV gel 'safe for regular use').

India's advantages include relatively well-equipped research institutes engaged in national and international collaborations, a large "at risk" population, and low cost of trials.

But the country still needs to improve its pool of trained clinical researchers, laboratory infrastructure, and capability in pre-clinical screening and toxicology studies, Ganguly said.

The approval process for research with foreign institutes is also unclear and India needs to resolve ethical and intellectual property issues surrounding clinical trials, he added.

A key challenge to **microbicide** research in developing countries is the absence of sound surveillance data to track infection trends, Roger Detels, professor at the epidemiology faculty at the University of California, Los Angeles, said.

He said clinical trials should be designed to address access by marginalised and high-risk groups, early education for trial participants, community involvement, and reducing cultural barriers.

"Research, awareness vital to the program"

Date: 04 March 2008

Source: *The Tennessean*

Author(s): James Hildreth

<http://www.tennessean.com/apps/pbcs.dll/article?AID=/20080304/OPINION01/803040337/1008>

President Bush recently completed a multi-country trip to Africa to highlight his administration's commitment to eliminating diseases ravaging that continent, particularly malaria and AIDS.

While the motivation behind the timing of the trip, or even the intention of the programs themselves, will be debated at length, the President's Emergency Plan for AIDS Relief (PEPFAR) will doubtlessly be one of the president's greatest legacies.

Through this program, the United States has been a global leader in fighting AIDS; many thousands of Africans infected with HIV are now receiving anti-retroviral drugs (ARVs), the medical infrastructure of recipient countries has improved and interrelated health and educational programs shown effective, or at least instructive. This program has had a significant impact on the burden of AIDS in Africa's most resource poor countries. President Bush has pledged to increase funding for the PEPFAR program.

Funds are needed to provide drugs to all infected persons who need them. An effective vaccine is still the most desirable solution to AIDS. However, as indicated by the recent halting of the large Merck HIV vaccine trial, developing a successful vaccine for this virus has proven extremely difficult. Scientists are uncertain when or if an effective vaccine will be available. An alternative to a vaccine is a topical anti-**microbicide**. **Microbicides** are chemicals that neutralize disease-causing pathogens on contact.

*Focus on **microbicides***

In the context of HIV, the focus has been on a vaginal **microbicide** to protect women from infection during heterosexual sex. A safe vaginal **microbicide** for HIV would be especially valuable in countries where ARVs are not widely available - where HIV positive individuals have high levels of virus because of lack of treatment, putting their partners at higher risk of infection. More than 60 **microbicides** are currently under investigation.

Unfortunately, none of the **microbicide** candidates tested in women at risk for HIV have proven effective. However, valuable lessons have been learned from these **microbicide** trials that will be incorporated into ongoing and planned trials. Several other **microbicide** candidates have shown great promise including one being developed by our research team at Meharry Medical College.

HIV infection is completely preventable in the absence of both a vaccine and **microbicide**. The major drivers of the epidemic are unprotected sex and intravenous drug use. Behavioral interventions could have a profound impact on the AIDS epidemic, but as the current administration is learning through four years of PEPFAR, behavior change is

difficult.

Another major driver of the epidemic is the general lack of awareness about HIV among the populations most at risk. People are generally not informed about the biology of the virus and how it is transmitted. The biggest problem is the large fraction of infected persons that do not know they are positive.

These considerations point to the acute need to significantly increase resources for HIV awareness campaigns, HIV testing, and **microbicides** research. Funds invested in these areas will likely provide a significant return in reducing the burden of AIDS.

"Kenya: Pitfalls of exporting raw data"

Date: 02 March 2008

Source: *Business Daily (Kenya)*

Author(s): Liz Ng'ang'a

<http://allafrica.com/stories/200803030824.html>

Economic analysts often criticise Kenya, and indeed many African countries, for the continued dependency on raw material exports. They argue that by not adding value to products, through packaging or processing, developing countries lose out on market and much needed foreign exchange.

Some schools of thought allege that this unfortunate trend has extended beyond commodities such as coffee and tea. Apparently, Africa is now an exporter of raw data, which is then "value added" by scholars in the West.

For instance, in many studies done on African issues by Northern-based universities, only 30 per cent of the work is actually done on the continent. This is the case even in situations where the investigation is by Africans registered in such institutes.

Researchers parachute in to do the fieldwork, using methodologies designed for the needs of the West. They then take their data back to their universities, where it is put through analytical models, reporting and dissemination processes, all tailored for a western audience.

In my view, the repercussions of this scenario are quite similar to those endured through the export of raw agricultural products: Africa is denied true representation, and the accompanying benefits, in today's knowledge economy.

This was quite well illustrated in a seminar I recently attended. The presenter wanted to make a case on how the North-South research on HIV/Aids is perpetuating unbalanced collaborations. His key point was that the North is well intentioned and that poor structures in the South (in this case sub-Saharan Africa) are largely to blame for the tilted relationship. Africa, he argued, lacks the ability to develop a social science capacity.

Moreover, African researchers are so poorly paid that they are either too busy chasing consultancies to supplement their incomes to concentrate on their jobs, or they are just too demotivated.

And just in case anyone did not get the point of how badly paid these poor workers are, the speaker flushed out photos of "a typical African researcher's house." In it a beaming househelp and two children are pictured in a tiny bedroom that they all share.

He then contrasted this scenario with that in the North, where researchers are paid more, and therefore live better. As a result, when they come to work in Africa, they have no option than to demand international pay packets and to live in colonial bungalows. Whether this makes them perform better was not clear.

The Aids scourge is the ultimate test on African institutions, and one in which they have badly failed.

Understandably, these opinions will sound frivolous, callous and downright insulting to anyone with even the slightest idea of the work being done by local institutions to curb Aids. If anything, the challenges of this crisis point to the continent's capabilities.

While it is true that many of the efforts to stem Aids still require partnership and support from the West, there are national and local organisations taking the lead in many aspects. These range from the design and testing of drugs, vaccine and **microbicides** to the broader applications of basic HIV/Aids science.

All these tasks require different tools and expertise. In short, Africa has come a long way since World War II. Unfortunately, because many studies on Africa by Northern institutes are commissioned to endorse certain viewpoints, many efforts and achievements are cast aside. What is left is the saleable skeleton, the one that will entice academic journals.

In effect, the raw data is stripped off most of its value.

"Zimbabwe: And the greatest and best remains - prevention"

Date: 01 March 2008

Source: *The Herald (Harare, Zimbabwe)*

Author(s): Editorial

<http://allafrica.com/stories/200803030071.html>

"Faith and hope and love we see, joining hand in hand agree but the greatest of the three and the best is love."

Above are strong words from one of the best hymns I have sung in life and one of those verses that try as one might, just embed themselves on the soul.

They also happen to be some of the truest words I have come across in life and as such, I hold them dear and try to let them guide me as I traverse along this arduous journey called life. They are a maxim, a principle and a value- something to hold onto even during the darkest hour.

When things have gone so wrong that you lose all faith and hope and dislike and even hate begins to creep in, I often find myself remembering the days we sang this hymn in the Queen Elizabeth Girls High Hall. Once again I am able to forget, forgive and open my heart to love- that way leaving the past with its hurts and hates behind. Would it not be

good if that is how we could all take Prevention in light of HIV and AIDS?

If we could all design maxims such as Prevention, Treatment, Care and Support we need joining hand in hand agree but the greatest of them all and the best is Prevention. Letting the above statement guide each and everyone of us will go a long way towards cutting down new infections not only in Zimbabwe but in the whole of southern Africa. Agreed the whole package is essential in addressing HIV and AIDS for at any given time, there is need for prevention, treatment, care or support.

However at the very beginning, were our young people are found, where everyone who is HIV negative is, where most of those boys and girls who are just about to experiment with their lives are- there is and can be Prevention. Last week another damper was thrown on HIV programming when news that the first **microbicide** candidate to reach the final phase of testing had failed to prevent HIV transmission.

Testing of the **microbicide**, Carraguard, was carried out over a three-year period on 6 000 women in South Africa and was completed in March 2007. But there was no difference in HIV infections between women in the group using Carraguard compared to those not using it.

Plus News quotes Dr Khatija Ahmed, principal investigator of the trial saying "The trial was unable to demonstrate Carraguard's efficacy in preventing HIV transmission."

There had been hopes that a **microbicide** effective at reducing the risk of transmission was close to being discovered. This way many women would have been able to protect themselves by applying a gel to their genitalia before sexual contact. Unlike condoms, **microbicides** had brought excitement to women because one didn't have to tell their partner anything about wearing the gel unless they wished, which gave power to protect herself to the woman for once.

Many women fail to advocate for the use of condoms in their relationships because of the power dynamics at play in our societies, which leave the decision to have sex, safer or unprotected, in the man's hands. Before that it had been news that scientists were no closer to coming up with a vaccine for HIV and AIDS, which many among us in the HIV field had been hoping for. Again what this effectively means is that the best strategy that remains at our feet is that of Prevention. There are not that many options left to us.

Treatment is indeed essential in light of the fact that many people are already living with HIV and AIDS and by accessing treatment along with other care and support services, they can lead long, normal and healthy lifestyles. Before ARVs, many breadwinners, young people and those pushing industry were decimated by AIDS-related illnesses and today many more are faced with the same plight because of the unavailability and inaccessibility of the life-prolonging drugs.

That makes prevention also very essential especially when we consider that at 15,6 percent prevalence, many more people are HIV negative in this country, people who, if they don't recognise prevention for the important and crucial strategy that it is and should be, can also find themselves infected with HIV.

Research today will show that while more than 300 000 people are in desperate need of Antiretroviral treatment in Zimbabwe, less than half that number are accessing it. If we were to add even 10 more people to the number of those who need treatment, is it realistic to expect that the country systems would then be able to cope?

Activists are doing well to lobby for treatment for everyone who needs it because human beings should have the right to access treatment in order for them to live long and healthy lives.

However activists would do well to lobby for prevention too. According to the Executive director for Southern Africa HIV and AIDS Information Dissemination Service (SAfAIDS) Mrs Lois Chingandu, there is need to begin to reward people for being HIV negative. For a long time, societies have looked at one side of the coin, that of acknowledging and rewarding people living with HIV and AIDS, especially those who disclose, and it is high time both sides were looked at, she said.

Indeed people living with HIV and AIDS (those brave men and women who I cannot help but applaud too) who disclose their status have been acknowledged and rewarded in some instances, but we are still to hear of cases where people who have tested negative have been recognised, or rewarded. Of course the negative result has been met with sighs of relief, vows to lead clean and healthy lives and ululations in many a family but have we as communities learnt to reward and pat our children, cousins, colleagues and comrades for "testing negative HIV."

For abstaining, practising safer sex all the time, for regularly getting tested, for protecting themselves from re-infection, for being open in all sexual matters and talking openly about HIV and AIDS issues, people must be acknowledged. For being responsible fathers and mothers who do not have extra-marital affairs and for being real about HIV and AIDS, people must be rewarded along with those who test positive and decide to do something positive with their lives after that result.

For taking this maxim close to heart: Prevention, treatment, care and support we need, joining hand in hand agree, but the greatest of them all and the best is Prevention: must we not applaud someone?

"The NAPWA/TAEP HIV/AIDS Policy Report"

Date: 29 February 2008

Source: *Poz Magazine*

Author(s): Robert Greenwald, Kali Lindsey

http://www.poz.com/articles/napwa_aids_policy_2157_14059.shtml

Congress and President Bush have finalized the 2008 fiscal year federal appropriations, setting funding levels for the care and treatment of people living with HIV/AIDS in the United States at an all-time low.

Overall, HIV/AIDS programs did not receive increases in funding, despite the fact that new government estimates of the total number of people infected with HIV each year in the U.S. are reported to be 50 percent higher than previous calculations suggested. For the past decade, epidemiologists at the Centers for Disease Control and Prevention (CDC) estimated 40,000 new cases of HIV each year. They now believe that number is closer to 55,000 to 60,000. Reports continue to show very high (and growing) rates of new HIV infections among racial and ethnic minorities, particularly African-American women and younger men who have sex with men. HIV also continues to disproportionately impact those with low incomes and without access to adequate health care - two groups most in need of the life-saving support that can only be provided through adequately funded government programs.

Advocates who had hoped for larger increases in domestic AIDS spending in FY 2008 are disappointed with Congress's inability to influence the Bush administration's budget priorities. They argued that a significant budget increase is needed to slow new infections and support the range of programs that people living with HIV and AIDS depend on to survive.

During the current budget negotiations process, President Bush threatened to veto any funding increases beyond his budget requests. This put Congressional leaders on the defensive, forcing them to drastically scale back health and human services funding bills. In FY 2008, the president sought increased funding for the war in Iraq while simultaneously rejecting domestic spending for health and human service programs. He has vetoed such proposals as the State Children's Health Insurance Program (SCHIP) bill - a bill intended to provide health care coverage for 10 million low-income children in the U.S. over the next five years. Meanwhile, the administration petitioned Congress for and received an additional \$192 billion for the Iraq war.

Advocates fear that HIV/AIDS funding increases will also not take place in FY 2009, as the administration will continue to prioritize funding the war over much-needed domestic programs.

The Treatment Access Expansion Project (TAEP) and National Association of People with AIDS (NAPWA) assert that if Congress is to meet the diverse challenges posed by the U.S. HIV/AIDS epidemic, Congressional leaders and the president the must make adequate funding available. It is essential to fund further research in order to find an effective **microbicide**, vaccine and cure. Until such time, prevention and education efforts must be strengthened. We must fund initiatives to mitigate AIDS-related stigma and increase access to publicly funded voluntary counseling and testing services to help reduce new infections. We must also ensure access to care and treatment, support services, adequate housing and treatment for substance abuse and mental health disorders. If we are going to continue making progress against HIV, we need the federal government to properly fund the fight against AIDS in America.

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3. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Inhibitory effect of PRO 2000, a candidate microbicide, on dendritic cell-mediated HIV transfer"

Author(s): Teleshova N, Chang T, Profy A, et al

Reference: N/A Epub ahead of print.

<http://aac.asm.org/cgi/content/abstract/AAC.00707-07v1?maxtoshow=&HITS=2&hits=2&RESULTFORMAT=&andexacttitle=and&andexacttitleabs=and&fulltext=microbicide%2C+microbicides&andexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct>

Published Abstract: Without an effective vaccine against HIV infection, topical **microbicide** development has become a priority. The sulfonated polyanion PRO 2000, a candidate topical **microbicide** now in Phase II/III clinical trials, blocks HIV infection of cervical tissue in vitro. Dendritic cells (DC) are among the first cell types to contact HIV in the genital tract and facilitate the spread of the virus. Thus, interfering with virus-DC interactions is a desirable characteristic of topical **microbicides** as long as that does not interfere with the normal function of DC. PRO 2000

present during capture of replication-defective HIVJRFL reporter virus or replication-competent HIVBaL by monocyte-derived DC (MDDC) inhibited subsequent HIVtransfer to target cells. Continuous exposure to PRO 2000 during MDDC-target cell co-culture effectively inhibited HIV infection of target cells. PRO 2000 inhibited HIV capture by MDDC. In addition, the compound blocked R5 and X4 HIV envelope-mediated cell-cell fusion. Interestingly, simultaneous exposure to PRO 2000 and LPS attenuated the cytokine production in response to stimulation, suggesting that the compound altered DC function. While efficient block of MDDC-mediated virus transfer and infection in the highly permissive MDDC-T cell environment reinforces the potential value of PRO 2000 as a topical **microbicide** against HIV, the impact of PRO 2000 on immune cell functions warrants careful evaluation.

"PEGylation of cyanovirin-N, an entry inhibitor of HIV"

Author(s): Zappe H, Snell ME, Bossard MJ

Reference: N/A 60(1):79-87.

<http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed&uid=17884238&cmd=showdetailview&indexed=google>

Published Abstract: Cyanovirin-N (CV-N) is a potent inhibitor of human immunodeficiency virus and many other viruses. It has a high potential for use as a systemic compound to control viral load or in the development of **microbicides** to prevent primary viral infection. Due to its cyanobacterial origin it is likely to show the typical drawbacks associated with pharmaceutical use of foreign proteins such as short plasma half-life, proteolysis and immunogenicity. Several strategies were used to covalently bond poly(ethylene glycol) (PEGylate) to CV-N. Random PEGylation at lysine residues resulted in poor retention of antiviral activity. Many site-directed mutants were made to test site-specific PEGylation. One mutant, where glutamine 62 was replaced with cysteine (CV-N(Q62C)) and PEGylated with maleimide activated PEG, retained significant anti-HIV activity in vitro.

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4. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Effect of herpes simplex suppression on incidence of HIV among women in Tanzania"

Author(s): Watson-Jones D, Weiss HA, Rusizoka M, et al

Reference: N/A Epub ahead of print.

<http://content.nejm.org/cgi/content/abstract/NEJMoa0800260v1?maxtoshow=&HITS=1&hits=1&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourceype=HWCIT&ct>

Published Abstract: *Background* Infection with herpes simplex virus type 2 (HSV-2) is associated with an increased risk of acquiring infection with the human immunodeficiency virus (HIV). This study tested the hypothesis

that HSV-2 suppressive therapy reduces the risk of HIV acquisition. *Methods* Female workers at recreational facilities in northwestern Tanzania who were 16 to 35 years of age were interviewed and underwent serologic testing for HIV and HSV-2. We enrolled female workers who were HIV-seronegative and HSV-2-seropositive in a randomized, double-blind, placebo-controlled trial of suppressive treatment with acyclovir (400 mg twice daily). Participants attended mobile clinics every 3 months for a follow-up period of 12 to 30 months, depending on enrollment date. The primary outcome was the incidence of infection with HIV. We used a modified intention-to-treat analysis; data for participants who became pregnant were censored. Adherence to treatment was estimated by a tablet count at each visit. *Results* A total of 821 participants were randomly assigned to receive acyclovir (400 participants) or placebo (421 participants); 659 (80%) completed follow-up. Mean follow-up for the acyclovir and placebo groups was 1.52 and 1.62 years, respectively. The incidence of HIV infection was 4.27 per 100 person-years (27 participants in the acyclovir group and 28 in the placebo group), and there was no overall effect of acyclovir on the incidence of HIV (rate ratio for the acyclovir group, 1.08; 95% confidence interval, 0.64 to 1.83). The estimated median adherence was 90%. Genital HSV was detected in a similar proportion of participants in the two study groups at 6, 12, and 24 months. No serious adverse events were attributable to treatment with acyclovir. *Conclusions* These data show no evidence that acyclovir (400 mg twice daily) as HSV suppressive therapy decreases the incidence of infection with HIV.

"Observational research, randomised trials, and two views of medical science"

Author(s): Vandembroucke JP

Reference: N/A 5(3):e67.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0050067>

Published Abstract: Two views exist of medical science: one emphasises discovery and explanation, the other emphasises evaluation of interventions. This essay analyses in what respects these views differ, and how they lead to opposite research hierarchies, with randomisation on top for evaluation and at bottom for discovery and explanation. The two views also differ strongly in their thinking about the role of prior specification of a research hypothesis. Hence, the essay explores the controversies surrounding subgroup analyses and multiplicity of analyses in observational research. This exploration leads to a rethinking of the universally accepted hierarchy of strength of study designs, which has the randomised trial on top: this hierarchy may be confounded by the prior odds of the research hypothesis. Finally, the strong opinions that are sometimes displayed in pitting the two types of medical science against each other may be explained by a difference in "loss function": the difference in penalty for being wrong. A longer, more detailed version of this paper is found in supplementary.

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

"Sexual behavior and reproductive health among HIV-infected patients in urban and rural South Africa"

Author(s): Lurie M, Pronyk P, de Moor E, et al

Reference: N/A 47(4):484-93.

<http://www.jaids.org/pt/re/jaids/abstract.00126334-200804010-00011.htm;jsessionid=HWFSKWTgP0hCk1N52d2dRW1kBq6v5G5KC817G2QmwHYrCnvDrDC!-830841920!181195629!8091!-1>

Published Abstract: *Background:* With the rollout of antiretroviral therapy in South Africa and its potential to prolong the lives of HIV-infected individuals, understanding the sexual behavior of HIV-positive people is essential to curbing secondary HIV transmission. *Methods:* We surveyed 3819 HIV-positive patients during their first visit to an urban wellness clinic and a rural wellness clinic. *Results:* Urban residents were more likely than rural residents to have current regular sex partners (75.1% vs. 46.0%; [chi]2 odds ratio [OR] = 3.531; P (less than) 0.001), to have any current sexual partners (75.3% vs. 51.2%; [chi]2 OR = 2.908; P (less than) 0.001), and to report consistent condom use with regular partners (78.4% vs. 48.3%; [chi]2 OR = 3.886; P (less than) 0.001) and with casual partners (68.6% vs. 48.3%; [chi]2 OR = 2.337; P (less than) 0.001). In multivariate analysis, independent predictors of consistent condom use with regular partners included across gender, urban residence, and higher education levels; for women, disclosure and younger age; and for men only, no history of alcohol consumption. Male and female participants with a casual sexual partner were less likely to use a condom consistently with regular partners. Additionally, urban residence and a CD4 count greater than 200 cells/mm³ as well as (for women only) a higher household income and a history of alcohol consumption were predictors of having a regular sexual partner. *Conclusions:* HIV prevention programs in South Africa that emphasize the importance of condom use and disclosure and are tailored to the needs of their attending populations are critical given the potential for HIV-infected individuals to resume risky sexual behavior with improving health.

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5. EPIDEMIOLOGY

"Sex infections found in quarter of teenage girls"

Date: 12 March 2008

Source: *The New York Times*

Author(s): Lawrence K Altman

<http://www.nytimes.com/2008/03/12/science/12std.html?ex=1362974400&en=43d84e7a0283251f&ei=5088&partner=rssnyt&emc=rss>

The first national study of four common sexually transmitted diseases among girls and young women has found that one in four are infected with at least one of the diseases, federal health officials reported Tuesday. Nearly half the African-Americans in the study of teenagers ages 14 to 19 were infected with at least one of the diseases monitored in the study - human papillomavirus (HPV), chlamydia, genital herpes and trichomoniasis, a common parasite. The 50 percent figure compared with 20 percent of white teenagers, health officials and researchers said at a news conference at a scientific meeting in Chicago.

The two most common sexually transmitted diseases, or S.T.D.'s, among all the participants tested were HPV, at 18 percent, and chlamydia, at 4 percent, according to the analysis, part of the National Health and Nutrition Examination Survey. Each disease can be serious in its own way. HPV, for example, can cause cancer and genital warts.

Among the infected women, 15 percent had more than one of the diseases. Women may be unaware they are infected. But the diseases, which are infections caused by bacteria, viruses and parasites, can produce acute symptoms like irritating vaginal discharge, painful pelvic inflammatory disease and potentially fatal ectopic pregnancy. The infections can also lead to longterm ailments like infertility and cervical cancer. The survey tested for specific HPV strains linked to genital warts and cervical cancer.

Officials of the Centers for Disease Control and Prevention said the findings underscored the need to strengthen screening, vaccination and other prevention measures for the diseases, which are among the highest public health priorities.

About 19 million new sexually transmitted infections occur each year among all age groups in the United States.

"High S.T.D. infection rates among young women, particularly young African-American women, are clear signs that we must continue developing ways to reach those most at risk," said Dr. John M. Douglas Jr., who directs the centers' division of S.T.D. prevention.

The president of the Planned Parenthood Federation of America, Cecile Richards, said the new findings "emphasize the need for real comprehensive sex education." "The national policy of promoting abstinence-only programs is a \$1.5 billion failure," Ms. Richards said, "and teenage girls are paying the real price."

Although earlier annual surveys have tested for a single sexually transmitted disease in a specified population, this is the first time the national study has collected data on all the most common sexual diseases in adolescent women at the same time. It is also the first time the study measured human papillomavirus.

Dr. Douglas said that because the new survey was based on direct testing, it was more reliable than analyses derived from data that doctors and clinics sent to the diseases center through state and local health departments.

"What we found is alarming," said Dr. Sara Forhan, a researcher at the centers and the lead author of the study. Dr. Forhan added that the study showed "how fast the S.T.D. prevalence appears." "Far too many young women are at risk for the serious health effects of untreated S.T.D.'s," she said.

The centers conducts the annual study, which asks a representative sample of the household population a wide range of health questions. The analysis was based on information collected in the 2003-4 survey. Extrapolating from the findings, Dr. Forhan said 3.2 million teenage women were infected with at least one of the four diseases.

The 838 participants in the study were chosen at random with standard statistical techniques. Of the women asked, 96 percent agreed to submit vaginal swabs for testing. The findings and specific treatment recommendations were available to the participants calling a password-protected telephone line. Three reminders were sent to participants who did not call.

Health officials recommend treatment for all sex partners of individuals diagnosed with curable sexually transmitted diseases. One promising approach to reach that goal is for doctors who treat infected women to provide or prescribe

the same treatment for their partners, Dr. Douglas said. The goal is to encourage men who may not have a physician or who have no symptoms and may be reluctant to seek care to be treated without a doctor's visit. He also urged infected women to be retested three months after treatment to detect possible reinfection and to treat it.

Dr. Forhan said she did not know how many participants received their test results.

Federal health officials recommend annual screening tests to detect chlamydia for sexually active women younger than 25. The disease agency also recommends that women ages 11 to 26 be fully vaccinated against HPV.

The Food and Drug Administration has said in a report that latex condoms are "highly effective" at preventing infection by chlamydia, trichomoniasis, H.I.V., gonorrhea and hepatitis B.

The agency noted that condoms seemed less effective against genital herpes and syphilis. Protection against human papillomavirus "is partial at best," the report said.

EDITOR'S NOTE: The NHANES Survey is available at <http://www.cdc.gov/nchs/nhanes.htm>

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6. OTHER PREVENTION APPROACHES

"Whatever happened to the female condom?"

Date: 08 March 2008

Source: *The Independent on Saturday*

Author(s): Nondumiso Mbuyazi

<http://www.tios.co.za/>

The female condom was introduced to South Africa 10 years ago amid much fanfare, but it has not made as much of an impact as had been hoped. When it was introduced, many women were optimistic about it, but they soon complained about how uncomfortable it was, that they were not freely available and that there was not very much information on how they were supposed to be used.

KwaZulu-Natal Health spokesman Chris Maxon says the response from females is gradually becoming more positive.

Challenges

"However, in rural areas they still pose a challenge, like any female-initiated method and mechanism," said Maxon.

Mmbatho Mngayi, a researcher at the Reproductive Health Research Unit (RHRU) at the University of Witwatersrand in Johannesburg, said: "The female condom allows the woman to take responsibility for her own protection. Because she has inserted it herself, she knows she's safe."

The female condom is a lubricated polyurethane sheath about 17cm long, with a ring on either end. The woman inserts it into her vagina before having sex. The condom, also known as the femidom, was introduced to empower

women to protect themselves from contracting sexually transmitted infections including HIV/Aids, and unplanned pregnancies.

It has received mixed reviews. One woman said: "Although it was difficult at first, I prefer it to the male condom." Some women said it was uglier and bigger than its male counterpart and made "funny noises".

Due to its cost - about R13 for three - the femidom is not as freely available as the male condom.

Maxon says the government is in the process of introducing them at more health facilities. Last year 24 610 female condoms were distributed in KwaZulu-Natal.

EDITOR'S NOTE: A subscription is required to view this article at its original location.

"Female condom for Rs 5 in India"

Date: 06 March 2008

Source: *The Times of India*

Author(s): Kounteya Sinha

http://timesofindia.indiatimes.com/Female_condom_for_Rs_5_in_India/articleshow/2841558.cms

A five-rupee female condom (FC) will now spearhead India's fight to control HIV spread among women.

Under the first phase, the National AIDS Control Organisation (Naco) is procuring 15 lakh female condoms from UK's Female Health Company (FHC), which will be doled out to sex workers and housewives in Andhra Pradesh, Maharashtra, Tamil Nadu and West Bengal over the next 8 months. A decision on a countrywide upscale will be undertaken after reviewing data from these four states.

According to Naco director-general K Sujatha Rao, a year-long pre-programme acceptability and feasibility study, involving 60,000 women in 13 sites - 11 involving high risk groups like sex workers and two family planning programmes - in eight states from November 2006, found 60% women re-purchasing the condom and over 98% of the users finding it comfortable. Naco through UNFPA had procured five lakh condoms from FHC for its acceptability study.

Rao told TOI: "The pilot project was highly successful showing consistent use of FCs. We have, therefore, decided to scale up the programme under which we will first train women on how to use these condoms."

Union health minister A Ramadoss said: "When a male partner refuses to wear a condom, women need self-initiated methods to protect themselves against unplanned pregnancies and HIV/AIDS."

According to Manoj Gopalakrishna from Hindustan Latex Limited, India till now imported FCs making them expensive. "We have now set up an FC manufacturing unit in Kochi. FHC has transferred the condom manufacturing technology to us. We will manufacture 10 million FCs annually. Though the cost of making each condom will be Rs 40, it will be available to women for Rs 5 through 200 NGO-led targeted interventions."

Esther Bayliss from the Female Health Foundation told TOI: "Female condoms - FC1 and FC2 - are the only ones approved by US FDA and WHO. These condoms are the first and only female-initiated barrier method that is safe and effective if used correctly and consistently providing dual protection against the transmission of sexually transmitted infections, including HIV/AIDS and unintended pregnancy."

Nearly 40% of the 2.5 million HIV positive victims living in India are women, most of them hapless housewives who don't look at their husbands as a threat and commercial sex workers unable to negotiate with clients refusing to use a condom.

"Uganda: Teenage sex rampant - research"

Date: 06 March 2008

Source: *The Weekly Observer (Kampala)*

Author(s): Richard M Kavuma

<http://allafrica.com/stories/200803060756.html>

A report to be launched in Kampala today shows that most Ugandans start sex before the age of 18, while many girls use condoms to guard against pregnancy and not to avoid infections like HIV/AIDS.

As a result, the report says, there is need to make sex education and such things as condoms more available to young people. The report, titled *Protecting the next generation in Uganda: New evidence on adolescent sexual and reproductive health needs*, is based on two national surveys conducted between 2004 and 2006, involving more than 16,000 males and females aged 12-49. Published by the Guttmacher Institute and distributed by Panos Eastern Africa, it is part of a larger project also conducted in Burkina Faso, Malawi and Ghana. Among the authors are Ugandans; Richard Kibombo, Stella Neema and Kalundi Serumaga.

"It is important to acknowledge that adolescence is a time when most people become sexually active and that meeting the needs of young people is integral to an effective national [HIV/AIDS] prevention campaign," the report says.

According to the survey, teenagers, especially girls, start having sex a lot earlier than most reproductive health programmes presuppose. For instance, among women aged 20-24, twenty percent said they had started sex before the age 15; but only 10 percent of boys in the same group had had sex before 15.

When the bar was raised, 64-four percent of women said they had started sex by age 18; fifty percent of the males had started sex by that age.

This is interesting in a country with strong Christian beliefs and where political leaders have passionately preached abstinence until marriage. Indeed the report says that most Ugandans aged 12-19 strongly believe in avoiding sex until they are married. But the reality is different.

"When asked about the reason for their first sexual intercourse, half of the women aged 15-19 and about eight in ten of the same-aged men who had had sex said they 'just felt like it'," the report says. "Thus simple, straight forward desire motivates sexual initiation."

While condoms have been hailed as a key part of Uganda's fight against HIV/AIDS (together with abstinence and faithfulness), the survey found that 41% of the women had used a condom to prevent pregnancy and not necessarily as a barrier against disease. While an equal percentage used condoms to prevent both disease and conception, this finding reflects changing attitudes about HIV/AIDS. Experts have lately warned that Ugandans have become more complacent about AIDS, especially with improved management of the condition.

Among its recommendations, the report urges more educational opportunities, especially for girls. This comes after finding that girls in school, urban women and women of a wealthier class were more likely to have less-risky sexual behaviour than their rural, uneducated or poorer counterparts.

It also calls for more sex education for adolescents, regular condom supply as well as an efficient youth-friendly health care system. This is important in a country where a 16-year-old demanding condoms from a middle-aged or elderly drug dispenser is likely to be sneered at as being of loose morals. Yet with or without the services, the report says, young people are having sex.

EDITOR'S NOTE: The report mentioned in this article is available for public access online at http://www.gutmacher.org/pubs/2008/03/05/PNG_Uganda_mono.pdf

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7. POLITICS AND POLICY

"FDA taps Chief for drug center amid scrutiny"

Date: 11 March 2008

Source: *Wall Street Journal*

Author(s): Anne Wilde Mathews

http://online.wsj.com/article_email/SB120517869663225003-IMyQjAxMDI4MDE1MTE4NzE4Wj.html

The Food and Drug Administration said former drug-center head Janet Woodcock will return to that post on a permanent basis.

Dr. Woodcock's second stint in the job, which she has held on an acting basis since September, is likely to be generally welcomed by the drug industry. Though she is seen as tough, she is a seasoned hand, having begun her previous directorship of the FDA's Center for Drug Evaluation and Research in 1994. In 2005, she was appointed a deputy commissioner at the FDA, later adding the title of chief medical officer. Dr. Woodcock, 59 years old, will relinquish both positions, an FDA spokeswoman said.

Because she is an architect of the FDA's current approach to drug regulation, industry officials don't view her as likely to attempt wholesale reversals. Still, Dr. Woodcock, an internist and rheumatologist, will take back her former job at a challenging time, overseeing major transitions at the center.

Her first and biggest task will be to implement a major law passed last year that will require the hiring of hundreds of new staffers and the drawing up of procedures to implement new authority over drugs already on the market. Under the new law, the FDA is able to take various actions if it believes a drug carries a potential safety concern, including requiring new studies and limiting distribution.

Dr. Woodcock will also take over as Congress has the FDA under particularly close scrutiny. A number of outside groups have said the agency needs more funding and changes in its culture and approach. Some drug-industry officials have ramped up their public venting of concerns that the FDA has become too risk-averse in its approvals, slowing the arrival of new treatments.

Among the congressional investigations focused on the agency are probes into its handling of the Sanofi-Aventis SA antibiotic Ketek and the safety of heparin, the blood-thinner that has been linked to hundreds of allergic reactions and some deaths.

"Pills for STDs lack FDA approval"

Date: 09 March 2008

Source: *The Miami Herald*

<http://www.miamiherald.com/actionline/story/448107.html>

The manufacturers of the over-the-counter drugs Tetrasil, Genisil, Aviralex, OXi-MED, Imulux, Beta-mannan, Micronutrient, Qina, and SlicPlus, which are intended to prevent sexually transmitted diseases, have been warned by the Food and Drug Administration to stop claiming they have FDA approval; they don't.

According to the FDA, the products claim to prevent a variety of STDs, including herpes, chlamydia, human papilloma virus, cervical dysplasia and HIV/AIDS. The FDA considers these to be unapproved new drugs being marketed in violation of the federal Food, Drug and Cosmetic Act. Further, they don't meet federal requirements for providing proper directions for use by consumers, and some are illegal because they make false and misleading claims.

The dangers for consumers arise in part from trusting these products to prevent or treat STDs when they may be ineffective at best and dangerous at worst. It also raises the chances of an infected person passing the disease to another partner.

"UNAIDS calls for lifting of HIV-related travel restrictions"

Date: 07 March 2008

Source: *Agence France Presse*

http://health.yahoo.com/news/afp/unhealthaids_080307202656.html

People with HIV face travel restrictions from some 74 nations, with 13 banning those with the disease from entering the countries completely, UNAIDS said Friday.

In addition, others infected while in their destination country can face deportation "often without confidentiality and into situations of great discrimination and economic devastation", the UN programme on AIDS and HIV said in a statement.

The travel restrictions based on HIV status show the "exceptionality of AIDS", said UNAIDS executive director Peter Piot.

"No other condition prevents people from entering countries for business, tourism, or to attend meetings," he said. "No other condition has people afraid of having their baggage searched for medication at the border, with the result that they are denied entry or worse, detained and then deported back to their country," he added.

An international task force on HIV-related travel restrictions, comprising governments, UN agencies and intergovernmental groups, civil society and people infected by the disease, met for the first time on February 25 and 26 in Geneva.

UNAIDS, which co-chairs the task force with the Norwegian government, said: "We hope that their combined efforts will ... influence governments to remove such restrictions."

The task force plans to raise this at several meetings in the coming months, including a high-level meeting on AIDS at the UN General Assembly in New York in June, and at the Global Forum on Migration and Development to be held in October in the Philippines.

"No more scavenger hunts"

Source: *Nature*. 2008 Mar 06;452(7183):1.

Author(s): Editorial

<http://www.nature.com/nature/journal/v452/n7183/full/452001a.html>

The recent media flap over antidepressants highlights the need for data to be transparent - and for a mandatory database of all clinical trials.

It was not the media's finest hour. When a study was released last week challenging the effectiveness of several popular antidepressant drugs, (I. Kirsch et al. PLoS Med. 5, e45; 2008) some news outlets, particularly in the United Kingdom, responded with headlines blaring 'the drugs don't work' - even though the drugs often do work. Yes, the study showed that the drugs often performed no better than a placebo. But what many of the media missed was that the placebo effect can be remarkably strong in psychological and neurological disorders, especially in mild depression. Doctors scrambled to assure patients that they should not abandon treatment.

Almost buried in the hubbub, though, was a more important story. To access the data needed for this study - a meta-analysis of 35 clinical trials - the researchers had to file a Freedom of Information Act request with the US Food and Drug Administration. And the information they finally received was incomplete: crucial data were missing for several studies that failed to find a significant benefit of the drug compared with the placebo. The missing data limited the analysis, and forced the researchers to abandon their investigation of two drugs altogether.

Such data chaos has become all too familiar in the world of clinical trials. And that fact, combined with recent scandals about antidepressants, diabetes drugs and cholesterol medications, has spurred an outcry to make clinical-trial registries mandatory.

That outcry has not been ignored - the past few years have seen dramatic improvements in data transparency. The International Committee of Medical Journal Editors took a valuable step forward in 2004 when it demanded that authors list and describe their clinical trials in an accepted registry. The number of clinical trials registered in the US National Institutes of Health database rose from 13,153 to 22,714 in a single month, and now stands at more than 52,000 trials spanning 153 countries. Other databases are also active, including an international trial registry hosted by the World Health Organization, which has declared the registration of all interventional trials a "scientific, ethical and moral responsibility".

That responsibility remains unfulfilled. The existing databases are neither comprehensive nor mandatory. Researchers in search of clinical-trial data still have to embark on a scavenger hunt through missing trials and incomplete database entries. Yet the taste of success has been enough to move some open-access advocates to the next step: asking for a description not only of a trial's protocol, but also its results.

Critics argue that results databases could undermine the peer-review process, reveal competitive information or enable sloppy meta-analyses that set off public panics. They have a point: public registries are no substitute for peer-reviewed literature. But such results databases would still serve an important purpose - as repositories for the negative data that often go unpublished, but that can reveal a drug or treatment regime as ineffective. These data are crucial for meta-analyses, and could improve the design of subsequent trials. Despite reluctance by some pharmaceutical companies to participate, the registries could be helpful to them.

So what can be done to encourage recalcitrant investigators to deposit their data? Several prominent medical journals have removed one barrier by reassuring authors that depositing an abstract or table of results will not be considered 'prior publication'. Politicians in several countries have expressed interest in mandating clinical-trial registries, with some emphasizing the importance of depositing trial results as well. But true fulfilment of that moral responsibility will require international cooperation and enforcement by regulatory authorities - an unprecedented degree of organization and commitment. It is a daunting goal, but one worthy of the struggle.

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8. PHARMACEUTICAL INDUSTRY

"Slow going for drug development"

Date: 31 January 2008

Source: *Drug Discovery News*

Author(s): David Hutton

<http://www.drugdiscoverynews.com/index.php?newsarticle=1993>

With clinical trial protocols becoming more complex, the demands on investigative site personnel and study volunteers are leading to lengthier clinical trials and efforts to recruit and retain patients are being hampered, according to a new study by the Tufts Center for the Study of Drug Development.

Ken Getz, a senior research fellow at the Tufts Center and lead investigator on the study, tells Drug Discovery News there has been a steady increase in the number and frequency of procedures per protocol during the past 10 years, paired with a similar rise in the number of enrollment eligibility criteria and pages per case report form. These protocol design changes are largely due to the nature of diseases currently under investigation and intensifying competition among drug developers.

The Tufts CSDD study is the first ever to quantify the impact of changes in protocol design on clinical trial performance. According to the survey, the annual growth rate of unique procedures per protocol grew 6.5 percent between 1999 and 2005. It also found that clinical trials are taking longer. Between 1999 and 2002 and 2003 to 2006, the total time from protocol design readiness to database lock rose from 460 to 780 days, or nearly 70 percent.

Volunteer rates dropped from 75 percent in 1999 to 2002 to 59 percent in 2003 to 2006. Volunteer retention rates declined from 69 percent to 48 percent during the same period. Moreover, the work effort required of investigative site personnel to administer protocols is rising faster than the rate of growth of unique procedures or their frequency per protocol.

"If anything, the implications of our analysis suggest that sponsors really need to take a closer look at the design of their studies and project the impact they believe it may have on the work burden their sites have to bear, and the patient recruitment and enrollment challenges," Getz says. "If anything, the results point to the need for companies to be much more mindful of the domino effect that occurs when protocols become more demanding and complex."

As a result, Getz points out the increasing complexity of protocol designs is contributing to the growing time, cost and risk in drug development. "The rise in protocol complexity represents a significant challenge for drug developers," he says. "There are just more procedures that have to be performed to satisfy the requirements of the study."

The first question that arises out of the analysis, according to Getz, is whether the added complexity of the protocol really is necessary. If the answer to the question is no, Getz contends much of the increased demands may not be critical.

"It has to be determined if all of this additional complexity and the more demanding requirements of the protocol are necessary for companies to collect the data that is needed to demonstrate the safety and the efficacy of the product to get regulatory approval" Getz says. It then raises the question of what can be simplified in the protocol.

"In our study, we offer some insight as to where to look first," he says. "For example, there are certain procedures that add significant burden on the investigative site personnel. You could prioritize procedures to those that are deemed important and those that have minimal impact on site personnel."

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9. ANNOUNCEMENTS

Less Silence, More Science

<http://www.aidschicago.org/rectalmicrobicides/docs/IRMAColorFinalWeb.pdf>

International Rectal **Microbicide** Advocates (IRMA) released **Less Silence, More Science: Advocacy to Make Rectal Microbicides a Reality in India** on 24 February 2008 at the Rectal **Microbicides** Update at the **Microbicides** 2008 conference. The report serves as an authoritative reference on recent developments and current efforts in rectal **microbicide** research, and describes global challenges, and key advocacy goals and strategies to advance scientific discovery on topical rectal products conferring protection against HIV transmission.

EDITOR'S NOTE: The report is available for public download at

<http://www.aidschicago.org/rectalmicrobicides/docs/IRMAColorFinalWeb.pdf>. IRMA's official Press Release is available at <http://www.aidschicago.org/rectalmicrobicides/news.php>

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