



# ALLIANCE FOR MICROBICIDE DEVELOPMENT

**18 January 2008, Volume 9, Number 3**

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

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

Its purpose is to:

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

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

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#### 1. MEDIA COVERAGE OF MICROBICIDES

##### "HIV prevention rests on gel that comes from seaweed"

**Date:** 17 January 2008

**Source:** *The Star (South Africa)*

**Author(s):** Louise Flanagan

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

Phillipine Metsing's help in testing a **microbicide** gel made from seaweed may one day help to protect her tiny daughter from HIV infection. "I do think so. The more we try to find a cure, the more we will find it," said Metsing (22),

holding her month-old baby Kabelo ("Gift") in her arms.

Metsing was one of 6 000 women in South Africa who took part in the clinical tests of Carraguard, a **microbicide** gel designed for women to use to block HIV infection during sex. The main ingredient of the gel, inserted into the vagina before sex and used in combination with condoms during the trial, is carrageenan, which comes from seaweed.

The phase 3 clinical trial for Carraguard is being conducted at three sites. Metsing took part at the Setshaba Research Centre in Soshanguve, north of Pretoria, where 2 402 women took part in the three-year trial. The trial ended last year, and results are due to be announced within weeks. The research team is cautiously optimistic.

"We are keeping our fingers crossed," said the principal investigator at Setshaba, clinical microbiologist Dr Khatija Ahmed. The trial aimed to establish two things: is Carraguard safe for use and is it effective in preventing HIV infection in women? Ahmed said the safety aspect was confirmed, and the trials were closely monitored by independent monitoring groups and ethics committees. If there had been any hint of concerns over safety, it would have been halted.

Recently, two clinical trials were stopped internationally - one an unrelated **microbicide** and another for an HIV vaccine. The trial team watched both with interest and concern, but reassured their participants during the halting of the other trials. And even if the results don't show Carraguard is effective, Ahmed said the work wasn't wasted. "There's nothing that has been lost in a study like this, both from a scientific point of view and from a community point of view."

Knowledge gained added to research in the field, while the participants and communities benefited from the knowledge of HIV and research. Over 15 000 people in Soshanguve were educated through the trial, said community liaison official Malebo Ratlhagana. She and three others were responsible for recruiting women to take part in the trial. They spoke to more than 15 000 people in the community about the trial, screened over 4 000 women as potential participants and finally enrolled 2 402 in the trial.

"Even if Carraguard doesn't prove to be effective, the information we gave is enormous," said Ratlhagana. "I'm definitely proud of that. I've done what God wanted me to do." Ratlhagana was diagnosed with HIV before the trial started and made it her mission to work in this field to help the community. "I told myself there is a reason why I am in this field and why I am HIV-positive," she said.

Many women could not participate as they were already HIV-positive, and many were scared of undergoing HIV tests for fear of the results. Ratlhagana disclosed her own status to encourage them and initiated a support group for those who tested positive. "I saw the need and wanted to reduce the burden on the counsellors - we would screen 10 people and five would be HIV-positive." Now she hopes, both for the sake of the research and for herself, that Carraguard will be useful in preventing HIV infection.

Trial participants were split into two groups - one given Carraguard and the other a placebo. All were urged to use condoms and the gel whenever they had sex. Ratlhagana said some participants never told their partners.

So how will researchers know whether Carraguard or the condom prevented HIV infection? More HIV infections in the placebo than the Carraguard group points to the **microbicide's** efficacy. If it is even 30% effective, said Ahmed, "the number of new infections we can stop is astronomical".

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

## "The role of the media in HIV prevention trials"

**Date:** 30 November 2007

**Source:** *Exchange Magazine (Netherlands)*

**Author(s):** David Ngilangwa

[http://www.kit.nl/net/KIT\\_Publicaties\\_output/ShowFile2.aspx?e=1407](http://www.kit.nl/net/KIT_Publicaties_output/ShowFile2.aspx?e=1407)

HIV and AIDS statistics remind us that safe and effective HIV prevention methods such as **microbicides**, vaccines, genital herpes suppression medicines and use of antiretrovirals as pre-exposure prophylaxis are urgently needed to reduce HIV infections. Before these can be produced, their safety and efficacy need to be established through clinical trials. Currently many of these approaches are being tested, requiring more than 80,000 participants worldwide to participate. Yet recruiting volunteers to participate is a serious challenge that slows down efforts of coming up with new HIV prevention methods in the near future.

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### *Inaccurate reporting*

Recently, CONRAD discontinued its trials of **microbicide** candidate Ushercell gel, after discovering that instead of preventing HIV infection in women who used the product, it seemed to increase risk of infection (2) Following this development, Family Health International also stopped a trial of the same gel in Nigeria as a precaution. These developments were widely reported, with most of the reports carrying inaccuracies. For example, in South Africa, the media referred to trial participants as guinea pigs while journalists in Tanzania confused **microbicides** with antiretrovirals.

Generally, there is little understanding by journalists about the number, types and functions of **microbicides** studies that are underway in different countries. Journalists also lack knowledge about the current development stages of the products under trial, and some do not even know that they are not on the market yet. Headlines appearing in the print media following the halting of the Ushercell trials were discouraging; stigmatizing participants, if not threatening people not to participate in HIV clinical trials. As a result, recruitment and retention of trial participants became a challenge in various sites in Africa, including in Tanzania. In another example of inaccurate reporting, BBC Kiswahili Service interviewed a trial participant in one of AMREF's trials of **microbicide** candidate Pro 2000 in Mwanza, Tanzania. During the interview, the reporter informed the woman that the World Health Organization had banned the use of this gel worldwide. The reporter went on to ask another woman whether or not she was going to notify other women not to use the gel anymore. Being a credible and powerful channel within the region, the BBC's report threatened to affect recruitment and retention of trial participants in Mwanza and other KRHP's trials in Moshi, if we had not taken urgent measures to portray a true picture of the situation. We organized a press conference and education sessions about **microbicides** for journalists based in the programme area. We also developed reading materials in the local language to clarify issues about the trial which had been misreported by the media.

### *Vicious circle*

It should be noted that trials are not only discontinued as a result of failure, but can also be stopped prematurely because an interim analysis shows that a life-saving drug or technology is that effective that it is deemed unethical to deny people its use. Notable examples are the male circumcision trials conducted in 2005 and 2006 in Kenya, South Africa and Uganda, which were stopped prematurely due to consistent evidence of effectiveness.

Most journalists lack background knowledge in science, which leads to inability to comprehend the clinical trials procedures. On the other hand, there is an unwillingness by scientists to cooperate with the media, based on fear or suspicion fed by past and present experiences of inaccurate reporting. Sometimes, researchers fear losing control when they are interviewed. This leads to a vicious circle of inaccurate reporting. Media could be an important stakeholder in promoting the research agenda for the benefit of communities. However, it is necessary to equip them with appropriate knowledge and skills about complicated scientific ethics and procedures. In tackling HIV and AIDS, researchers and the media have a common goal of fighting the same enemy with two different weapons.

**EDITOR'S NOTE: The above is an excerpt of a larger article, available for public access at the above website.**

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## **2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC**

### **"Antiretroviral pre-exposure prophylaxis prevents vaginal transmission of HIV-1 in humanized BLT mice"**

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

**Reference:** N/A 5(1):e16.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050016>

**Published Abstract:** *Background* Worldwide, vaginal transmission now accounts for more than half of newly acquired HIV-1 infections. Despite the urgency to develop and implement novel approaches capable of preventing HIV transmission, this process has been hindered by the lack of adequate small animal models for preclinical efficacy and safety testing. Given the importance of this route of transmission, we investigated the susceptibility of humanized mice to intravaginal HIV-1 infection. *Methods and Findings* We show that the female reproductive tract of humanized bone marrow-liver-thymus (BLT) mice is reconstituted with human CD4+ T and other relevant human cells, rendering these humanized mice susceptible to intravaginal infection by HIV-1. Effects of HIV-1 infection include CD4+ T cell depletion in gut-associated lymphoid tissue (GALT) that closely mimics what is observed in HIV-1-infected humans. We also show that pre-exposure prophylaxis with antiretroviral drugs is a highly effective method for preventing vaginal HIV-1 transmission. Whereas 88% (7/8) of BLT mice inoculated vaginally with HIV-1 became infected, none of the animals (0/5) given pre-exposure prophylaxis of emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) showed evidence of infection (Chi square = 7.5, df = 1, p = 0.006). *Conclusions* The fact that humanized BLT mice are susceptible to intravaginal infection makes this system an excellent candidate for preclinical evaluation of both **microbicides** and pre-exposure prophylactic regimens. The utility of humanized mice to study intravaginal HIV-1

transmission is particularly highlighted by the demonstration that pre-exposure prophylaxis can prevent intravaginal HIV-1 transmission in the BLT mouse model.

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

**<http://www.dallasnews.com/sharedcontent/dws/dn/latestnews/stories/011508dnmethivdrug.1a19ebe.html> and <http://www.newkerala.com/one.php?action=fullnews&id=12847>, among other sources.**

**"Can the new humanized mouse model give HIV research a boost"**

**Author(s):** Shacklett BL

**Reference:** N/A 5(1):e13. Perspectives.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050013>

**Published Abstract:** Over the last few months, the medical community has received both good and bad news concerning the AIDS epidemic. The "good" news: the number of individuals infected with HIV worldwide was revised downward and was estimated at 33 million rather than 40 million [1]; although lower than expected, this still represents a staggeringly high figure. The bad news: two highly publicized vaccine trials were prematurely terminated due to a high frequency of seroconversions among vaccine recipients [2]. The obvious message from both of these reports is that more research is needed to uncover better strategies for preventing HIV transmission and more effective treatments for those already infected.

#### *Limitations of Current Animal Models for HIV*

Infection of rhesus macaques with simian immunodeficiency virus (SIV) has provided an excellent nonhuman primate model for studying HIV pathogenesis (reviewed in [3]). SIV is closely related to HIV on a molecular level, its replication may be inhibited by many of the same antiretroviral compounds, and it induces an acquired immunodeficiency syndrome (AIDS) that mimics human AIDS in many important respects. SIV can also be transmitted experimentally to rhesus macaques across the cervicovaginal or rectal mucosa, providing a means of testing **microbicides** as well as studying the earliest events involved in mucosal transmission. However, the SIV model also has two major disadvantages. First, rhesus macaques are costly and in high demand, and must be housed in accredited primate facilities; there are a limited number of such facilities nationwide. Second, despite its similarity to HIV, SIV and HIV differ in numerous subtle ways, including genetic organization (for example, the Vpx gene is unique to SIV; Vpu is unique to HIV) and disease course (simian AIDS generally develops within six to 12 months of infection with SIV, while it can take many years for human AIDS to develop after infection with HIV).

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

## "Epigallocatechin gallate inactivates clinical isolates of herpes simplex virus"

**Author(s):** Isaacs CE, Wen GY, Xu W, et al

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

<http://aac.asm.org/cgi/content/abstract/AAC.00825-07v1?ct=ct>

**Published Abstract:** In the absence of a fully effective herpes simplex virus (HSV) vaccine, topical **microbicides** represent an important strategy for preventing HSV transmission. (-) Epigallocatechin gallate (EGCG) (MW 458.4) is the primary catechin in green tea. The present study shows that EGCG has greater anti-HSV activity than other green tea catechins and inactivates multiple clinical isolates of HSV-1 and HSV-2. EGCG reduced HSV-2 titers by 1,000-fold in 10-20 minutes and reduced HSV-1 titers by the same amount in 30-40 minutes. The anti-HSV activity of EGCG is due to a direct effect on the virion and incubating Vero and CV1 cells with EGCG for 48 hours prior to infection with HSV-1 and HSV-2 respectively does not reduce HSV production. Electron microscopical (EM) studies showed that purified virions exposed to EGCG were damaged and EM immunogold labelling of the envelope glycoproteins gB and gD was significantly reduced following EGCG treatment while capsid protein labelling was unchanged. When the purified HSV-1 envelope glycoproteins gB and gD were incubated with EGCG and then examined by SDS gel electrophoresis, lower molecular weight gB and gD bands decreased and new higher molecular weight bands appeared indicating the EGCG dependent production of macromolecular complexes. gB and gD are essential for HSV infectivity and these results suggest that EGCG could inactivate HSV virions by binding to gB, gD or another envelope glycoprotein. EGCG is stable in the pH range found vaginally and appears to be a promising candidate for use in a **microbicide** to reduce HSV transmission.

## "Topical microbicides: a promising approach for controlling the AIDS pandemic via retroviral zinc finger inhibitors"

**Author(s):** Turpin JA, Schito ML, Miller Jenkins LM, et al

**Reference:** N/A 56:229-56. 2008.

<http://www.ncbi.nlm.nih.gov/pubmed/18086414?dopt=Abstract>

**Published Abstract:** As the HIV/AIDS pandemic has become feminized over the last 25 years, with women and girls representing over 50% of the new infections, topical **microbicides** have been proposed as a method to prevent HIV transmission. Topical **microbicides** may consist of gels, creams, films, and other alternative solid dosage forms or devices that deliver inhibitors of HIV entry and replication to vaginal, rectal, and/or penile mucosal surfaces. Although we are yet to realize the promise of a topical **microbicide**-based prevention strategy, the eminence of results from ongoing Phase III clinical trials has spurred efforts to ensure a vibrant **microbicide** development pipeline, generating new candidates to improve upon or compliment the first generation **microbicides**. We have developed a new class of topical **microbicides** targeting the mutationally intolerant HIV01 nucleocapsid protein (NCp7) zinc fingers, leading to loss of HIV replication capacity and production of noninfectious virus. WE present the rationale for development of neutral thioester-based, S-acyl-2-mercaptobenzamide, HIV01 NCp7 zinc finger inhibitors as topical **microbicide** candidates and advance the hypothesis that their development could add substantially to the

**microbicide** pipeline. We have identified this new class of **microbicides** as pluripotent (for multiple antiviral targets) HIV-specific virucides.

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

**"Treating curable sexually transmitted infections to prevent HIV in Africa: still an effective control strategy?"**

**Author(s):** White RG, Orroth KK, Glynn JR, et al

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

[http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list\\_uids=18176323&dopt=AbstractPlus](http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=18176323&dopt=AbstractPlus)

**Published Abstract:** BACKGROUND:: Evidence regarding the effectiveness of sexually transmitted infection (STI) treatment for HIV prevention in Africa is equivocal, leading some policy makers to question whether it should continue to be promoted for HIV control. We explore whether treating curable STIs remains a cost-effective HIV control strategy in Africa. METHODS:: The model STDSIM was fitted to the characteristics of 4 populations in East and West Africa. Over the simulated HIV epidemics, the population-attributable fractions (PAFs) of incident HIV attributable to STIs, the impact of syndromic STI management on HIV incidence, and the cost per HIV infection averted were evaluated and compared with an estimate of lifetime HIV treatment costs (US \$3500). RESULTS:: Throughout the HIV epidemics in all cities, the total PAF for all STIs remained high, with less than or equal to 50% of HIV transmission attributed to STIs. The PAF for herpes simplex virus type 2 increased during the epidemics, whereas the PAF for curable STIs and the relative impact of syndromic management decreased. The models showed that the absolute impact of syndromic management remains high in generalized epidemics, and it remained cost-saving in 3 of the 4 populations in which the cost per HIV infection averted ranged between US \$321 and \$1665. CONCLUSION:: Curable STI interventions may remain cost-saving in populations with generalized HIV epidemics, particularly in populations with high-risk behaviors or low male circumcision rates.

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### 4. EPIDEMIOLOGY

**"H.I.V. rises among young gay men"**

**Date:** 14 January 2008

**Source:** *The New York Times (Op-Ed)*

<http://www.nytimes.com/2008/01/14/opinion/14mon2.html?ex=1200978000&en=fb4490180e248df1&ei=5070&emc=eta1>

AIDS appears to be making an alarming comeback. The Journal of the American Medical Association reports that the incidence of H.I.V. infection among gay men is shooting up, following an encouraging period of decline. The rise of infections among younger gay men, especially black and Hispanic men, is troubling, and the study carries the clear implication that people at high risk of contracting the disease are becoming less cautious.

Statistics gathered by New York City health officials show that new diagnoses of H.I.V. infection - the virus that causes AIDS - in gay men under age 30 rose 32 percent between 2001 and 2006. Among black and Hispanic men, the figure was 34 percent. Most troubling, the number of new diagnoses among the youngest men in the study, those between ages 13 and 19, doubled.

New York officials say increased alcohol and drug use may be partly responsible since they make unprotected sex more likely. Other basic precautions, including finding out whether a potential partner is infected, are also apparently being ignored.

The one bright spot in this bleak picture was the 22 percent decline in infections among men over 30 in the New York study. Awareness of the disease's devastating effects, as much as maturity, may explain the difference. A large number of these older men came of age when AIDS was all but untreatable. They may have buried friends who died after being horribly ill.

When the disease was new and terrifying, the gay community helped change behavior by preaching loudly against taking sexual risks. From San Francisco to New York, bathhouses notorious for promoting casual sex changed the way they did business or closed down. Condoms were encouraged, and so was H.I.V. testing. "Silence equals death" was the motto of the day.

Silence now seems to be winning the day. Nearly 6,000 gay men died of AIDS in the United States in 2005; still, many young men appear to have persuaded themselves that the infection is no longer such a big deal. It is true that antiretroviral therapy has improved the outlook for anyone who becomes infected. But the treatments are still too new to know whether they can work much beyond a decade. Public health officials need to continue to distribute condoms, encourage testing and treat those who are ill. Leaders in the hardest-hit communities need to start speaking out again. The fight against AIDS is far from over.

### **"New York: Government HIV survey: New Yorkers may not be as safe as they think"**

**Date:** 11 January 2008

**Source:** *Associated Press*

<http://www.aegis.com/channel/s/AD080079.html>

According to a city health department survey released Thursday, many New Yorkers think they are at low risk for HIV infection despite engaging in high-risk activities. The department said 18 percent of the city's adults have multiple sex partners or inject drugs; yet among this population, 92 percent believed they were not at risk. Using blood samples,

researchers determined that about 1.4 percent of adults in the city are HIV-positive - a prevalence rate almost four times that of the nation as a whole.

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## 5. HIV/AIDS VACCINES

### "Protection of macaques against vaginal SHIV challenge by systemic or mucosal and systemic vaccinations with HIV-envelope"

**Author(s):** Barnett SW, Srivastava IK, Kan E, et al

**Reference:** N/A 22(3):339-48.

<http://www.aidsonline.com/pt/re/aids/abstract.00002030-200801300-00003.htm;jsessionid=HMxh24z0gjQ0rcD5hvyYldjxh2zV91nLwyVBWX894XVtWnvn1WDQ!-1829525682!181195628!8091!-1>

**Published Abstract:** *Background:* Worldwide, the majority of human immunodeficiency virus (HIV) infections occur by heterosexual transmission. Thus, the development of a vaccine that can prevent intravaginal HIV infection is an important goal of AIDS vaccine research. *Objectives:* To determine which single or combination of systemic and mucosal routes of immunizations of female rhesus macaques with an HIV-1SF162 envelope protein vaccine induced protection against intravaginal challenge with SHIV. *Design:* Female rhesus macaques were immunized with an HIV-1SF162 envelope protein vaccine administered systemically (intramuscularly), or mucosally (intranasally), or as a sequential combination of both routes. The macaques were then challenged intravaginally with SHIVSF162P4, expressing an envelope that is closely matched (homologous) to the vaccine. *Results:* Macaques receiving intramuscular immunizations, alone or in combination with intranasal immunizations, were protected from infection, with no detectable plasma viral RNA, provirus, or seroconversion to nonvaccine viral proteins, and better preservation of intestinal CD4+ T cells. Serum neutralizing antibodies against the challenge virus appeared to correlate with protection. *Conclusions:* The results of this study demonstrate that, in the nonhuman primate model, it is possible for vaccine-elicited immune responses to prevent infection after intravaginal administration of virus.

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## 6. OTHER PREVENTION APPROACHES

### "Confronting approach to HIV in gay community"

**Date:** 10 January 2008

**Source:** *The Age*

**Author(s):** Julia Medew

<http://www.theage.com.au/news/national/confronting-approach-to-hiv-in-gay-community/2008/01/09/1199554741755.html>

Full-page images of men having sex will be splashed across gay newspapers in Melbourne today as part of a bold advertising campaign designed to stem rising HIV infections in Victoria.

Four advertisements - which show men having sex, with a dialogue box discussing safe sex issues covering their genitalia - will appear in Bnews and MCV newspapers as part of the Victorian AIDS Council's latest campaign to target gay men who have unprotected sex.

Executive director Mike Kennedy said the decision to use images of penetrative sex in the campaign was based on interviews with gay men about what they best responded to at a time when HIV infections in the community were rising. "We're doing it not because we're trying to push the envelope but because the focus groups are telling us that this is what we need to do to have the conversation we need to have," he said. "When we showed people in the focus groups words alone, they said 'nup, doesn't work for us'. But when we showed images of real people, they said 'this says to us you're fair dinkum'. It doesn't look like stuff people have seen 100 times before."

Mr Kennedy said the campaign would be accompanied by another more public campaign urging people to get tested for HIV and other sexually transmitted infections, called "The Drama Down Under". Tea-towels showing images of men having sex alongside safe-sex messages about condom use and water-based lubricants would also be distributed at gay festivals in coming months. He said the organisation had a proposal to State Government to be reimbursed for the \$630,000 campaign, which would run for at least six months.

The campaign comes after HIV infections reached their highest level in Victoria in 20 years. The Department of Human Services was notified of 334 cases in 2006, 17% higher than the 285 in 2005 and the highest number since 1987.

The director of The Alfred hospital's infectious diseases unit, Professor Sharon Lewin, said the campaign appeared to be targeting the group responsible for rising infections - gay men in their 30s having casual, unprotected sex. "What we know is that new infections are predominantly occurring in gay men and that unsafe sex practices are common," she said. "One of the recent lessons from NSW was that they had a very targeted and explicit safe-sex campaign... and it seemed that that was quite effective. The number of new infections has not increased in NSW, whereas they have in Victoria and Queensland."

BNews news editor Doug Pollard said the campaign followed much criticism of the Victorian AIDS Council from gay people who thought the organisation was not going hard enough. He said staff at his newspaper decided the message was too serious to ignore.

### **"Nations Cup: Ghana floods hotels with free condoms"**

**Date:** 10 January 2008

**Source:** *Vanguard (Lagos)*

**Author(s):** Tony Ubani

[http://www.vanguardngr.com/index.php?option=com\\_content&task=view&id=4240&Itemid=0](http://www.vanguardngr.com/index.php?option=com_content&task=view&id=4240&Itemid=0)

As the zero hour approaches swiftly for the African Cup of Nations in Ghana, the Ghana AIDS Commission has started distributing condoms to hotels that will accommodate guests who will be in the country for the Ghana 2008 tournament, taking place January 20 to February 10. The objective of the condom distribution is to reduce the spread of HIV/AIDS pandemic during the tournament. The condoms being distributed free to the hotels run into millions with a massive campaign urging both women and men to make use of the free condoms when the need arises.

Ghana is known to have very beautiful women who are irresistible. Professor Sakyi Awuku Amoa, the Director General of the Ghana AIDS Commission (GAC) disclosed this in an interview with the Times in Accra. He said the GAC with the support of the United Nations Fund for Population Activities (UNFPA) will distribute 5,000 condoms to the hotels. He advised people to be mindful of the spread of HIV/AIDS as over one million visitors will enter the country for the tournament.

Prof Amoa said the number of HIV/AIDS cases recorded as at 2005 and 2006 was over 300,000 out of which 21, 828 involved children between the ages of 0 to 14. Most of the cases were the result of unprotected sex, blood transfusion, and the use of unsterilized sharp tool. He said the youth, especially girls, should not be enticed by the money they will earn through unprotected sex with some of the visitors. They should place their health over monetary consideration, he said.

Currently there are about 84 treatment centres nationwide catering for 11,500 people living with HIV/AIDS (PLWHA) while 21,000 PLWHA are on the waiting list.

### **"Sex, drugs, and HIV/AIDS in China"**

**Source:** *Watts J. Lancet 371(9607): 103-104, 12 Jan 2008. World Report.*

<http://www.thelancet.com/journals/lancet/article/PIIS0140673608600872/fulltext>

China has made impressive strides in the past couple of years to control the spread of HIV/AIDS but if it is to quell the new wave of infections in the general population, it will have to confront the country's changing patterns of sexual behaviour. Jonathan Watts reports from Beijing.

In most of the tens of thousands of gaudy neon-lit karaoke parlours that have sprung up around China over the past decade, customers are usually offered three menus. The first for songs, the second for drinks, and the third - always unwritten, and only explained to men - for sexual services.

It is a similar story in the countless pink-lit barber shops and massage businesses that can be seen in every town and city. In many hotels too, single male guests can expect to be propositioned in the lobby or by a call from the receptionist touting a special "room service".

The rise of industrial-scale prostitution has been one of the most visible signs of China's move from a closed, ideologically focused state to an open, market-driven economy. Coming alongside an increase in personal freedoms, rising affluence, the spread of the internet, and growing curiosity about overseas norms of behaviour, it has contributed to a far more permissive and promiscuous society than was the case in the past. The trend is apparent not just in brothels, but also in high schools and universities.

Until a few years ago, that might have been primarily of interest only to moralists and sociologists, but new statistics showing that heterosexual sex has overtaken intravenous drug use as the main route of transmission for HIV/AIDS has suddenly made sexual behaviour a central concern for public-health policymakers.

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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

### "2008 NIH budget nearly flat -- again"

**Date:** 21 January 2008

**Source:** *American Medical News*

**Author(s):** Doug Trapp

<http://www.ama-assn.org/amednews/2008/01/21/gvsa0121.htm>

For the fifth consecutive year, the National Institutes of Health budget will fail to keep pace with growth in the cost of conducting biomedical research, research groups said. On Dec. 26, 2007, President Bush signed a \$555 billion fiscal 2008 domestic spending package, one week after the House and eight days after the Senate adopted the measure. While the nearly flat NIH budget left research advocates warning that the U.S. edge on biomedical research is eroding, community health centers were thankful for an increase.

The budget measure provides a \$133 million, 0.5% increase for the NIH. The figure is adjusted for an earlier bipartisan agreement to transfer \$295 million of the institutes' budget to the Global Fund to Fight Aids, Tuberculosis and Malaria. Biomedical research inflation, however, is expected to remain steady at 3.7% this year, according to the Dept. of Commerce's Bureau of Economic Analysis.

The act includes \$65.6 billion in discretionary Dept. of Health and Human Services spending -- about \$2.9 billion less than the version Bush vetoed on Nov. 13. Although the president said the appropriations package was more responsible than the earlier spending bills, he said he would have vetoed the measure without its \$70 billion in funding for the war on terror. Bush also chided Congress for including 9,800 special projects, or earmarks, in the legislation at a cost of nearly \$10 billion. "These projects are not funded through a merit-based process and provide a vehicle for wasteful government spending," the president said.

Rep. David Obey (D, Wis.), chair of the House Appropriations Committee, said the act is a true compromise. "The omnibus appropriations bill is totally inadequate to meet the long-term investment needs of the country, but it is a whole lot better than the country would have without a Democratic Congress." The nearly status-quo federal funding for medical science also is the result of lawmakers' inability to override the president's veto. The rejected HHS bill would have increased the fiscal 2008 NIH budget by \$1.1 billion, to \$30 billion.

There aren't many positives for scientific research in the 2008 budget, said David Moore, senior associate vice president for government relations for the Assn. of American Medical Colleges. "What we're going to see is less research, a slowing down of certain research programs," he said. "It's a slowing of medical progress."

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

### **"U.S. dominance in science at risk, report says"**

**Date:** 16 January 2008

**Source:** *The New York Times*

**Author(s):** Cornelia Dean

<http://www.nytimes.com/2008/01/16/science/15cnd-nsf.html?ex=1358139600&en=0c5b5e623627b7bc&ei=5088&partner=rssnyt&emc=rss>

The United States remains the world leader in scientific and technological innovation, but its dominance is threatened by economic development elsewhere, particularly in Asia, the National Science Board said on Tuesday in its biennial report on science and engineering.

The country's position is especially delicate, the agency said, given its reliance on foreign-born workers to fill technical jobs. The board is the oversight agency for the National Science Foundation, the nation's leading source of funds for basic research in the physical sciences.

The report, available at [www.nsf.gov/statistics/indicators](http://www.nsf.gov/statistics/indicators), recommends increased financing for basic research and greater "intellectual interchange" between researchers in academia and industry. The board also called for better efforts to track the globalization of manufacturing and services in the high-tech sector, and their implications for the American economy.

Over all, it said, surveys of science and mathematics education are both "disappointing and encouraging." Fourth- and eighth-grade students in all ethnic groups showed improvement in math, the report said, but progress in science is far less robust. And knowledge gaps persist between demographic groups, with European- and Asian-Americans scoring higher than students from other groups.

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

## "NIH announces public-access policy"

**Date:** 11 January 2008

**Source:** *ScienceDaily*

**Author(s):** Jocelyn Kaiser

<http://sciencenow.sciencemag.org/cgi/content/full/2008/1111/1?etoc>

Starting in April, most U.S. biomedical scientists will have to send copies of their accepted, peer-reviewed manuscripts to the U.S. National Institutes of Health (NIH) for posting in a free archive. If they don't, they could have trouble renewing their grants or even lose research funding.

That's the gist of NIH's announcement today describing how it will carry out a new "public access" mandate. The directive, touted as a way to disseminate results of taxpayer-funded research, was part of an NIH spending law passed by Congress in December. It makes mandatory a policy in effect since May 2005 that requests that NIH-funded investigators submit accepted manuscripts to NIH, which posts the full text in its free PubMed Central archive no more than 12 months after the article is published in a journal. Most grantees have ignored the request: Of roughly 65,000 eligible articles per year, only about 12% are being submitted by authors, says David Lipman of NIH's National Library of Medicine in Bethesda, Maryland.

NIH's brief notice on its grants Web site simply says that its existing public-access policy is now mandatory for all articles accepted on or after 7 April. Making sure that submissions comply with the journals' copyright policy is up to investigators and their institutions. The policy applies only to peer-reviewed research and reviews, not editorials or book chapters, NIH says.

To motivate scientists, NIH will require that investigators include the PubMed Central or NIH submission number for all applicable papers referenced in their grant applications and progress reports. Other possible ways of enforcing the policy include a call from an NIH program director and suspension of funds, says NIH Deputy Director for Extramural Research Norka Ruiz Bravo. "We hope we're not going to get there," she says.

The public-access policy has long been controversial. Some researchers and publishers worry about confusion resulting from having two versions of the article online: the PubMed Central author manuscript, which hasn't been copyedited, and the published paper. Many publishers also fret that making articles free will cut into subscription income needed to run journals and fund society activities. The Association of American Publishers has warned that a mandatory policy "undermines" publishers' copyright and is "inconsistent with" U.S. laws (*Science*, 11 January, p. 145). The association also says that the rule limits academic freedom by preventing researchers from publishing in journals that don't comply.

But most major biomedical research journals (including *Science*) already allow authors to submit manuscripts to PubMed Central, so the mandatory policy won't mean a big change. However, says Martin Frank, executive director of the American Physiological Society, journals will have to step up their policing by asking NIH to remove articles that have been mistakenly posted because they are still under embargo or are too old to fall under the policy.

## "FDA's science infrastructure failing"

**Source:** *JAMA* 299(2): 157-58, 9/16 January 2008. *Medical News and Perspectives*.

**Author(s):** Bridget M Kuehn

<http://jama.ama-assn.org/cgi/content/extract/299/2/157>

Two decades of inadequate funding have rendered the Food and Drug Administration's (FDA's) scientific capacity insufficient to meet the growing demands of ensuring the public's health and safety, according to a report issued in December by an advisory group to the agency.

Advances in science, greater complexity in the products it regulates, and globalization of FDA-regulated industries are among the trends placing unprecedented demands on the FDA, yet resources for the agency's science infrastructure and staff have been stagnant, according to the 300-page report (

[http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf)).

The report was published by a subcommittee of the FDA Science Board, which advises FDA Commissioner Andrew C. von Eschenbach, MD, and convened the subcommittee at his request.

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**EDITOR'S NOTE:** *As no abstract exists for this article, the first 100 words are provided. A subscription is required to view the full article at the above website.*

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## 8. PHARMACEUTICAL INDUSTRY

### "Teva pharma to invest Rs 4,000 cr in India"

**Date:** 10 January 2008

**Source:** *Business Standard (India)*

**Author(s):** P B Jayakumar

<http://www.business-standard.com/common/storypage.php?autono=310274&leftnm=1&subLeft=0&chkFlg=>

Israel's Teva Pharmaceutical Industries, the world's largest manufacturer of copycat patented drugs (generics), plans to invest over \$1 billion in India to acquire Indian drug companies and set up greenfield manufacturing facilities. The investment is planned for the next 24 months. Around \$250-\$300 million will be utilised for manufacturing facilities and the rest to fund acquisitions in India.

A few weeks ago, Teva had acquired over 100 acres of land near Gwalior, Madhya Pradesh, to set up active pharmaceutical ingredient (API) manufacturing facilities that will match the production capacity of domestic generic majors such as Ranbaxy, Cipla, Dr Reddy's, Sun Pharma and Wockhardt, sources told Business Standard. Sources said Teva would start civil works at the site after it obtains necessary government clearances.

"Teva considers India an interesting geographical region and is looking to broaden its activities in the country," Shir Altay, a company spokesperson said in an e-mail.

Teva is also likely to integrate Regent Drugs, which it acquired from JK Industries in 2003, with its API business (TAPI). Regent Drugs, now a 100 per cent subsidiary of Teva, manufactures some APIs that Teva requires for its global business. The company also sources APIs from many Indian companies. V K Batra, managing director, Regent Drugs, declined comment.

Teva has an Indian arm, Teva India, and a research and development centre in New Delhi which it started a couple of years ago. Merchant banking sources said Teva has been aiming at a major acquisition in India for the past three years, but no deal has been struck yet, perhaps due to high valuations. Targets include such drug majors as Cipla, Aurobindo, Matrix and Orchid, as well as Saraca Laboratories of Hyderabad.

India is an interesting geography not just for Teva, but for several global drug majors, which are attracted by the huge talent pool, scientific skills and cheap labour that has enabled Indian companies make drugs at about a third of the cost in the West.

### **"Into Africa - Roche expands HIV tech transfer"**

**Date:** 09 January 2008

**Source:** *in-Pharma Technologist.com*

**Author(s):** Anna Lewcock

<http://www.in-pharmatechnologist.com/news/ng.asp?n=82430&m=2IPE111&c=fcswojzbacwmbng>

Roche today announced a handful of new charitable technology transfer agreements with manufacturers in Africa and Asia, allowing local production of generic HIV drugs. These deals are the latest in the Swiss firm's AIDS Technology Transfer Initiative, kicked off in 2006 to provide free technical expertise to allow manufacturers in sub-Saharan Africa and other less developed countries to produce generic HIV medication based on Roche's Invirase (saquinavir) manufacturing processes.

Another four transfer agreements were announced this morning, bringing the grand total to nine companies signing up for Roche's help in establishing their manufacturing processes. The latest companies to join the scheme are Regal Pharmaceuticals in Kenya, CAPS Holdings in Zimbabwe, Shelys Pharmaceuticals in Tanzania and Beximco Pharmaceuticals in Bangladesh. Each of these firms will apparently profit from on-site assistance from Roche reps at their manufacturing facilities, as well as from the company's headquarters in Switzerland.

Roche has received expressions of interest from a total of 35 manufacturers in 15 'eligible' countries, though companies must fulfil certain criteria to be lucky enough to benefit from Roche's expertise. The most important requirement is apparently the possession of (or willingness to acquire) the film coated tablet machine required for saquinavir's manufacture, but Roche will also take into account applicants' facilities, capacity and general standards when considering whether to work with them on the technology transfer scheme. According to a company spokesperson, Roche then provides detailed, specific feedback to the potential partnering firm in terms of what needs to be done before they can be enrolled on the programme.

Although the scheme has been running since January 2006, none of the companies have actually implemented the saquinavir manufacturing processes recommended by Roche as yet.

"The regulatory timelines to register new medicines in Africa are very slow," Roche spokesperson Maria Vigneau told in-PharmaTechnologist.com. "We are still in the process [of transferring the expertise], but the timeline is in their hands."

The companies taking part in the technology transfer will be able to produce generic saquinavir throughout their countries, and will not need to apply for a voluntary license as Roche has committed not to enforce patents on antiretroviral meds within sub-Saharan Africa and those defined as 'least developed' by the United Nations.

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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

**\$100m Gates Foundation Initiative to Support Innovative Global Health Research; sign up for email updates at [www.gcgh.org](http://www.gcgh.org)**

<http://www.gcgh.org/GrandChallenges/GCNewFeature/default.htm>

Grand Challenges Explorations is a new five-year US\$100 million fast-track grants initiative of the Bill and Melinda Gates Foundation to support innovative global health research. The initiative will support hundreds of early-stage research projects pursuing creative concepts for new global health solutions, including vaccines, drugs, diagnostics, and other technologies for health problems disproportionately affecting poor countries.

Projects will initially be funded at the level of US\$100,000 each, with the opportunity for additional funding in the future for projects that show promise.

Specifically, the initiative aims to:

- Support paradigm-changing ideas that have never before been tested, and that might not stand up to traditional peer review

- Involve scientists from a wide range of disciplines, as well as young investigators
- Involve scientists from around the world, including innovators in the developing world and the private sector

The initiative is an expansion of the foundation's commitment to the Grand Challenges in Global Health initiative, which since its creation in 2003 has made important progress in accelerating the discovery of new technologies to improve global health.

#### FAST-TRACK GRANTS

To make it as easy as possible for scientists to apply, the Explorations initiative will use a new fast-track grantmaking approach that complements the foundation's traditional grantmaking process:

- Applicants for Explorations grants will be asked to submit relatively short funding proposals.
- Applicants will not necessarily be required to show preliminary data.
- Proposals will be reviewed within approximately three months
- Grants will be solicited and awarded multiple times per year
- Each funding round will address a few specific topics or themes

The first call for proposals will be posted on the Grand Challenges in Global Health website - [www.gcgh.org](http://www.gcgh.org) - in early 2008, along with the list of topics being addressed and application instructions. You can sign up now at [www.gcgh.org](http://www.gcgh.org) to receive email updates on the initiative.

#### **International AIDS Conference Deadlines in February 2008**

[www.aids2008community.org](http://www.aids2008community.org)

This is a reminder about impending deadlines for the International AIDS Conference to be held in Mexico City, August 3-8, 2008 (AIDS2008). Applications for most Conference programmes will close in February:

Closing date February 19, 2008

- Abstract Sessions
- Global Village Booths
- Cultural Activities
- Global Village Networking Zones
- Skills Building Sessions
- Youth Activities

Closing date February 26, 2008

- Scholarships
- Media Scholarships

For more information on how to get involved with AIDS2008, visit the Guide to Community Involvement in AIDS2008

site at [www.aids2008community.org](http://www.aids2008community.org) or go directly to the official website [www.aids2008.org](http://www.aids2008.org). All deadlines can be seen in calendar form at [www.icaso.org/aids2008community/calendars.html](http://www.icaso.org/aids2008community/calendars.html).

## **Nominations for Society for AIDS in Africa Elections**

[www.saafrica.org](http://www.saafrica.org)

The Society for AIDS in Africa (SAA) organizes the bi-annual ICASAs (International Conference on AIDS and STDs in Africa) in collaboration with other regional, continental and international organizations. They are calling for nominations for their Administration Council. As part of the strategic reengineering the Society is going through, we will be conducting elections in the first quarter of the coming year (2008), to elect an Administrative council.

Only SAA members are eligible to vote and be voted for, provided that you meet the stipulated criteria. For SAA eligibility, please visit <http://www.saafrica.org/nominationform.php>.

## **Request for Proposals (RFP) for Community Partners Involved in HIV Vaccine Research and Education**

[http://www.avac.org/pdf/National\\_Partners\\_RFP.pdf](http://www.avac.org/pdf/National_Partners_RFP.pdf)

The National Institute for Allergies and Infectious Diseases (NIAID) HIV Vaccine Research and Education Initiative (NHVREI) has launched a Request for Proposals (RFP) for community partners. The Academy for Educational Development (AED), a nonprofit organization that NIAID contracted to implement NHVREI, just announced an RFP for the National Partnership Program.

The Division of AIDS in NIAID launched NHVREI in 2006 to create an environment in which HIV-affected communities and individuals are more aware, educated, and supportive of HIV vaccine research and have more positive attitudes towards clinical trial volunteerism. More information on NHVREI and their outreach work is at [www.bethegeneration.org](http://www.bethegeneration.org).

The National Partnership Program aims to build strong collaboration among NIAID, key influencers, national HIV prevention leaders, and the community to foster an environment that supports HIV vaccine research and to increase individuals' willingness/intent to participate in HIV vaccine clinical trials in the US. By engaging national and local organizations in the US, tapping into their extensive networks, and reaching deeper into communities most affected by HIV/AIDS, NHVREI hopes to build greater support for HIV vaccine research and HIV vaccine clinical trial participants.

Proposals for the NHVREI National Partnership Program must be submitted to AED by January 31 at 5 P.M. (Eastern) in accordance with the terms of the RFP which can be found online at [http://www.avac.org/pdf/National\\_Partners\\_RFP.pdf](http://www.avac.org/pdf/National_Partners_RFP.pdf).

If you have questions about the RFP, please contact Stacey Little, Director of Community Partnerships and Project Co-Director of AED at (202) 884-8727 or by e-mail at [slittle@aed.org](mailto:slittle@aed.org).

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