



# ALLIANCE FOR MICROBICIDE DEVELOPMENT

**27 June 2008, Volume 9, Number 25**

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/cs/weekly\\_news\\_digest](http://www.microbicide.org/cs/weekly_news_digest). 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

**"Expert: New AIDS threat emerging in India among 'call center Romeos'"**

**Date:** 22 June 2008

**Source:** *Associated Press*

<http://www.iht.com/articles/ap/2008/06/22/asia/AS-MED-Asia-India-Call-Center-Romeos.php>

A new AIDS threat is rising in India's numerous call centers, where young staff are increasingly having unprotected sex with multiple partners in affairs developed during night shifts, a top AIDS expert has warned.

While India has made great strides in bringing down its HIV infection rate, the promiscuity among "call center Romeos" is a great concern, Dr. Suniti Solomon, who detected the first HIV case in India in 1986, told an international medical conference Saturday. According to the United Nations, about 2.5 million Indians are living with HIV and AIDS now, down from 5.2 million in 2006.

"India has reached a plateau of the infections," Solomon told the International Congress on Infectious Diseases, which ends Sunday. Her concern now is the call centers, where many of the young staff work at night to correspond with the daytime working hours of their American and European clients. "They have all the money. They huddle together in the night. They are young, they are sexually active, so naturally they start," Solomon, who runs an AIDS center in the southern city of Chennai, told The Associated Press in a separate interview. She said at least three or four call center workers visit her clinic every week to get tested for HIV because they are worried after having unprotected sex.

It is estimated that India's call centers employ some 1.3 million people, mostly youths fresh out of school and colleges, earning a starting salary of 25,000 rupees (US\$600) a month, more than a government doctor's paycheck.

"You will see call center Romeos are a major high risk for HIV," Solomon said. There are no figures for how many call center workers are infected with HIV.

Citing confessions by the visitors to her center, Solomon said groups of young men and women rent apartments along the beach during the weekends and end up having multiple-partner sex.

"If they are having sex just among themselves, and all are non-infected it is fine. But if there is one person who has gone out of this group and brought in the virus, it will spread to everyone," she said.

While the "call center Romeo" situation is a reflection of recent liberal values, India's anti-AIDS fight is also hampered by society's coexisting conservatism, Solomon told the conference. She said this is evident in Hindu activists' opposition to circumcision - which is proven to help inhibit HIV transmission - on the grounds that it is against tradition and religion of Hindu-majority India. Solomon said she does not expect India to accept circumcision for preventing HIV infections. A recent government study to gauge the acceptance for circumcision triggered a massive backlash by Hindu fundamentalists, who called it "obnoxious" and "a conspiracy."

"If you go out into the streets and say I will do this (circumcision) to reduce HIV, there will be a chaos," she said.

"Vaccines have failed. **Microbicides** have failed. This is one tool we have in hand but we can't use it."

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## 2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

### "Catalytic antibodies to HIV: Physiological role and potential clinical utility"

**Author(s):** Planque S, Nishiyama Y, Taguchi H, et al

**Reference:** N/A 7(6):473-79.

<http://highwire.stanford.edu/cgi/medline/pmid;18558365>

**Published Abstract:** Immunoglobulins (Igs) in uninfected humans recognize residues 421-433 located in the B cell superantigenic site (SAg) of the HIV envelope protein gp120 and catalyze its hydrolysis by a serine protease-like mechanism. The catalytic activity is encoded by germline Ig variable (V) region genes, and is expressed at robust levels by IgMs and IgAs but poorly by IgGs. Mucosal IgAs are highly catalytic and neutralize HIV, suggesting that they constitute a first line of defense against HIV. Lupus patients produce the Igs at enhanced levels. Homology of the 421-433 region with an endogenous retroviral sequence and a bacterial protein may provide clues about the antigen driving anti-SAg synthesis in lupus patients and uninfected subjects. The potency and breadth of HIV neutralization revives hopes of clinical application of catalytic anti-421-433 Igs as immunotherapeutic and topical **microbicide** reagents. Adaptive improvement of anti-SAg catalytic Igs in HIV infected subjects is not customary. Further study of the properties of the naturally occurring anti-SAg catalytic Igs should provide valuable guidance in designing a prophylactic vaccine that amplifies protective catalytic immunity to HIV.

### "Early events in HIV transmission through a human reconstructed vaginal mucosa"

**Author(s):** Bouschbacher M, Bomsel M, Verronese E, et al

**Reference:** N/A 22(11):1257-66.

<http://www.aidsonline.com/pt/re/aids/abstract.00002030-200807110-00002.htm;jsessionid=LfTJc1xSNVm9vnYn1BLbhy1KIL3H3wPXpy42JyLJ2LTQnLtTkxhV!544421999!181195628!8091!-1>

**Published Abstract:** Objective: The early steps of HIV entry into intact vaginal mucosa still need to be clarified. Here we investigated how HIV translocated across the vaginal pluristratified epithelium, either by transcytosis or by uptake in Langerhans cells. Methods: Using human primary fibroblasts and vaginal epithelial cells, we developed an in-vitro model of vaginal mucosa in which Langerhans cells could also be integrated. Owing to the absence of T lymphocytes and macrophages, we specifically studied the role of Langerhans cells in HIV transmission and the transcytosis of cell-associated HIV. Results: Our model has a normal mucosal tissue architecture and Langerhans cells were efficiently integrated within the pluristratified epithelium. In addition, tight junction proteins' expression, high transepithelium resistance and low fluorescein isothiocyanate-BSA passage confirmed the integrity and impermeability of the reconstruction. Furthermore, we showed that human Langerhans cells also expressed tight junction proteins. Then, we demonstrated that neither transcellular nor intercellular transport of free infectious virus released by R5-infected or X4-infected peripheral blood mononuclear cells inoculated apically occurred in the vaginal mucosa, irrespective to the presence of Langerhans cells. Conclusion: For the first time, we documented that, within 4 h following contact with HIV-infected cells, translocation of free HIV particles across a pluristratified mucosa is not detectable and that, in this context, it seemed that Langerhans cells do not increase HIV transmission. Moreover, we provided a useful model for the development of strategies preventing HIV entry into the female genital tract, especially for testing the efficiency of various **microbicides**.

## "Inhibition of herpes simplex virus type 1 and 2 in vitro infection by sulfated derivatives of K5 Escherichia coli polysaccharide"

**Author(s):** Pinna D, Oreste P, Coradin T, et al

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

[http://aac.asm.org/cgi/content/abstract/AAC.00359-](http://aac.asm.org/cgi/content/abstract/AAC.00359-08v1?maxtoshow=&HITS=1&hits=1&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct)

[08v1?maxtoshow=&HITS=1&hits=1&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct](http://aac.asm.org/cgi/content/abstract/AAC.00359-08v1?maxtoshow=&HITS=1&hits=1&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct)

**Published Abstract:** Herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) are neurotropic viruses and common human pathogens causing a major public health problem such as genital herpes, a sexually transmitted disease also correlated to increased transmission and replication of the human immunodeficiency virus type-1 (HIV-1). Therefore, compounds capable of blocking HIV-1, HSV-1 and HSV-2 transmission represent candidate **microbicides** with a potential added value vs. molecules acting selectively against either infection. We here report that sulfated derivatives of the Escherichia coli K5 polysaccharide, structurally highly similar to heparin and previously shown to inhibit in vitro HIV-1 entry and replication, also exert suppressive activities against both HSV-1 and HSV-2 infections. In particular, the N, O-sulfated [K5-N,OS(H)] and the O-sulfated epimerized form [Epi-K5-OS(H)] inhibited HSV-1 and 2 infection of Vero cells and their 50% inhibitory concentration (IC<sub>50</sub>) was between 3 +/- 0.05 and 48 +/- 27 nM while not being toxic to the cells at concentrations up to 5 microM. These compounds impaired the early steps of HSV-1 and HSV-2 virion attachment and entry into host cells and reduced cell-to-cell spread of HSV-2. Since K5-N,OS(H) and Epi-K5-OS(H) also inhibit HIV-1 infection, they may represent valid candidates for their development as topical **microbicides** preventing sexual transmission of HIV-1, HSV-1 and HSV-2.

## "Vaginal microbicide and diaphragm use for sexually transmitted infection prevention: a randomized acceptability and feasibility study among high-risk women in Madagascar"

**Author(s):** Behets FM, Turner AN, Van Damme K, et al

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

<http://highwire.stanford.edu/cgi/medline/pmid;18562985>

**Published Abstract:** BACKGROUND:: In preparation for a randomized controlled trial (RCT), we conducted a pilot RCT of the acceptability and feasibility of diaphragms and candidate vaginal **microbicide** for sexually transmitted infection prevention among high-risk women in Madagascar. METHODS:: Participants were randomized to four arms: (1) diaphragm (worn continuously) with Acidformtrade mark applied in the dome; (2) diaphragm (worn continuously) with placebo gel hydroxyethylcellulose (HEC) in the dome; (3) HEC applied intravaginally before sex; (4) Acidform applied intravaginally before sex. All women were given condoms. Participants were followed weekly for 4 weeks. We fit unadjusted negative binomial regression models with robust variance estimators to generate the proportion of sex acts with casual partners where condoms and experimental study products were used. RESULTS:: Retention was 98% among 192 participants. Experimental product use with casual partners was high, reported in 85%, 91%, 74%, and 81% of sex acts for women in the Acidform-diaphragm, HEC-diaphragm, HEC-alone, and Acidform-alone arms,

respectively. However, the proportion reporting product use during 100% of acts with casual partners over the full follow-up period was much lower: 28% to 29% in the gel-diaphragm arms and 6% to 10% in gel-alone arms. Women used condoms in 62% to 67% of sex acts with casual partners, depending on the randomization arm. Participants found diaphragms easy to insert (97%) and remove (96%). Acidform users (with or without the diaphragm) reported more genitourinary symptoms than HEC users (14% vs. 5% of visits). CONCLUSIONS:: A sexually transmitted infection prevention RCT of candidate **microbicide** with and without the diaphragm appears acceptable and feasible in this population.

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

#### "Reassessing the hypothesis on STI control for HIV prevention"

**Source:** *Lancet*. 2008 Jun 21;371(9630):2064-65. *Comment*.

**Author(s):** Ronald H Gray, Maria J Wawar

<http://www.thelancet.com/journals/lancet/article/PIIS014067360860896X/fulltext>

Two randomised trials of HIV prevention, one in Tanzania<sup>1</sup> and the other multicentre (HPTN 039) trial reported in today's *Lancet*,<sup>2</sup> assessed the effects of suppressing herpes simplex virus type 2 (HSV-2) with aciclovir 400 mg twice daily in initially HIV-uninfected HSV-2-seropositive participants. Both trials found no effect of HSV-2 suppression on HIV acquisition. This finding is unexpected, since many observational studies suggest that HSV-2 and genital ulcer disease are risk factors for HIV infection; so it was plausible that herpes suppression might reduce HIV acquisition.<sup>3</sup> Surprisingly, the Tanzanian trial only reported nine clinically observed genital ulcers or vesicular lesions in the intervention group (2-3%) and six in the control group (1-4%).<sup>1</sup> In the HPTN 039 multicentre trial, clinically observed genital ulcer disease was reduced by 47% and HSV-2-positive ulcers by 63% in the aciclovir group,<sup>2</sup> but the investigators comment that this efficacy was less than expected. African studies into causes of genital ulcer disease have failed to identify known sexually transmitted pathogens in a high proportion of clinical ulcers,<sup>4,5</sup> so ulceration unrelated to HSV-2 could have diluted the expected effect of aciclovir. Also, the aciclovir regimen might be inadequate to completely suppress herpetic ulceration or subclinical HSV-2 reactivation.<sup>1,2</sup> Compliance with aciclovir was high in the multicentre trial,<sup>2</sup> but moderate in the Tanzanian study in which only a third of a subset of 144 participants had detectable aciclovir in their urine at 12 and 24 months.<sup>1</sup>

The apparent discrepancy between the observational studies compared with the negative results of randomised trials for HSV-2 suppression is similar to the discrepancy between observational and trial evidence about bacterial sexually transmitted infections and HIV. Observational data suggested that bacterial sexually transmitted infections increase HIV acquisition and genital HIV shedding,<sup>6</sup> leading to the hypothesis that control of such bacterial infections would reduce HIV transmission and acquisition. However, five of six trials of such bacterial control, all in Africa, did not have any effect on HIV incidence.<sup>5,7-10</sup> The one trial reporting reduced HIV incidence was in a population with atypically low rates of HIV, so the results cannot be generalised elsewhere in Africa.<sup>11</sup>

This cumulative experience raises two crucial questions. Why is there an apparent contradiction between the hypothesis-generating observational data and hypothesis-testing randomised trials of control of sexually transmitted infections, and what should be our policy on control of sexually transmitted diseases in HIV-prevention programmes?

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**EDITOR'S NOTE:** *The full text of this article is available with a free subscription at the above website.*

**"Risk compensation is not associated with male circumcision in Kisumu, Kenya: A multi-faceted assessment of men enrolled in a randomized controlled trial"**

**Author(s):** Mattson CL, Campbell RT, Bailey RC, et al

**Reference:** N/A 3(6):e2443.

<http://clinicaltrials.ploshubs.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0002443>

**Published Abstract:** *Background* Three randomized controlled trials (RCTs) have confirmed that male circumcision (MC) significantly reduces acquisition of HIV-1 infection among men. The objective of this study was to perform a comprehensive, prospective evaluation of risk compensation, comparing circumcised versus uncircumcised controls in a sample of RCT participants. *Methods and Findings* Between March 2004 and September 2005, we systematically recruited men enrolled in a RCT of MC in Kenya. Detailed sexual histories were taken using a modified Timeline Followback approach at baseline, 6, and 12 months. Participants provided permission to obtain circumcision status and laboratory results from the RCT. We evaluated circumcised and uncircumcised men's sexual behavior using an 18-item risk propensity score and acquisition of incident infections of gonorrhea, chlamydia, and trichomoniasis. Of 1780 eligible RCT participants, 1319 enrolled (response rate = 74%). At the baseline RCT visit, men who enrolled in the sub-study reported the same sexual behaviors as men who did not. We found a significant reduction in sexual risk behavior among both circumcised and uncircumcised men from baseline to 6 ( $p < 0.01$ ) and 12 ( $p = 0.05$ ) months post-enrollment. Longitudinal analyses indicated no statistically significant differences between sexual risk propensity scores or in incident infections of gonorrhea, chlamydia, and trichomoniasis between circumcised and uncircumcised men. These results are based on the most comprehensive analysis of risk compensation yet done. *Conclusion* In the context of a RCT, circumcision did not result in increased HIV risk behavior. Continued monitoring and evaluation of risk compensation associated with circumcision is needed as evidence supporting its' efficacy is disseminated and MC is widely promoted for HIV prevention.

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#### **4. OTHER PREVENTION APPROACHES**

**"AIDS affecting more local women"**

**Date:** 21 June 2008

**Source:** *New Straits Times (Malaysia)*

**Author(s):** Annie Freeda Cruz

[http://www.nst.com.my/Current\\_News/NST/Saturday/National/2273045/Article/index\\_html](http://www.nst.com.my/Current_News/NST/Saturday/National/2273045/Article/index_html)

Malaysia will focus on the prevention of HIV/AIDS through heterosexual spread and marginalised groups, said Dr Christopher Lee Kwok Choong. The Sungai Buloh Hospital Department of Medicine (infectious Diseases) head and senior consultant physician said this was because the new HIV/AIDS cases reported last year showed some new trends which was worrying.

"We found that out of some 4,900 new HIV/AIDS cases reported last year, 16 per cent of the victims were women. This is worrying because 10 years ago, women comprised only one per cent of the total number of cases reported," he told the New Straits Times.

He said heterosexual spread was the main cause for women becoming victims of the deadly disease. Some 60 per cent of the new cases are drug users and the majority of the victims are still men.

Dr Lee, who was a recent delegate to the UN High Level Meeting on HIV/AIDS held in New York last week, said the number of new HIV/AIDS cases had dropped from some 7,000 in 2002 to 4,900 last year. "This is a positive sign that Malaysia's harm reduction and needle-exchange programmes have helped reduce tremendously new HIV/AIDS cases," he said. However, he added, the ministry had now got to focus on preventing women and young people from becoming victims of the disease.

Until the end of last year, there were 80,938 HIV cases reported, with 13,000 of them diagnosed with AIDS and over 10,000 died. The meeting in New York attended by all UN countries was to review progress made in implementing the 2001 Declaration of Commitment on HIV/AIDS and the 2006 Political Declaration on HIV/AIDS. The meeting had called on governments to allocate greater resources to address women and HIV/AIDS, generally, and the links between violence against women and HIV/AIDS, in particular.

Dr Christopher said Malaysia, just like other countries, would also focus on prevention and treatment of the disease especially in harm reduction and reducing vulnerability of women and young people to HIV/AIDS. "We will ensure there is easy access to treatment and care for marginalised groups such as sex workers, drug addicts and victims of the disease," he said, adding that the government would now expand its harm reduction and needle exchange programmes to 70 sites nationwide by end of this year.

At present, there are some 50 centres providing both the programmes, mainly at government hospitals and health centres.

"Methadone is given free by the government to those who want to quit drug addiction," said Dr Christopher. He said the government would continue its public awareness on HIV/AIDS to reduce young people from becoming victims of the disease. "Some 7,000 people have undergone the Highly Active Antiretroviral Therapy so far and we expect the number to reach 10,000 by 2010," he added.

Asked where Malaysia stands in terms of HIV/AIDS among the Asean countries, Dr Christopher said: "We are in the middle. Thailand still tops the list followed by Cambodia and Myanmar." He said the situation in Malaysia was more of focal concentrated epidemic, meaning its not a widespread problem but confined to certain areas.

Dr Christopher added that the issue of HIV/AIDS in Malaysia and around the region and world would also be discussed in depth at the 13th International Conference on Infectious Diseases to be hosted by the country on Thursday. "This is the first time Malaysia is hosting the yearly conference where some 3,500 people, mostly foreign scientists and health experts will attend and discuss various current issues on infectious diseases, research and training," he added.

He said Malaysians, for the first time, would get first hand information on what's happening around the world and Malaysia where infectious diseases are concerned and how they could play an important role to prevent an outbreak or being infected.

### **"The pleasure principle: Women brigade embrace the female condom"**

**Date:** 21 June 2008

**Source:** *Yahoo! India News*

<http://in.news.yahoo.com/32/20080622/1056/tnl-the-pleasure-principle-women-brigade.html>

"Yeh mahila kundom badhiya hai, beemarion se bachata hai (female condom is good, it prevents diseases)," says Archana Mahipal, trying to stifle a bout of giggles. In UP's Moradabad district, where for the first time a pilot study is being done to test the acceptability of the female condom (FC), Mahipal and a handful of women from the nearby Jat-dominated areas are discussing its benefits.

As the only female-initiated device available to protect against unintended pregnancies and HIV/ STIs (sexually transmitted infections), the polyurethane sheath is already popular with female sex workers. Buoyed by the success of a pre-programme 2007 pilot study with them in eight states, the National Aids Control Organisation (NACO) is now scaling up the project in Andhra Pradesh, Tamil Nadu, Maharashtra and West Bengal.

Based on the outcome, it will consider countrywide scaling up next year, within the high-risk population. A condom manufacturing plant with a capacity of 40 lakh has been set up in Cochin in technical collaboration with the UK-based Female Health Company (FHC), making India the only country manufacturing the FC for its own market.

Here, the 'improved' FC is made out of nitrile polymer. It doesn't rustle and it heightens pleasure.

Now, it's with the general population - both low income and the urban, for whom it's marketed as Velvet - that the product is slowly trying to break through. In the past six months since the Hindustan Latex Family Planning Promotion Trust (HLFPPT) and NACO initiated the Moradabad project amongst the self-help group members, old attitudes are slowly being overcome.

"At first it looked like a gubbara (balloon). Slowly we learnt how to use it and share the experience," Mahipal tells us.

Adds another user Aruna Devi, "Some men are alcoholics and abusive, so women can wear it hours before." Like Aruna and Mahipal, 60 other 'facilitators' are trying to create a need for the five-rupee FC here.

"Just the tacit acceptance that their husbands might be having multiple sexual relations, and hence the need to use protection, is a great achievement," feels Kavita Pattouri, national programme manager, HLFPPT. Besides, some are

also discovering the pleasure element. "It's fun because it's lubricated and doesn't tear. Now we don't use the male condom," whispers Mahabiri, 30. While few others like her may have been able to negotiate its use, for some it's still novel.

"They may not buy it if the price is higher," says Kanchan Sharma of the NGO Bhartiya Gram Vikas Sansthan (BGVS), that's marketing the FC here. Nevertheless, the potential is high as a tool for family planning amongst the available choices, says Arvind Kumar of BGVS. But many like Vandana Mahajan, gender and HIV expert at UNIFEM feel we need to address the power to negotiate its use "because of a woman's weak situation."

Esther Bayliss, Asia programme manager of the Female Health Foundation, the non-profit wing of the FHC, agrees. "Women here are not used to inserting condoms inside their vagina. Also, more often than not, men are responsible for decision making within sexual relationships." Factors like cost - the FC is heavily subsidised - and availability need to be addressed as well, vis-a-vis the male condom, priced much lower.

In the urban market, the growth has been even slower: The Velvet vending machines in the Capital pubs had to be pulled down due to losses early this year. Interestingly, while the FC in the 90s flopped in UK, in developing countries where women don't have a choice of saying 'no', it seems to have taken off.

"Even urban men refuse to wear a condom," says Manoj Gopalkrishna, CEO, HLPPT. Efforts are now on to pitch the product to fill that gap for the high-income group by educating the customers and marketing it in retail formats where women can pick up a pack of 3 for Rs 100, on their own. But as Gopalakrishna points out worldwide "95 per cent of the FC is in the global public sector" due to high costs.

Will it ever replace its male counter part? "No, because the responsibility should lie with both partners, not just in anyone of them," Mahajan says. Only then will the naya daur that the FC pack promises, begin.

### **"Thailand: Condom use not catching on among youth"**

**Date:** 19 June 2008

**Source:** *PlusNews*

<http://www.irinnews.org/report.aspx?ReportID=78823>

In spite of massive spending on efforts to counter HIV/AIDS, experts warn that many young Thais are still having unsafe sex.

The problem, according to Sittichok Chaisupasin, a 16-year-old peer educator, is not a lack of knowledge about HIV, but a lack of interest among young people in acting on what they know.

"Many people know HIV is transmitted by having sex," he said. "We also know we should stand up and give our seat to old people on the bus, but we don't do it," he said.

Survey findings confirm Chaisupasin's observation. While young people consistently demonstrate extremely high levels of knowledge about HIV in surveys, only about 25 percent of young men report using condoms when engaging in casual or risky sex, often because they do not view sex with other young people as risky.

"The real challenge is one of pushing Thai youth (and their elders as well) into converting their 'knowledge' or 'awareness' of HIV risk into changes in their own individual behaviour," said Patrick Brenny, UNAIDS Thailand country director.

Scott Bamber, head of HIV/AIDS for the UN Children's Fund (UNICEF) in Thailand, agreed and noted that while young people were aware of the risks of HIV, they often lacked access to life-skills training and services that would help them translate knowledge into behavioural change. They didn't know, for instance, how to negotiate condom use with a reluctant partner.

Since Thailand reported its first HIV case in 1984, the country has succeeded in reducing the number of new infections from 140,000 a year a decade ago to about 14,000 in 2007. Thailand's goal is to cut new HIV infections by a further 50 percent by 2010, but there has been an increase in incidence among commercial sex workers, men who have sex with men, and young people, according to UNAIDS. Unprotected sex accounts for an estimated 90 percent of all new infections.

The Global Fund to Fight AIDS, Tuberculosis and Malaria recently gave almost \$100 million to support Thailand's prevention and treatment strategy over the next six years and some inroads are being made. Through its Teenpath project, PATH, a nonprofit global health organisation, is training young people to work as informal sex educators at schools.

"Many young people don't prepare themselves when they're in a relationship, because sex education focuses more on anatomy and not on real-life situations. That's why we support teachers to develop a sex education curriculum," explained Arisa Sumamal, a Teenpath project assistant in Bangkok.

Teenpath sex educator, Saranya Thinvilai, 16, said some of her peers were having sex with as many as four different partners a week, with condom usage infrequent at best.

"Young people think other people will get [HIV] not them," Thinvilai told IRIN/PlusNews. "For first love relationships, many people don't use condoms because they trust their partners. It's not good, because you don't know how many partners they've had before."

### **"Hope for a Needle-Free TB Vaccine"**

**Date:** 31 May 2008

**Source:** *Harvard Public Health Review*

**Author(s):** Charlie Schmidt

<http://www.hsph.harvard.edu/news/hphr/infectious-diseases/spr08tbvaccine/index.html>

Aiming to make immunization safer and more cost-effective for the developing world, Harvard School of Public Health Dean Barry R. Bloom and two bioengineers at Harvard, David Edwards and doctoral student Yun-Ling Wong, have developed a new method for delivering vaccines that does not require needles. Prepared by spray drying, a technology used to make powdered milk and other food products, their innovation is a dry-powder preparation of the live, attenuated anti-tuberculosis vaccine, bacille Calmette-Guerin (BCG), that can be delivered by aerosol through the

mouth or nose to the lungs.

BCG is the most widely used vaccine in the world, given annually to more than 100 million children. Its protective effects are highly variable, however, ranging from 0 to 80 percent in different parts of the world.

In the March issue of the Proceedings of the National Academy of Sciences (PNAS), the researchers found their new aerosol vaccine more effective in laboratory animals than a comparable dose of BCG given by injection.

The Bill and Melinda Gates Foundation funded the team's work as part of the foundation's Grand Challenges program to encourage safer, lower-cost alternatives to injectable immunizations. According to Bloom, the new dry-spray form would end children's exposure to reused, unsterilized needles, which are common in developing countries. Half of all injections in developing countries are given with non-sterile needles and syringes, which cause 8 to 16 million infections per year of hepatitis B, 2 to 5 million cases of hepatitis C, and 80,000 to 160,000 cases of HIV, explains Bloom, a principal investigator on the project and a world renowned immunologist who has studied TB for nearly four decades.

What's more, Bloom says, the novel dry-spray vaccine is more heat stable than standard lyophilized, or freeze-dried, vaccines. It is therefore potentially ideally suited for use in resource-poor and rural areas.

Rising rates of tuberculosis and drug-resistant forms of the disease in the developing world amply illustrate the need for a more effective TB vaccine. But the hope is that a dry-spray version might become a generalizable manufacturing technology. "If the results seen in animals can be confirmed in human studies, this technology could be used not only for TB vaccines, but also for other vaccines that could protect millions of people against other infectious diseases," Bloom says.

#### *Nano-size particles key*

The dry-spray technology is the brainchild of Edwards, the Gordon McKay Professor of the Practice of Biomedical Engineering at the Harvard School of Engineering and Applied Sciences, whom Bloom calls a "genius in nanoparticles and their delivery potential." Edwards and doctoral student Wong first described how to make the dried vaccine in PNAS in 2006. Their method involves feeding a liquid jet of BCG vaccine instantaneously through a hot gas, then cooling it rapidly. The end product remains stable at room temperature for at least four months.

"The mycobacteria in the dried vaccine are weakened, but alive," Edwards says. "They revive all their ordinary properties as soon as they enter the body."

In guinea pigs, a species highly sensitive to TB, the inhaled vaccine was markedly more effective than the standard injected vaccine, according to the 2008 PNAS report, co-authored by Edwards, Bloom, and colleagues at the University of North Carolina-Chapel Hill; the Aeras Global TB Vaccine Foundation; MEND South Africa; and Manta Product Development, Inc., a Cambridge, Massachusetts-based design and engineering group. In animals given the inhaled vaccine and then exposed to TB, less than 1 percent of lung and spleen tissue showed damaging effects of the disease. By contrast, in animals treated with the same dose of the standard injectable vaccine, pathology following TB exposure consumed about 5 percent of lung and 10 percent of spleen tissue.

Edwards speculates that the inhaled vaccine may be more protective because it goes straight to the lungs instead of the bloodstream. Particles form at micrometer and nanometer scales in spherical and elongated shapes, which

appears to improve dispersal in the mouth, he adds. According to Bloom, these minute particles may be taken up more readily by TB-fighting immune cells.

#### *Human trials next*

If the laboratory work continues to go well, patient trials could begin as soon as this year in South Africa, where the TB burden is high. Testing would be conducted in collaboration with MEND, a nongovernmental organization created by Edwards to develop drug-delivery systems for low- and middle-income countries. More studies must be done to confirm the vaccine's stability and effectiveness. Regulatory hurdles, too, must be cleared before it is deemed safe for human testing. "What is exciting," says Bloom, "is the opportunity brought about by this interdisciplinary collaboration that would not have been possible by individuals working alone."

"There is a pressing need for a better TB vaccine," says Duke University vaccine expert Richard Frothingham. "We don't yet know whether this new route will be safe in diverse human populations. However, environmental stability and needle-free delivery are advantages for a vaccine that's to be used in the developing world."

**EDITOR'S NOTE: The abstract of the above-mentioned publication is available at**

**<http://www.pnas.org/cgi/content/abstract/104/8/2591?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=dry+spray&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>**

#### **"Environmental support and HIV prevention behaviors among female sex workers in China"**

**Author(s):** Hong Y, Fang X, Li X, et al

**Reference:** N/A 35(7):662-67.

<http://www.stdjournals.com/pt/re/std/abstract.00007435-200807000-00005.htm;jsessionid=LvLC4wbHJFFHMcYQVwPnSSnH4hY255DrTdM13LGp05ZN2IGgnvQy!-1787533625!181195629!8091!-1>

**Published Abstract:** Objective: To examine the influence of environmental support on HIV prevention behaviors (i.e., condom use behaviors, communication and intention, and HIV/STD testing) among female sex workers (FSWs) in China. Methods: A cross-sectional survey was administered among 310 FSWs recruited from entertainment establishments in Liuzhou City in Southwest China in 2006. Sex workers were asked about their demographic and working characteristics and their HIV prevention behaviors. Environmental support was measured by a scale consisting of 8 items regarding condom availability, managerial, and social support of HIV prevention (Cronbach [alpha] = 0.73). Results: After adjusting for demographic and working characteristics, condom use self-efficacy and knowledge, environmental support was strongly associated with following HIV prevention behaviors: overall consistent condom use (aOR = 1.7, 95% CI = 1.3, 2.3), consistent condom use in the last 3 sexual acts (aOR = 1.5, 95% CI = 1.1, 2.0), intention to use condoms consistently (aOR = 1.6, 95% CI = 1.1, 2.2), and HIV testing (aOR = 1.6, 95% CI = 1.1, 2.2). Conclusion: Environmental support is a significant predictor of HIV prevention behaviors among establishment-based FSWs in China. The data underscore the importance of developing environmental/structural HIV/STD interventions for FSWs. Condoms need to be easily accessible in the establishments. Gatekeepers need to be educated to create a supportive environment for condom use and HIV prevention.

## 5. NON-HIV STIS AND REPRODUCTIVE HEALTH

### "Male circumcision and women's risk of incident chlamydial, gonococcal, and trichomonal infections"

**Author(s):** Turner AN, Morrison CS, Padian NS, et al

**Reference:** N/A 35(7):689-95.

<http://www.stdjourn.com/pt/re/std/abstract.00007435-200807000-00010.htm;jsessionid=LvLfMvZKQyyLq2hLDYLGyhrJRbcf1FzLbphzcBshrtXVz19MVhdR!-1787533625!181195629!8091!-1>

**Published Abstract:** Background: Male circumcision (MC) decreases the risk of human immunodeficiency virus (HIV) acquisition in men. We explored associations between MC of the primary sex partner and women's risk of acquisition of chlamydial (Ct), gonococcal (GC), or trichomonal (Tv) infections. Methods: We analyzed data from a prospective study on hormonal contraception and incident human immunodeficiency virus/sexually transmitted infection (STI) among women from Uganda, Zimbabwe, and Thailand. At enrollment and each follow-up visit, we collected endocervical swabs for polymerase chain reaction identification of Ct and GC; Tv was diagnosed by wet mount. Using Cox proportional hazards models, we compared time to STI acquisition for women according to their partner's MC status. Results: Among 5925 women (2180 from Uganda, 2228 from Zimbabwe, and 1517 from Thailand), 18.6% reported a circumcised primary partner at baseline, 70.8% reported an uncircumcised partner, and 9.7% did not know their partner's circumcision status. During follow-up, 408, 305, and 362 participants had a first incident Ct, GC, or Tv infection, respectively. In multivariate analysis, after controlling for contraceptive method, age, age at coital debut, and country, the adjusted hazard ratio (HR) comparing women with circumcised partners with those with uncircumcised partners for Ct was 1.25 [95% confidence interval (CI) 0.96-1.63]; for GC, adjusted HR 0.99 (95% CI 0.74-1.31); for Tv, adjusted HR 1.05 (95% CI 0.80-1.36), and for the 3 STIs combined, adjusted HR 1.02 (95% CI 0.85-1.21). Conclusions: MC was not associated with women's risk of acquisition of Ct, GC, or Tv infection in this cohort.

### "Risk factors for incident herpes simplex type 2 virus infection among women attending a sexually transmitted disease clinic"

**Author(s):** Gallo MF, Warner L, Macaluso M, et al

**Reference:** N/A 35(7):679-85.

<http://www.stdjourn.com/pt/re/std/abstract.00007435-200807000-00008.htm;jsessionid=LvLSCYTj2QNLJNhchWY4RTvGQN4Q8vypjpLnT5HW1LD7KwjvnC22!1873265815!181195628!8091!-1>

**Published Abstract:** Objectives: To estimate the incidence of herpes simplex type 2 virus (HSV-2) infection, to identify risk factors for its acquisition, and to assess the protective effect of condoms. Study Design: Prospective study of 293 HSV-2 seronegative women, aged 18 to 35 years, attending a sexually transmitted disease clinic in Alabama from 1992 to 1995. Results: Incidence of HSV-2 infection was 20.5 per 100 woman-years [95% confidence interval (CI), 13.1-30.5]. Young women (18-20 years) had a significantly higher risk of incident HSV-2 infection [adjusted hazard ratio (HR), 2.8; 95% CI, 1.3-6.4] than older women. Women diagnosed with prevalent or incident bacterial vaginosis had a higher incidence of HSV-2 infection than those who were not so diagnosed (adjusted HR, 2.4; 95% CI, 1.1-5.6). No significant protective effect was observed for consistent (100%) condom use without breakage and slippage against HSV-2 acquisition (adjusted HR, 0.8; 95% CI, 0.2-2.3). Conclusion: Acquisition of HSV-2 infection among study participants was higher than previous estimates for adult female sexually transmitted disease clinic attendees, and no protective effect for condoms was demonstrated. The high incidence of HSV-2 infection with its potential for adverse health consequences emphasizes the need for better prevention strategies.

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## 6. POLITICS AND POLICY

### "Patients to be told about clinical trials"

**Date:** 24 June 2008

**Source:** *Financial Times (London)*

**Author(s):** Nicholas Timmins

<http://www.ft.com/cms/s/0/4af55496-415a-11dd-9661-0000779fd2ac,s01=1.html>

Patients are to be given the right to be told about clinical trials in a move aimed at making the National Health Service a more attractive place for pharmaceutical and biotechnology companies to do research.

The aim is also to improve patients' access to innovative drugs and treatments.

The move will be announced on Tuesday by Gordon Brown, the prime minister, as part of a package of measures aimed at boosting medical research, innovation and the swifter uptake of new treatments.

Other initiatives include creating five to 10 academic health science centres combining universities' medical research departments with teaching hospitals. Some leading doctors, including Lord Darzi, health minister, believe such a move helps account for the pre-eminence of the US in both medical research and the rapid uptake of new treatments.

Imperial College London has already merged its medical faculty with St Mary's, the Hammersmith and Charing Cross Hospitals to create the first such centre in the UK. Its chief executive, Professor Steve Smith, argues that the fusion of teaching, research and care will help keep UK medical science and practice in the same league as the academic health science centres at Harvard, Stanford and Johns Hopkins in Baltimore, consistently rated the top US hospital.

A panel is to be set up to establish a standard that academic health science centres will have to meet to claim the name. King's College, London, is already exploring the idea with Guy's and St Thomas' Hospitals, while Oxford, Cambridge and University College London Hospitals are also likely candidates. The idea could spread in time to other big cities with strong medical schools and universities, such as Manchester, Birmingham and Newcastle.

The idea of giving patients a formal right to be informed of clinical trials from which they might benefit moves beyond the current position where registers of clinical trials are available.

But the right to be informed may depend on the deployment of the NHS's electronic patient record, running four years late.

Pfizer pulled out of four planned clinical trials in the UK, including one for a cancer drug: it could not find enough patients receiving the current "gold standard" treatment to make the trials possible.

### **"Guidelines for reporting health research: The EQUATOR network's survey of guideline authors"**

**Source:** *PLoS Med.* 2008 Jun 24;5(6):e139.

**Author(s):** Iveta Simera, Douglas G Altman, David Moher, et al., et al

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050139>

Scientific publications are one of the most important outputs of any research, as they are the primary means of sharing the findings with the broader research community. The quality and relevance of research is mostly judged through the published report, which is often the only public record that the research was done. Unclear reporting of a study's methodology and findings prevents critical appraisal of the study and limits effective dissemination. Inadequate reporting of medical research carries with it an additional risk of inadequate and misleading study results being used by patients and health care providers. Patients may be harmed and scarce health care resources may be expended on ineffective health care treatments through such inadequate reporting. There is a wealth of evidence that much of published medical research is reported poorly [1-12]. Yet a good report is an essential component of good research.

Reporting guidelines, such as the CONSORT (Consolidated Standards of Reporting Trials) Statement for reporting the findings of randomised controlled trials [13], can lead to important improvements in the quality and reliability of published research. Since the development of the CONSORT Statement in 1996, several other guidelines have been developed relating to other types of research studies. Examples include QUOROM (for meta-analyses of randomised trials) [14], STARD (Standards for Reporting of Diagnostic Accuracy Studies) [15], STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) [16], and REMARK (Reporting Recommendations for Tumour Marker Prognostic Studies) [17].

At present, no coordination or focused collaboration in the development of reporting guidelines exists as there is in, for example, the clinical practice guidelines field. Guideline development methods vary greatly. Dissemination and implementation of reporting guidelines relies mostly on passive publication of the guidelines, occasionally accompanied by editorials. Reporting guidelines are not routinely used on a large scale, and their potential is not being fully realised.

To remedy this situation, the National Knowledge Service of the UK National Health Service provided funds to set up the EQUATOR Network (Enhancing the Quality and Transparency of Health Research; <http://www.equator-network.org/>). This new initiative seeks to improve the quality of scientific publications by promoting transparent and accurate reporting. The Network provides resources and training relating to the reporting of health research and assists in the development, dissemination, and implementation of reporting guidelines.

The first project of the EQUATOR Network was to: (1) identify all available guidelines for reporting health research studies and (2) survey the authors of these guidelines to gather details about their development methodology, dissemination and implementation strategies, and problems encountered during those processes. Given sparse information on the benefits of guidelines [18,19], we also asked authors about published and unpublished evaluations of impact. This article reports the findings of our survey.

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

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## 7. HIV/AIDS FUNDING

### "Gates-backed aid group to invest in HPV vaccines"

**Date:** 25 June 2008

**Source:** *Reuters*

**Author(s):** Laura MacInnis

[http://today.reuters.co.uk/news/articlenews.aspx?type=healthNews&storyid=2008-06-25T130941Z\\_01\\_L2498772\\_RTRIDST\\_0\\_HEALTH-VACCINES-GAVI-DC.XML](http://today.reuters.co.uk/news/articlenews.aspx?type=healthNews&storyid=2008-06-25T130941Z_01_L2498772_RTRIDST_0_HEALTH-VACCINES-GAVI-DC.XML)

An international partnership that funds vaccines for children in poor countries agreed on Wednesday to expand its scope and start investing in vaccinations aimed at adult women. The board of the Global Alliance for Vaccines and Immunization (GAVI), which is backed by the Gates Foundation, endorsed in Geneva a new \$3.5 billion vaccine investment plan specifying diseases it will tackle from 2009 to 2020.

"This strategy will attack some of the world's major killers and gives us a new challenge in our efforts to provide good health to the world's most vulnerable people," GAVI Executive Secretary Julian Lob-Levyt said in a statement.

A vaccine to immunize women against the human papilloma virus (HPV), the main cause of cervical cancer, and one to prevent miscarriages or birth defects caused by rubella virus, were among the seven priority investments approved by the board. Merck and Co and GlaxoSmithKline have both recently introduced rival HPV vaccines, called Gardasil and Cervarix, that are seen by industry analysts as multi-billion-dollar sellers but are expensive for developing countries.

GAVI's new spending strategy also prioritizes vaccines to protect children in impoverished nations against cholera, typhoid, rabies, meningitis A and Japanese encephalitis, according to a draft obtained by Reuters.

"The portfolio ... has the potential to avert approximately 2 million deaths across different age groups and all GAVI countries within 10 years," according to the Geneva-based group, which supports immunizations in more than 70 countries, from Afghanistan to Zimbabwe. "Moreover, with HPV and rubella vaccines, GAVI would have an opportunity to protect vulnerable women against a serious and fatal disease and congenital anomalies of their newborns," it said in its report to the board, whose members include the World Health Organization, UNICEF, the World Bank and vaccine makers.

The vaccination programs GAVI already supports for diphtheria, tetanus, whooping cough and measles are thought to prevent 2.5 million child deaths a year. Such campaigns, as well as those for hepatitis B, yellow fever, pneumococcal disease and rotavirus, will continue alongside the new investments.

GAVI was launched in 2000 as a private-public partnership. Its major backers include the Bill and Melinda Gates Foundation, which gave it \$1.5 billion, and governments including Britain, France, Norway, South Africa and Brazil. The vaccines GAVI supports through market commitments and other programs are made by pharmaceutical companies including Crucell, Novartis, Sanofi Pasteur and Wyeth.

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## 8. PHARMACEUTICAL INDUSTRY

### "Counterfeiting conference to hear of burden in developing world"

**Date:** 26 June 2008

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

**Author(s):** Phil Taylor

<http://www.in-pharmatechnologist.com//news/ng.asp?n=86148&c=W1FT1f7k%2BplkoISBKRCd8A%3D%3D>

Visiongain's third annual conference on Pharmaceutical Anti-counterfeiting Strategies kicks off next week, covering many aspects of the problem from technological deterrents, regulatory developments in the EU and US and the implications for parallel trade.

Ahead of the conference, in-PharmaTechnologist.com spoke with the event's chair, Dr Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers Associations, about some of the key factors facing the industry as it steps up attempts to combat the problem.

One of the most important things that needs to be considered is the very real difference in the impact of counterfeits between the developed and developing world, where in some countries up to 30 per cent of the total medicines supply may be fake, said Noehrenberg, who is director of international trade and market policy and public health advocacy at the IFPMA.

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

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## **9. ANNOUNCEMENTS**

### **Has the HIV epidemic peaked?**

[http://www.popcouncil.org/mediacenter/newsreleases/PDR34\\_2\\_Bongaarts.html](http://www.popcouncil.org/mediacenter/newsreleases/PDR34_2_Bongaarts.html)

The Population Council's most recent *Population and Development Review* is now available, including an article entitled "Has the HIV epidemic peaked?" by Population Council Vice President and Distinguished Scholar John Bongaarts and three colleagues affiliated with the United Nations Population Division. The *Population and Development Review* seeks to advance knowledge of the interrelationships between population and socioeconomic development and provides a forum for discussion of related issues of public policy.

### **Past, Present and Migration All Crucial to Contraceptive Choices in Thailand Community**

[http://www.icrw.org/docs/Edmeades\\_The\\_Legacies\\_of\\_Context.pdf](http://www.icrw.org/docs/Edmeades_The_Legacies_of_Context.pdf)

Women's behavior and choices related to contraceptive use directly affect their lives in several ways, including altering their risk to HIV and their social and economic well-being. We know that communities play a key role in shaping these decisions because of the social environment and the services and information provided. But much less is known about whether and to what degree women's contraceptive decisions are influenced by historical exposure to a community 'contraceptive environment' or how migrating from a rural to an urban area where contraceptive use is much higher may influence contraceptive decisions.

Recent research published in the May issue of *Demography* by ICRW's Jeff Edmeades broadens our understanding of women's contraceptive decision making by using a "life-course" framework to consider these factors. "The Legacies of Context: Past and Present Influences on Contraceptive Choice in Nang Rong, Thailand" suggests that while current social context strongly influences contraceptive use, past context has an indirect effect by shaping norms. The study also found that the past contraceptive environment changed the way that living in an urban area affected contraceptive behavior, suggesting that past context does have an enduring effect on behavior.

### **Poor Health, Poor Women: How Reproductive Health Affects Poverty**

[http://www.icrw.org/docs/ECSP\\_Focus\\_Greene.pdf](http://www.icrw.org/docs/ECSP_Focus_Greene.pdf)

Does poor reproductive health prevent women from escaping poverty? Co-authors Margaret Greene of ICRW and Thomas Merrick of the World Bank found that poor reproductive health outcomes - early childbearing, maternal mortality/morbidity, and unintended/mistimed pregnancy - do have negative effects on overall health, and under certain circumstances, on education and household well-being. Their findings, published in a new Woodrow Wilson Center publication, help make the case that improving women's reproductive health is an important factor to alleviating poverty.

***EDITOR'S NOTE: The published report is available for public access at the above website.***

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