



16 May 2008 Volume 9, Number 19

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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## **Areas covered in this *News Digest*:**

### **1. ALLIANCE UPDATES AND COMMUNITY NEWS**

- [VivaGel well tolerated: Starpharma](#)
- [New AVAC Report Analyzes AIDS Vaccine Field; Provides Recommendations for Moving Forward](#)
- [Recent International Rectal Microbicide Advocates \(IRMA\) Activities](#)

### **2. MEDIA COVERAGE OF MICROBICIDES**

- [25 years of HIV](#)
- [South Africa: Govt urges understanding of HIV before doing research](#)
- [Reassessing HIV prevention](#)

### **3. NEW PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC**

- [Distribution of a vaginal gel \(Invisible Condom\(R\)\) before, during and after simulated sexual intercourse and its persistence when delivered by two different vaginal applicators: a magnetic resonance imaging study](#)
- [HIV-1 integration: a potential target for microbicides to prevent cell-free or cell-associated human immunodeficiency virus type-1 infection](#)
- [Male circumcision: hope for HIV infection decrease in southern Africa](#)

### **4. NEW PUBLISHED RESEARCH: RELEVANT SCIENCE**

- [Male genital tract chlamydial infection: implications for pathology and infertility](#)
- [Simian Immunodeficiency Virus \(SIV\) is susceptible to inhibition by carbohydrate-binding agents\(CBAS\) in a similar manner as human immunodeficiency virus \(HIV\). Implications for further preclinical drug development](#)
- [Bacterial vaginosis, not HIV, is primarily responsible for increased vaginal concentrations of proinflammatory cytokines](#)
- [T-ACASI reduces bias in STD measurements: the national STD and behavior measurement experiment](#)
- [Human papillomavirus infection and cervical abnormalities in Nairobi, Kenya, an area with a high prevalence of human immunodeficiency virus infection](#)
- [Heterosexual anal intercourse: prevalence, cultural factors, and HIV infection and other health risks, Part I](#)

## 5. EPIDEMIOLOGY

- ['People do stupid things - that's what spreads HIV'](#)
- [HIV cases soar among Kampala sex workers](#)

## 6. HIV/AIDS VACCINES

- [Return to the basics might breathe life into HIV vaccine pipeline](#)

## 7. HIV/AIDS FUNDING

- [Bill and Melinda Gates name new foundation head](#)

## 8. POLITICS AND POLICY

- [Initial treatment for HIV infection - an embarrassment of riches](#)
- [Moral scales in the Senate](#)
- [Communicating the results of clinical research to participants: attitudes, practices, and future directions](#)

## 9. PREVENTION AND BEHAVIOR

- [What's a girl to do?](#)
- [Taking care of business](#)
- [Men's condom use in higher-risk sex: trends and determinants in five sub-saharan countries](#)

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## 1. ALLIANCE UPDATES AND COMMUNITY NEWS

## "VivaGel well tolerated: Starpharma"

**Author(s):** Kate McDonald

**Date:** 12 May 2008

**Source:** *Australian Life Scientist*

<http://www.biotechnews.com.au/index.php/id:886606318>

Melbourne biotech Starpharma has released positive results of a clinical trial for its topical **microbicide** VivaGel.

The double-blind trial of 54 women in the US and Kenya demonstrated that VivaGel was safe and well-tolerated in sexually abstinent women.

It means the product has been deemed suitable for continued development as a topical **microbicide** for the prevention of HIV and genital herpes. Starpharma is also investigating its efficacy in human papillomavirus (HPV).

The clinical study was funded by the US Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and conducted by DMID in collaboration with the Sexually Transmitted Infections Clinical Trials Group (STI-CTG).

It was the first study to be conducted under the US Investigational New Drug application (IND) for VivaGel for prevention of genital herpes.

[Return to Table of Contents](#)

## New AVAC Report Analyzes AIDS Vaccine Field; Provides Recommendations for Moving Forward

<http://www.avac.org/>

The AIDS Vaccine Advocacy Coalition (AVAC) released a new report on May 15th, ahead of HIV Vaccine Awareness Day on May 18th. AVAC's 11th annual Report on AIDS vaccines, entitled *The Search Must Continue*, lays out the state of the AIDS vaccine field and calls for a renewed commitment to AIDS vaccine research and development. It provides a comprehensive review of recent developments in the field, looks at the comparative advantages of major players, including the U.S. National Institutes of Health and the International AIDS Vaccine Initiative, analyzes the current environment for decision-making and makes recommendations for moving the field forward. An embargoed copy of the report is attached.

The report comes at a critical time for HIV prevention research. Over the past 12 months, several trials have yielded disappointing results of no efficacy. These include vaccine, **microbicide**, cervical barrier method and herpes-treatment trials. A slew of editorials and media coverage have spotlighted AIDS vaccine research and, in some instances, included calls recently to end public funding for AIDS vaccine research or to reappportion funding away from research toward existing interventions. At the same time, there are ongoing discussions at the NIH about whether to launch another vaccine efficacy trial using a strategy developed by the NIH's Vaccine Research Center.

Key recommendations from the report include:

- Articulate the human discovery trials agenda and balance vaccine discovery and development.
- Learn from the STEP study and direct prevention-research resources to underserved populations.
- Systematically improve community engagement strategies, especially as decisions are made around the design of the PAVE 100 vaccine trial.
- Clearly communicate and manage expectations of all prevention research trials and results.
- Increase support for pre-exposure prophylaxis (PrEP) research as well as community stewardship of this promising area of research.
- Engage in meaningful dialogue around the scaling-up of male circumcision programs that adequately address HIV testing and gender.
- Reconsider how clinical trials infrastructure is sustained and clinical research agendas are developed-in discussion led by developing country voices.

**EDITOR'S NOTE:** *The report is available for public download at [www.avac.org](http://www.avac.org).*

[Return to Table of Contents](#)

### **Recent International Rectal Microbicide Advocates (IRMA) Activities**

<http://www.rectalmicrobicides.org>

The International Rectal Microbicide Advocates have been busy with a new website, new blog, and upcoming activities! Below is a list of recent IRMA updates.

- New Rectal Microbicide Advocates in the "Meet IRMA Advocates" section of the IRMA website
- A very active blog with new posts: <http://irma-rectalmicrobicides.blogspot.com/>
- An upcoming Reading List populated by IRMA members
- IRMA-ALC (America Latina y El Caribe): a new sister organization that will focus on rectal microbicide advocacy and research efforts in Latin America and the Caribbean
- Upcoming Teleconference: "Beginning to Cross the Rectal Rubicon" with Dr. Peter Anton: 29 May 2008 (more information available at [www.rectalmicrobicides.org](http://www.rectalmicrobicides.org))
- IRMA will present at the MSM Preconference at IAS 2008: "The Invisible Men: Gay Men and Other MSM in the Global HIV/AIDS Epidemic." More information about the preconference event is available at <http://www.msmandhiv.org/2008aids/index.html>

[Return to Table of Contents](#)

## **2. MEDIA COVERAGE OF MICROBICIDES**

## "25 years of HIV"

**Author(s):** Anthony S. Fauci

**Source:** *Nature*. 2008 May 15;453:289-90. Essay.

<http://www.nature.com/nature/journal/v453/n7193/full/453289a.html>

*Reflecting on how far we have come scientifically since isolating HIV in 1983, Anthony S. Fauci urges a renewed commitment to the far greater challenges ahead, especially that of vaccine development.*

The HIV/AIDS catastrophe has been one of the defining features of the past quarter of a century. Although it is short-lived in the scheme of public-health crises, the pandemic ranks among the most devastating microbial scourges in human history, one whose full impact has yet to be realized.

Sixty million people have been infected with the human immunodeficiency virus (HIV); nearly half have died, and the toll on families, communities and even entire nations has been profound. Meanwhile, the biomedical research effort directed at HIV/AIDS has resulted in some breathtaking successes. Unlike many other diseases that affect mostly the poor, marginalized and disenfranchised, HIV/AIDS captured the attention of world leaders, the medical, public-health and activist communities, funding agencies, philanthropists and many celebrities. This resulted in an unprecedented scientific and public-health response to the disease, and in welcome attention to some of the many other problems endemic in those populations most severely afflicted with HIV/AIDS, such as malaria, tuberculosis and gender inequality.

Much remains to be accomplished in the global fight against HIV. There are many more scientific and medical hurdles to be cleared and numerous logistical and operational obstacles to making therapies and other interventions available to poor countries, where per capita income is sometimes only a few hundred dollars a year and health-care spending a tiny fraction of that. Reflecting on the era of HIV/AIDS, we must learn from our mis-steps, build on our successes in treatment and prevention, and renew our commitment to developing the truly transforming tools that will one day put this scourge behind us.

### *Baffling beginnings*

People living through historic events often fail to recognize the significance of what they experience. Such was the case for me, and many of my colleagues, in the first months of the AIDS pandemic. Only in retrospect can we identify its different stages. The first began in June 1981, when physicians in New York and California reported unusual clusters of rare diseases in previously healthy gay men, notably *Pneumocystis carinii* pneumonia and a form of cancer called Kaposi's sarcoma. When we in the medical profession read those initial cases 27 years ago - and treated some of the early AIDS patients - our prevailing emotion was bewilderment.

I had seen other 'mystery' diseases in my career, such as the legionnaires' disease outbreak of 1976. But AIDS was from the beginning much more insidious and enigmatic. As cases began to appear among distinctly different social groups in 1981-82, and as we began to understand better the profound and complex immunodeficiency of our patients, it became clear that we were witnessing the unfolding of something truly novel and frightening. The severity of AIDS and the signs that it apparently could be spread by a ubiquitous human activity - sex - suggested that we were in for a difficult time.

The scientific community marshalled its resources and talent to fight AIDS; investigators from different disciplines began working on this new disease. Within months of the recognition of the first cases in the summer of 1981, I shifted the direction of my laboratory from the study of inflammatory diseases to this curious new syndrome. My research has been closely intertwined with HIV and AIDS ever since. For nearly two years, the cause of AIDS

remained elusive; the scientific community was largely baffled, lacking good leads for developing therapies or even a diagnostic test. Those of us caring for patients with AIDS had few tools at our disposal. The only treatments we could provide were largely palliative and the lifespan of most of our patients was measured in months. Those years were the darkest of my professional career.

### *Glimmer of hope*

Twenty-five years ago this month came a glimmer of hope. In 1983, Luc Montagnier's research team in Paris published in *Science* the first paper (pictured) providing evidence linking a retrovirus to AIDS. The following year, further data from Robert Gallo's group in the United States provided convincing evidence that this retrovirus (later named HIV) was the cause of AIDS. That these two outstanding scientists became embroiled in a controversy - largely played out in the media - about who discovered HIV was an unfortunate distraction. As they would later write in *The New England Journal of Medicine*: "Many lessons can be drawn from this early intense period, and most suggest that science requires greater modesty." A quarter of a century on, the importance of collaboration, collegiality and, yes, modesty, are ever more apparent, as it becomes clear that no single research group or discipline will solve the puzzles of HIV/AIDS.

After the discovery of HIV, research moved at a breathtaking pace. A blood test to diagnose patients and to screen the blood supply quickly followed, as did enormous progress in understanding the genetics and structure of HIV and its disease-causing mechanisms. The rapid clinical testing and licensing in 1987 of the first effective drug against HIV, zidovudine (AZT), caused great excitement. In retrospect this was unfounded, as the molecular characteristics of HIV, notably its propensity to replicate and mutate rapidly, made any single drug unlikely to hold the virus in check. Previous experience with antimicrobials for other diseases and the inevitable emergence of drug-resistant pathogens should have made us more cautious about the prospects for AZT monotherapy.

HIV quickly developed resistance to AZT and the benefits of the drug rapidly waned. Initial optimism about therapy gave way to sobering reality as the AIDS pandemic continued to grow in the United States and elsewhere. Clinicians remained hobbled by a lack of effective anti-HIV drug regimens, and many more patients were lost to AIDS.

Gradually, the fruits of cutting-edge drug development began to appear. In late 1995, the first of a new class of antiretroviral drugs - protease inhibitors - reached the market. Other new drugs that attacked the virus in different ways followed, and we soon had a greater number of effective drugs for HIV than for all other viral diseases combined. The new therapies used in combination with older medicines rapidly improved the prognosis for vast numbers of HIV-infected patients. The AIDS death rate in the United States fell by more than two-thirds within two years of the licensing of the first protease inhibitor. Despite certain limitations of the new treatments, notably toxicity and drug resistance, they launched a new era of optimism.

But HIV/AIDS is predominantly a disease of the developing world, where access to scientific advances and therapies is difficult. Fewer than one-third of the people who need antiretroviral therapy are currently receiving it, despite heroic efforts on the part of individuals and organizations, and some truly transforming and innovative programmes such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria and the US President's Emergency Plan for AIDS Relief. Furthermore, it is clear that treatment alone will never end the AIDS pandemic. New infections far outstrip our ability to treat everyone infected with the virus: around three people are newly infected for every person put on therapy - and current HIV therapy is a life-long commitment.

### *More mountains*

To improve these formidable odds, we have two main options. The first is to cure patients, that is, to purge every vestige of virus from their bodies so that a course of treatment could be measured in weeks or months rather than a

lifetime. Sadly, because of the ability of HIV to hide within cells from both drugs and the immune system, such a treatment regime has proved elusive, although important work in this area is being pursued.

This leaves us with the second option: preventing HIV infection in the first place. We have a proven array of HIV-prevention and harm-reduction strategies: behavioural modification; condom distribution; antiretroviral drug regimes to prevent HIV transmission from mother to baby; and the provision of clean needles and syringes to drug users. We must now do better at delivering prevention: less than 20% of those at risk of HIV infection are currently receiving such help.

Encouragingly, new means of preventing HIV are emerging. Large randomized and controlled clinical trials in Africa suggest that adult male circumcision, if properly and hygienically performed and accompanied by appropriate counselling and post-surgical care, can help prevent men becoming infected with HIV by heterosexual intercourse. Ongoing work to develop **microbicial** gels or creams to be applied before sex offers the hope of empowering women to protect themselves from HIV infection when the use of condoms or the refusal of sexual intercourse is not feasible.

Yet the major goal of HIV/AIDS research eludes us: the development of a safe and effective HIV vaccine, our best hope for ultimately ending the pandemic. The search for a vaccine has been made extremely difficult by the nature of the virus, particularly its ability to integrate into the genome of host cells, to mutate readily and to conceal that part of its outer coat that would induce protective antibodies.

It is now clear that we were naive to think there would be a straight path from the discovery and characterization of HIV to the development of a vaccine. HIV has proved very different from those viruses for which we have developed effective immunizations. We must solve the mystery of how to prompt the human body to produce a protective immune response that is even better than the one elicited by natural infection. This will require a commitment to fundamental research to address the many questions that remain about HIV and its interactions with its human host. HIV/AIDS science, particularly that involving a vaccine, is in some ways still in its infancy. We must move forward by fostering creative thinking over many different disciplines.

In this regard, the pursuit of new research avenues by established scientists and especially by younger investigators is critical. In addition to the disciplines classically associated with HIV research - virology and immunology - we must encourage more 'cross-fertilization' with other fields such as genetics, structural biology, systems biology and peptide chemistry as we strive to generate the knowledge needed to develop an HIV vaccine.

Delivering HIV interventions for the people it most affects requires political will, a long-term supply of considerable financial resources, scientific and public-health vision, and dedication from all sectors of society. With these ingredients, the trajectory of our fight against the HIV/AIDS pandemic in the next quarter of a century could move from cautious optimism towards triumph. Absent any of these factors, and history will not judge us kindly.

[Return to Table of Contents](#)

## "South Africa: Govt urges understanding of HIV before doing research"

**Author(s):** Gabi Khumalo

**Date:** 15 May 2008

**Source:** *BuaNews (Tshwane)*

<http://allafrica.com/stories/200805150822.html>

Health researchers and scientists have been challenged by Health Minister Manto Tshabalala-Msimang to ensure they have a full understanding of the biology of HIV and AIDS.

She said although some progress had been made in enhancing scientific knowledge, there were some outstanding issues in the current research on vaccines and **microbicides**.

Speaking at a colloquium on the Science of HIV and AIDS held at Boksburg on Thursday, Ms Tshabalala-Msimang said researchers and scientists had to ask themselves whether they had a full understanding of the biology of the HI-virus and humane immune system.

This was necessary to ensure effective prevention methods and best intervention approaches.

The colloquium was aimed at sharing experiences and informing future policy approaches with regard to HIV and AIDS-related clinical trials in South Africa.

It follows the decision to hold the discussion during the meeting between the department and principal investigators of **microbicide** clinical trials in February this year.

Discussions at the colloquium were focussed on the recent setbacks in HIV- related trials.

These included the Nonoxynol-9 or "N9" study which indicated increased risk of HIV transmission amongst those using the product, the Cellulose Sulphate gel trial where participants sero-converted; the HVTN 503 vaccine trial (Phambili) which was suspended following information suggesting that it did not show that the vaccination would meet efficacy endpoints as well as the Carraguard trial which indicated that the product was not effective in preventing male-to-female HIV transmission during vaginal intercourse.

The minister stressed the need to understand the functioning of our immune systems before establishing the means to regulate them in order to make appropriate interventions.

"We need to put more emphasis on the understanding of basic science and our medicine regulatory authority has to ensure that all clinical trials meet rigorous requirement for pre-clinical stage before they are approved."

She said government had a responsibility to ensure that all planned research was necessary, conducted in an ethical manner and meant to benefit the participants and their communities.

Professor Lynn Morris from the National Institute for Communicable Diseases said there was a definite need to develop a new vaccine.

"No vaccine is 100 percent effective, most are between 70 and 95 percent," said Professor Morris.

She added that the reason it is difficult to make new vaccine is that nobody has recovered from HIV infection.

HIV is highly variably and constantly changing, it gets around the drugs, Professor Morris said.

**EDITOR'S NOTE: Another media article that discusses the above-mentioned colloquium is below:**

- Manto: Assesss HIV and AIDS tools

[Return to Table of Contents](#)

### "Reassessing HIV prevention"

**Author(s):** Malcolm Potts, Daniel Halperin, Douglas Kirby

**Source:** *Science*. 2008 May 09;320(5877):749-50. *Policy Forum*.

<http://www.sciencemag.org/cgi/content/full/sci;320/5877/749>

Several decades into the AIDS pandemic, HIV transmission in most of the world remains firmly concentrated among sex workers, men who have sex with men (MSM), injecting drug users (IDUs), and their sex partners (1). In some parts of Africa, where over two-thirds of infections occur globally, HIV has expanded outside these high-risk groups, creating generalized, predominantly heterosexual epidemics. In nine southern African countries, more than 12% of adults are infected with HIV. Such devastating epidemics have frequently been attributed to poverty, limited health services, illiteracy, war, and gender inequity. Although these grave problems demand an effective response in their own right, they do not appear to be the immediate causes of generalized epidemics (2).

Some assumptions that drive current HIV prevention strategies are unsupported by rigorous evidence. The presumption, for example, that poverty increases vulnerability to HIV infection is challenged by studies such as an analysis of recent Demographic and Health Surveys (DHSs) from Africa, which shows a strong positive correlation between HIV prevalence and wealth in eight countries examined (3, 4) [see supporting online material (SOM)]. Among Kenyan women, HIV prevalence is 3.9% in the lowest economic quintile and 12% in the highest. A study of serodiscordant couples found that, across 12 African nations, the woman was the HIV-infected partner in 34 to 62% of these couples, which suggests that many infections are not, as is commonly assumed, brought into the relationship by the man (4, 5). African regions suffering from conflict, genocide, and rape, such as Rwanda, Congo, and Angola, are much less affected by AIDS than peaceful, wealthier, and more literate countries such as Botswana or Swaziland, which have the world's highest HIV prevalence (6).

Where multiple sexual partnerships, especially concurrent ones, are uncommon, and particularly where male circumcision (MC) is common, HIV infection has remained concentrated in high-risk populations (7). Niger, a Muslim country where sexual behavior is relatively constrained and MC is universal, has an adult HIV prevalence of 0.7% (1), despite being the lowest ranking country in the Human Development Index. Botswana, the second wealthiest country in Sub-Saharan Africa, has high levels of multiple concurrent partnerships among both sexes and lack of MC (8), with an HIV prevalence of 25% (1) (see SOM).

Several current prevention approaches have value, and the search for new, more effective interventions must continue. However, especially given the severe human resource constraints in Africa, we are arguing for a shift in prevention priorities.

#### *Weaker Evidence for Effectiveness*

For generalized epidemics, most emphasis has been placed on the three "established" pillars of HIV prevention: condom promotion and distribution, voluntary counseling and testing (VCT), and treatment of other sexually transmitted infections (STIs) (4). Recently, the USA's global AIDS program has also promoted abstinence. Although it can be difficult to assess exactly why HIV prevalence has fallen in some generalized epidemics, two other factors stand out as particularly important: the epidemic's natural progression, as the most susceptible

populations become infected and die (9), and behavior change, particularly declines in multiple sexual partnerships (2, 4, 7, 9-11).

UNAIDS resource allocation estimates to achieve "universal access" to HIV prevention by 2010 (in millions of U.S. dollars). Although interventions for high-risk populations are crucial, the resource allocation recommended by UNAIDS is too small for those approaches likely to have a major impact on generalized heterosexual epidemics. (Note: Much of the funding for categories such as "high-risk populations" would actually go for interventions like condom promotion.)

*Condom use.* Condom promotion is effective in epidemics spread mainly through sex work, as in Thailand (7, 10, 11) and also, to some extent, among other high-risk groups such as MSM. Although condom use has also likely contributed to HIV decline in some generalized epidemics, there is no evidence of a primary role (2, 4, 10, 11). This is because consistent condom use has not reached a sufficiently high level, even after many years of widespread and often aggressive promotion, to produce a measurable slowing of new infections in the generalized epidemics of Sub-Saharan Africa. When most transmission occurs within more regular and, typically, concurrent partnerships, consistent condom use is exceedingly difficult to maintain (2, 4, 7, 10).

*HIV testing.* Unfortunately, reviews of many studies have shown no consistent reduction in risk for those who test HIV-negative, although risk reductions in some who test positive have been reported (4, 12, 13). Several HIV and STI incidence studies in Africa have found no population-level impact of VCT (12-14). Although a critical link to life-prolonging treatment, HIV testing is therefore unlikely to substantially alter the epidemic's course [the potential for domestic violence against women who test positive must also be considered (15)].

*Treatment of other STIs.* Six randomized controlled trials (RCTs) to measure the impact of STI treatment on HIV transmission have been published. Although the first study, in Mwanza, Tanzania, found a nearly 40% reduction in HIV when STIs were treated through syndromic management, subsequent trials found no effect on HIV (16). Two recent RCTs to prevent HIV acquisition by treating genital herpes have been similarly discouraging (17). Although STI treatment remains critical for broader public health programs, the population-level evidence for impact on HIV transmission, especially in generalized epidemics, appears minimal.

*Vaccines and microbicides.* Work on vaccine development has been sadly disappointing. In 2007, large-scale efficacy trials were stopped prematurely owing to lack of impact or possibly even harm (17). Attempts to develop a female-controlled prevention method have been similarly discouraging; several **microbicide** candidates (and the cervical diaphragm) have failed (16). **Microbicides** would have considerably lower biological effectiveness than condoms and, even if effective, might be unlikely to be used consistently enough, especially in longer-term partnerships, to slow a generalized epidemic.

*Abstinence.* Abstinence completely prevents sexual transmission, and young people should be encouraged to delay sexual debut (18). However, most HIV infections occur among people in their 20s or older, when most are sexually active and, thus, abstinence is unlikely to have a major epidemiological impact (4, 11).

Interventions such as blood screening and preventing maternal-to-child transmission (PMTCT) are clearly effective, but only address a relatively small proportion of total HIV transmission.

#### *What Works*

*Male circumcision.* Over 45 observational, biological, and other studies from the last 20 years have shown that MC significantly reduces the risk of heterosexual HIV infection (2, 7, 19, 20). The population-level effect of widespread MC is observed in west Africa, where HIV has been present for many decades, yet prevalence remains relatively low (1, 7, 19, 20). All three recent RCTs of MC in Africa were stopped early for ethical reasons when initial findings demonstrated at least 60% reduction in HIV risk (19, 20). The population-level impact, taking into

account "herd immunity," could be even greater if a large proportion of men become circumcised (19, 20). Unlike most other interventions, MC is a one-time procedure that confers lifelong protection. Modeling suggests that MC could avert up to 5.7 million new HIV infections and 3 million deaths over the next 20 years in Sub-Saharan Africa, many of these among women (21).

A dozen acceptability studies and on-the-ground experience in many high-HIV-prevalence African countries demonstrate that the majority of uncircumcised men and their female partners accept and want MC services (typically for reasons of hygiene and sexual pleasure) (22). In Swaziland, men almost rioted because circumcision services were not available (20). Studies suggest that up to 80% in high HIV-prevalence countries like Botswana and Swaziland would seek MC if it were safe and inexpensive (22).

Donor agencies have the opportunity to be proactive, but African governments and civil society must take the lead, as has begun to occur in several countries (19). MC must be combined with behavior change, especially promotion of partner reduction and consistent condom use (1, 2, 19). Over time MC, which has been called a "surgical vaccine," would probably protect more women, albeit indirectly, than nearly any other achievable HIV prevention strategy (19-21).

Reducing multiple sexual partnerships. Another preventive measure that has had a powerful impact and that could have even greater effect, if it were more widely and assertively promoted, is partner reduction (2, 4, 7, 11, 18, 23-25). In Uganda, HIV prevalence declined dramatically following the extensive "Zero Grazing" campaign of the late 1980s (2, 7, 11, 23). WHO surveys conducted in 1989 and 1995 found a greater than 50% reduction in the number of people reporting multiple and casual partners (11, 23-25). In Kenya, partner reduction and fidelity also appear to have been the main behavioral change associated with the recent HIV decline (2, 4, 7). Similar behavior change has been reported in DHS surveys in Zimbabwe, where HIV has also fallen (1, 2, 7, 26), along with Ethiopia (7, 11), Cote d'Ivoire, and urban Malawi (see SOM). In Swaziland, the number of people reporting two or more partners in the past month was halved after an aggressive 2006 campaign focusing on the danger of having a "secret lover" (7).

There are, however, few demonstrated replicable approaches to reducing multiple sexual partnerships on a large scale. Nonetheless, mass mobilization of the community, as occurred with gay men in the United States and among heterosexuals in Uganda, can effectively encourage behavior change (18, 23, 25). And the Ugandan experience suggests that both partner reduction and combating stigma can be successfully achieved (24, 25).

#### *What Can Be Done Now?*

Currently, the largest donor investments are being made in interventions for which evidence of large-scale impact is increasingly weak, whereas much lower priority is given to interventions for which the evidence of potential impact is greatest (see figure, page 749). About 1% of total requested funding is for MC, and probably only a fraction of "community mobilization and mass media" and "workplace" efforts would be focused on reducing multiple and concurrent sexual partnerships. This balance needs to be reassessed.

**EDITOR'S NOTE:** *References for this article are available with a subscription at the above website. A media write-up of this article is available at <http://www.physorg.com/news129475364.html>.*

[Return to Table of Contents](#)

### **3. NEW PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC**

**Distribution of a vaginal gel (Invisible Condom(R)) before, during and after simulated sexual intercourse and its persistence when delivered by two different vaginal applicators: a magnetic resonance imaging study**

**Author(s):** Omar RF, Trottier S, Brousseau G, et al.

**Reference:** Contraception. 2008 Jun;77(6):447-55.

<http://www.ncbi.nlm.nih.gov/pubmed/18477496?dopt=Abstract>

**Published Abstract:** *Objective* The objective of this study was to evaluate the vaginal distribution of a microbicide gel (Invisible Condom(R)) before, during and after simulated intercourse using an artificial phallus. The gel was delivered using either a new proprietary vaginal applicator (PVA), which has multiple lateral and apical holes, or a commercial applicator (CA), which has a single apical hole. The persistence of the gel was evaluated up to 24 h after its administration. *Study Design* Nine women (five women using the PVA and four women using the CA) applied the vaginal gel once, and pelvic images were taken immediately after application. An artificial phallus was inserted and the women had 30 vaginal thrusts, then another set of images was taken while the phallus was still inside the vagina. On exit of the phallus, one more set of images was taken. Images were subsequently taken at 30 min, 2 h, 6 h and 24 h after gel application. *Results* Immediately after gel application, the PVA distributed the gel throughout the vaginal/cervical mucosae, while the CA delivered the gel only to the cervical area. During simulated intercourse, the phallus further pushed the gel delivered with the CA into the fornix, whereas it spread the gel delivered with the PVA more evenly throughout the mucosal surface. After simulated intercourse, both applicators gave similar gel distributions between 30 min and 6 h after application. However, at 24 h, using the PVA, only 5% of the gel persisted in the vagina, compared to 40% of the gel using the CA. *Discussion and Conclusion* Using the new PVA, the Invisible Condom(R) covered the vaginal/cervical mucosae before and during simulated intercourse, offering immediate protection, whereas only the cervical mucosa was covered using the CA. Forty percent of the gel persisted mostly in the upper vaginal/cervical area at 24 h following its administration with the CA, while only 5% of the gel was left using the PVA. The new applicator, with its unique design, ensures an even and immediate coating lasting throughout the first 6 h and could prevent potential **microbicide** vaginal toxicity at 24 h.

[Return to Table of Contents](#)

**HIV-1 integration: a potential target for microbicides to prevent cell-free or cell-associated human immunodeficiency virus type-1 infection**

**Author(s):** Terrazas-Aranda K, Van Herrewege Y, Hazuda D, et al.

**Reference:** Antimicrob Agents Chemother. 2008 May 12;Epub ahead of print.

<http://aac.asm.org/cgi/content/abstract/AAC.01627-07v1?maxtoshow=&HITS=3&hits=3&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcectype=HWCIT&ct>

**Published Abstract:** Conceptually, blocking HIV-1 integration is the last possibility to prevent irreversible cellular infection. Using co-cultures of monocyte-derived dendritic cells (MDDC) and CD4+ T cells, which represent primary targets in sexual transmission, we demonstrate that blocking integration with integrase strand transfer inhibitors (InSTIs), particularly the L-870812, could consistently block cell-free and cell-associated HIV-1 infection. In a pre-treatment setting where the compound was present before and during infection and afterwards

gradually diluted during the culture period, the naphthyridine carboxamide L-870812 blocked infection with cell-free and cell-associated HIV-1 Ba-L strain at respectively 1,000 or 10,000 nM. The potency of L-870812 was similar to that of the nucleotide reverse transcriptase inhibitor (NtRTI) PMPA but one or two orders lower than the non-nucleoside RTIs UC781 and TMC120. The InSTIs diketo acid RDS-derivatives showed clear-cut but weaker antiviral activity as compared to L-870812. Moreover, L-870812 completely blocked subtype C and CRFO2\_AG primary isolates, which are prevalent in the African heterosexual epidemic. Furthermore, addition of micromolar concentrations of L-870812 even 24 hours after infection could still block both cell-free and cell-associated Ba-L, opening the perspective for post-exposure prophylaxis. Finally, evaluation of combined antiviral activity of L-870812 with either T20, AZT, PMPA, UC781 or TMC120 against replication deficient HIV-1 Ba-L(env) pseudovirus suggested synergistic activity for all combinations. Importantly, compounds selected for the study in the co-culture model were devoid of acute or delayed cytotoxic effects at HIV blocking concentrations. Therefore these findings provide evidence to consider HIV-1 integration as target for **microbicides** development.

[Return to Table of Contents](#)

#### **Male circumcision: hope for HIV infection decrease in southern Africa**

**Author(s):** Legeai C, Auvert B

**Reference:** Med Sci (Paris). 2008 May 01;24(5):499-504.

<http://highwire.stanford.edu/cgi/medline/pmid;18466727>

**Published Abstract:** Given the magnitude of the HIV pandemic, development of new prevention means is necessary. Male circumcision reduces HIV transmission from female to male by 57 % [95 % Confident Interval (CI) : 42-68 %]. Its generalization in sub-Saharan Africa could avert, among men and women, from 1 to 4 millions new HIV infections over the next ten years. Acceptability of this new prevention mean is high in countries which could benefit the most from male circumcision, that means located in southern Africa, a region where in majority men are uncircumcised and where HIV prevalence is high. Male circumcision is a cost-effective prevention strategy. Actual prevention means (condoms, sexual abstinence and fidelity) are not used enough to curb the HIV epidemic. Research is ongoing on other prevention means (vaccine, pre- and post-exposition prophylaxis, **microbicides**, diaphragm) but their efficiency has not been demonstrated yet. Nevertheless, generalization of circumcision in southern Africa is responsible for contestations in part due to the fact that this prevention mean protects only partially from HIV infection. Moreover, for now, only a few countries integrated circumcision in their HIV prevention program in spite of WHO (World Health Organization) recommendations supporting male circumcision acknowledgement as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men. Significant available funding should allow the situation to evolve quickly. At the same time, research goes on in order to know more about the effects and to facilitate the generalization of this prevention mean which is a great hope for southern Africa.

[Return to Table of Contents](#)

#### **4. NEW PUBLISHED RESEARCH: RELEVANT SCIENCE**

### **Male genital tract chlamydial infection: implications for pathology and infertility**

**Author(s):** Cunningham KA, Beagley KW

**Reference:** Biol Reprod. 2008 May 14;Epub ahead of print.

<http://www.biolreprod.org/cgi/content/abstract/biolreprod.108.067835v1?maxtoshow=&HITS=2&hits=2&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct>

**Published Abstract:** Chlamydia trachomatis infections are prevalent worldwide, but current research, screening and treatment is focussed on females, with the burden of disease and infertility sequelae considered predominantly a female problem. However, the prevalence of chlamydial infection is similar in males and females. Furthermore, a role for this pathogen in the development of male urethritis, epididymitis and orchitis is widely accepted. While the role of Chlamydia in the development of prostatitis is controversial, we suggest that Chlamydia is an aetiological agent, with incidences of up to 39.5% reported in prostatitis patients. Infection of the testis and prostate is implicated in a deterioration of sperm, possibly affecting fertility. Chlamydia infections may also affect male fertility by directly damaging the sperm, as sperm parameters, proportion of DNA fragmentation, and acrosome reaction capacity are impaired with chlamydial infection. Furthermore, the proportion of male partners of infertile couples with evidence of a Chlamydia infection is greater than documented in the general population. An effect of male chlamydial infection on the fertility of the female partner has also been reported. Thus the need for a vaccine to protect both males and females is proposed. The difficulty arises because the male reproductive tract is an immune privileged site which can be disrupted, potentially affecting spermatogenesis, if inappropriate inflammatory responses are provoked. Examination of responses to infection in humans and in experimental animal models suggest that an IgA-inducing vaccine will be able to effectively target the male reproductive tract, while avoiding harmful inflammatory responses that may impair fertility.

[Return to Table of Contents](#)

### **Simian Immunodeficiency Virus (SIV) is susceptible to inhibition by carbohydrate-binding agents(CBAs) in a similar manner as human immunodeficiency virus (HIV). Implications for further preclinical drug development**

**Author(s):** Francois K, Auwerx J, Schols D, et al.

**Reference:** Mol Pharmacol. 2008 May 12;Epub ahead of print.

<http://molpharm.aspetjournals.org/cgi/content/abstract/mol.108.047621v1?maxtoshow=&HITS=3&hits=3&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct>

**Published Abstract:** Carbohydrate-binding agents (CBAs) like the plant lectins HHA (Hippeastrum hybrid agglutinin) and UDA (Urtica dioica agglutinin), but also the non-peptidic antibiotic pradimicin A (PRM-A) inhibit entry of human immunodeficiency virus (HIV) into its target cells by binding to the glycans of gp120. Given the high sequence identity and similarity between the envelope gp120 glycoproteins of HIV and simian immunodeficiency virus (SIV), the inhibitory activity of a variety of CBAs were evaluated against HIV-1, HIV-2 and SIV. There appeared to be a close correlation for the inhibitory potential of CBAs against HIV-1, HIV-2 and SIV replication in cell culture and syncytia formation in co-cultures of persistently SIV-infected HUT-78 cell

cultures and uninfected CEM cells. CBAs also inhibit transmission of the SIV to T-lymphocytes after capture of the virus by DC-SIGN-expressing cells. A total of 8 different SIV strains were isolated after prolonged HHA, UDA and PRM-A exposure in virus-infected cell cultures. Each virus isolate consistently contained at least 2 or 3 glycan deletions in its gp120 envelope and showed decreased sensitivity to the CBAs and cross-resistance towards all CBAs. Our data revealed that CBAs afford SIV and HIV-1 inhibition in a similar manner regarding prevention of virus infection, DC-SIGN-directed virus capture-related transmission, and selection of drug-resistant mutant virus strains. Therefore, SIVmac251-infected monkeys might represent a relevant animal model to study the efficacy of CBAs in vivo.

[Return to Table of Contents](#)

**Bacterial vaginosis, not HIV, is primarily responsible for increased vaginal concentrations of proinflammatory cytokines**

**Author(s):** Mitchell CM, Balkus J, Agnew KJ, et al.

**Reference:** AIDS Res Hum Retroviruses. 2008 May 07;Epub ahead of print.

<http://www.ncbi.nlm.nih.gov/pubmed/18462081>

**Published Abstract:** The relative effect of HIV-1 infection compared with vaginal infections on vaginal cytokine concentrations is not well characterized. We compared vaginal fluid samples from HIV-1-infected women with those from HIV-negative women, to assess the effect of HIV-1 infection on concentrations of vaginal proinflammatory cytokines and the mucosal defense molecule secretory leukocyte protease inhibitor (SLPI). Twenty-seven HIV-1-infected women and 54 HIV-negative controls, matched for bacterial vaginosis (BV) status, had proinflammatory cytokine [interleukin (IL)-1beta, IL-6, IL-8] and SLPI concentrations measured from archived cervicovaginal lavage and vaginal swab samples using an enzyme-linked immunosorbent assay (ELISA). Log-transformed concentrations were compared by BV and HIV status in univariate analysis using Student's t-test, and in multivariate analysis using a linear regression model. In univariate analysis there were no significant differences in cytokine concentrations among HIV-1-infected and HIV-negative women. In a multivariable linear regression model, BV was significantly associated with an increase in IL-1 beta ( $p = 0.003$ ). HIV infection was associated with an increased concentration of SLPI ( $p = 0.008$ ), while BV status was significantly associated with a decrease in SLPI concentrations ( $p = 0.005$ ). Neither HIV nor BV was associated with changes in IL-6 or IL-8. HIV does not have a major impact on vaginal concentrations of proinflammatory cytokines when controlling for the presence of bacterial vaginosis.

[Return to Table of Contents](#)

**T-ACASI reduces bias in STD measurements: the national STD and behavior measurement experiment**

**Author(s):** Villarroel MA, Turner CF, Rogers SM, et al.

**Reference:** Sex Transm Dis. 2008 May;35(5):499-506.

<http://www.stdjournal.com/pt/re/std/abstract.00007435-200805000-00014.htm;jsessionid=Lr6NYQ2pTwGGI0c1smnRT7FclbWhJ5r2ryQ2yqGZn822LqRjFJ2H!-2123996546!181195629!8091!-1>

**Published Abstract:** Background: Although telephone surveys provide an economical method for assessing patterns of diagnosed sexually transmitted diseases (STDs) and STD-related behaviors in populations, the requirement that respondents report such information to human telephone interviewers introduces an opportunity for substantial reporting bias. Telephone computer-assisted self-interviewing (T-ACASI) surveys substitute a computer for human interviewers when asking sensitive questions. Methods: A randomized experiment was embedded in a telephone survey that drew probability samples of the populations of the United States (N = 1543) and Baltimore city (N = 744). Respondents were randomly assigned to have sensitive questions asked either by a T-ACASI computer or by a human telephone interviewer. Results: Respondents interviewed by a T-ACASI computer were more likely to report STD symptoms [dysuria, genital sores, genital discharge, and genital warts; adjusted odds ratios (ORs) = 1.5-2.8] and a diagnosis of gonococcal or chlamydial infection during the past year (adjusted ORs = 3.6 and 6.1). T-ACASI respondents with a main sex partner in the past year were more likely to report that their partner has had an STD (adjusted OR = 2.4). For some measurements, the impact of T-ACASI was strongest among younger and less-educated respondents. When sampling weights were applied to project National STD and Behavior Measurement Experiment results to the populations of the United States and Baltimore, we found that reliance on data obtained by human interviewers would underestimate the annual incidence of chlamydial and gonococcal infections in these populations by factors of 2.4 to 9.7. Conclusions: Compared with human telephone interviewers, T-ACASI surveys obtain increased reporting of STD symptoms, infections, and STD-related behaviors.

[Return to Table of Contents](#)

**Human papillomavirus infection and cervical abnormalities in Nairobi, Kenya, an area with a high prevalence of human immunodeficiency virus infection**

**Author(s):** Yamada R, Sasagawa T, Kirumbi LW, et al.

**Reference:** J Med Virol. 2008 Mar 21;80(5):847-55.

<http://www3.interscience.wiley.com/journal/117946165/abstract>

**Published Abstract:** Human papillomavirus (HPV) infection and cervical abnormalities, and their association with human immunodeficiency virus (HIV) infection were studied in 488 women who visited a health center in Nairobi. PCR-based HPV and cervical cytology tests were carried out on all participants, and peripheral CD4+ T cells and plasma HIV RNA were quantitated in HIV positive women. HIV were positive in 32% (155/488) of the women; 77% of these were untreated, and the others had been treated with anti-retroviral drugs within 6 months. Cervical HPV infection was detected in 17% of HIV negative and 49% of HIV positive women. Low-grade squamous intraepithelial lesions were observed in 6.9% of HIV negative and 21% of HIV positive women, while high-grade squamous intraepithelial lesions and cancer were seen in 0.6% and 5.8%, respectively. Multivariate analysis revealed that HIV and HPV infections were associated with each other. Cervical lesions were significantly

associated with high-risk HPVs and with HIV infection, depending on HPV infection. HPV infection increased in accordance with lower CD4+ T cell counts and higher HIV RNA levels, and high-grade lesions were strongly associated with high-risk HPV infection and low CD4+ T cell counts. Immunosuppression as a result of HIV infection appears to be important for malignant progression in the cervix. Nationwide prevention of HIV infection and cervical cancer screening are necessary for the health of women in this area. High-risk HPV infection and low CD4+ T cell counts are the risk factors for cervical cancer.

[Return to Table of Contents](#)

**Heterosexual anal intercourse: prevalence, cultural factors, and HIV infection and other health risks, Part I**

**Author(s):** Halperin DT

**Reference:** AIDS Patient Care STDS. 1999 Dec;13(12):717-30.

<http://www.ncbi.nlm.nih.gov/pubmed/10743535>

**Published Abstract:** Studies of heterosexual HIV transmission have consistently found anal intercourse to be a highly predictive risk factor for seroconversion. Yet most AIDS prevention messages targeted at heterosexuals, presumably influenced by cultural taboos against acknowledging this sexual practice, continue to emphasize vaginal and, increasingly, oral sex transmission. The health risks of anal sex appear to be severely underestimated by a substantial proportion of sexually active women and men in North and Latin America as well as parts of South Asia, Africa, and other regions. Among heterosexuals reported rates of condom use are nearly universally lower for anal than for vaginal intercourse. This review examines anal sex among the general population, including its prevalence in various world regions, related sociocultural factors, and other associated health problems including anorectal STDs, Hepatitis B infection, and HPV-related anal cancer in women. U.S. survey and other data suggest that, in terms of absolute numbers, approximately seven times more women than homosexual men engage in unprotected receptive anal intercourse. Research among higher risk subpopulations, including bisexual men, injecting drug users, female sex workers, inner-city adolescents, and serodiscordant heterosexual couples, indicates that persons particularly at risk of being infected by or transmitting HIV are also more likely to practice anal sex. Considering this finding, along with the much greater efficiency for HIV infection as well as lower rates of condom usage, a significant proportion of heterosexual transmission in some populations is due to anal intercourse. This typically stigmatized and hidden sexual practice must be given greater emphasis in AIDS/STD prevention, women's care, and other health promotion programs.

**EDITOR'S NOTE:** *Though published in 1999, this article is included in this Digest because it remains important, and has been the topic of recent discussions on listservs in the microbicide and allied communities.*

[Return to Table of Contents](#)

## 5. EPIDEMIOLOGY

## **"People do stupid things - that's what spreads HIV"**

**Author(s):** Decca Aitkenhead

**Date:** 13 May 2008

**Source:** *The Guardian*

<http://www.guardian.co.uk/world/2008/may/13/aids.hiv>

When Elizabeth Pisani began her career as an HIV epidemiologist, fewer than 1.5m cases of Aids had been reported across the world. Within a year, by the end of 1997, 30 million people were estimated to be infected with HIV. As Pisani wrote in her first report for World Aids Day, that meant one in every 100 sexually active adults aged between 15 and 49 worldwide.

Today, just over a decade later, the global figure is estimated to be closer to 40 million, with more than 1.5m new infections every year. Yet there is a widespread impression that the world is now winning the fight against the virus. The perception that it threatens only sex workers, heroin addicts and gay men has been replaced by the urgent consensus that this is a universal problem - backed by mind-boggling sums.

Ten years ago, the developing world received roughly \$300m a year from the west. By 2007, the figure was \$10bn. This year the US alone has budgeted \$5bn for HIV in developing countries - and last month the US Congress voted to commit a further \$50bn over the next five years. The President's Emergency Plan For Aids Relief (Pepfar), personally initiated by George W Bush, has been described in Washington as the most successful foreign aid programme since the Marshall Plan, and "the best thing that ever happened to the poor people I work with" by one HIV programme leader in Africa. On a recent visit to the continent, Bush was feted as the saviour who has put one and a half million Africans on life-saving drugs.

"We used to sit around fantasising about having unlimited resources," Pisani recalls. "Like winning the lottery." Today, the Aids industry - "or Aids mafia", in her words - effectively has won the lottery. But Pisani is not celebrating. Her book, *The Wisdom of Whores*, published this week, condemns the global strategy for Aids as an ill-conceived waste of money which is not saving but costing lives.

"HIV is mostly about people doing stupid things in the pursuit of pleasure or money," declares the cover on a proof copy of the book. "We're just not allowed to say so." She suspects she will never work in the Aids industry again for saying so. "But it's true."

Pisani, 43, spent 10 years working in the field of HIV, first for Unaided and then for a non-governmental organisation (NGO) in Indonesia. As an epidemiologist, she quickly identified the risk of the virus spreading among drug injectors, gay men and the sex trade across Asia, Latin America and Eastern Europe - underdeveloped countries with inadequate resources to prevent an epidemic. That placed 100 million at risk in Asia alone - equivalent to a third of the population of the Africa. But the data was clear: "HIV wasn't going to rage through the billions in the 'general population'. And we knew it."

Like most of her colleagues, however, she also quickly realised that "governments don't like spending money on sex workers, gay men and drug addicts". So she put her skills as a former journalist to work, and began producing the sort of reports that persuaded politicians in Washington and the west that it is not "wicked people" but "innocent wives" at risk. "Aids couldn't be about sex and drugs," she explains. "So suddenly it had to be about development, and gender, and blah blah blah."

The strategy was more successful than she could ever have imagined. "All these obsessively politically correct things started getting introduced." HIV publications and conferences began devoting more time and attention to

issues such as poverty, gender, development, vulnerability, leadership - what Pisani calls "sacred cows" - than to condoms and clean needles. "I'm just waiting for 'climate change and Aids'," she jokes sarcastically in her book - and sure enough, this week a headline appeared in an Australian newspaper: "Global warming set to fan HIV."

These were all far more palatable issues to politicians than sex and drugs, and the money began to roll in. But they are not, Pisani argues, what cause Aids. "We have to stop this nonsense now. Talking about 'vulnerability' will not stop people getting infected."

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

[Return to Table of Contents](#)

### **"HIV cases soar among Kampala sex workers"**

**Author(s):** Jane Nafula

**Date:** 09 May 2008

**Source:** *The Monitor*

[http://www.monitor.co.ug/artman/publish/regional-special/HIV\\_cases\\_soar\\_among\\_Kampala\\_sex\\_workers.shtml](http://www.monitor.co.ug/artman/publish/regional-special/HIV_cases_soar_among_Kampala_sex_workers.shtml)

The prevalence of HIV/Aids among women and girls involved in commercial sex in Kampala is on the rise. Cases of other sexually transmitted diseases like Syphilis and Gonorrhoea are also high among the sex workers.

The coordinator of the Breaking the Ice Project being implemented by Reproductive Health Uganda in Kampala, Mr Robert Kanwagi said a recent study done in Kampala indicated that the HIV prevalence among the sex workers was as high as 47.2 per cent compared to the national rate of 6.7 per cent.

The Breaking the Ice Project was launched in July last year by Reproductive Health Uganda (RHU) to enhance access to HIV/Aids services among sex workers in Kampala as well as reducing the social-cultural barriers to utilisation of HIV related services.

Mr Kanwagi said amongst young sex workers who are between 25-29 years, the prevalence of HIV is as high as 60 per cent and that 59.6 per cent were reported to be infected with other Sexually Transmitted Diseases (STDs). Mr Kanwagi was addressing journalists at training workshop for RHU staff on HIV and Gender held under the theme, "Theory and practice of gender oriented planning" in Kampala on Monday .

Mr Kanwagi said poverty was the major factor influencing women to practice commercial sex. He also said sex workers like any other women have not yet been empowered in negotiating safer sex. Sex workers who go in for unprotected sex are paid more money than those who opt for protected sex.

The National Programme Manager, Reproductive Health Uganda, Dr Peter Ibembe said women and young girls are becoming more infected with HIV due to social economic and cultural factors that deny them access to HIV prevention and treatment services.

"A poor woman or girl may not be able to deny a man sex because she needs money. Because of their lack of decision-making power in matters of sex, as well as other factors like poverty, they become more exposed to the risk of becoming infected than men," he said. He also said several men take advantage of poor women and girls and exploit them sexually.

[Return to Table of Contents](#)

## 6. HIV/AIDS VACCINES

### "Return to the basics might breathe life into HIV vaccine pipeline"

**Author(s):** Roxanne Khamsi

**Source:** *Nat Med.* 2008 May;14(5):469. News.

<http://www.nature.com/nm/>

As the financial world grapples with major market corrections, the HIV research community faces its own reality check. The scientific reassessment comes after disappointing results from a candidate HIV vaccine developed by Merck caused the company to halt human trials of the potential vaccine last September.

"There's no question in my mind that the vaccine effort is in need of a major midcourse correction," Warner Greene of the University of California, San Francisco told listeners at a government-sponsored summit on HIV vaccine research on 25 March in Bethesda, Maryland. Greene, who co-chaired the summit, emphasized the need for a return back to the basics to, for example, create better animal models for testing vaccines before racing ahead with numerous human clinical trials.

Talking about the need for more basic HIV vaccine research is easy, but figuring out how to fund more of such experiments is not.

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**EDITOR'S NOTE:** *The full text of this article is available with a subscription to Nature Medicine.*

[Return to Table of Contents](#)

## 7. HIV/AIDS FUNDING

### "Bill and Melinda Gates name new foundation head"

**Date:** 12 May 2008

**Source:** *National Public Radio*

<http://www.npr.org/templates/story/story.php?storyId=90373773>

Bill and Melinda Gates announced Monday that Microsoft executive Jeff Raikes will take the helm of their \$37 billion foundation - the world's largest such philanthropy - in September.

A 27-year veteran of Microsoft, Raikes will take over as chief executive of the foundation on Sept. 2, replacing Patty Stonesifer, who announced her resignation in January.

From their home in Medina, Wash., the Gateses tell Michele Norris in an exclusive interview that they picked Raikes because he shares their passion to try to help minimize poverty in the developing world and the U.S.

The head of Microsoft's business division, Raikes will now shift gears and start giving away massive amounts of the Microsoft fortune. The Bill and Melinda Gates Foundation distributes more than \$3 billion in grants each year. NPR has received grants from the foundation.

Raikes announced his resignation from Microsoft in January. Stephen Elop, former chief operating officer at Juniper Networks, will replace Raikes at the software giant. As of July, Bill Gates himself will transition from a day-to-day role with Microsoft - though he'll remain its chairman - to focus more on the foundation's work.

### *A Broad Philanthropic Agenda*

The Gateses have known Raikes and his wife, Tricia, for the past two decades, and the two couples have traveled extensively together. Bill and Melinda Gates say they were particularly impressed when Raikes chaired the United Way's 2006-2007 fundraising drive in King County, Wash. At the time, he also worked full time for Microsoft.

As part of his work with United Way, Raikes "went out at night on the homeless count to see what it means to sleep at 3 a.m. on the streets of Seattle," says Melinda Gates, who co-chairs the Gates Foundation with her husband. She says that got Raikes thinking about big-picture efforts to tackle homelessness.

That broad perspective has also characterized the Gates Foundation's approach to poverty and global health. The foundation has been the object of awe, envy and, at times, anger because of its big budget and broad agenda - which includes improving education, alleviating poverty and combating diseases such as malaria and HIV.

"We're focused on the diseases that are ignored, the diseases of the poor," says Bill Gates. "The market is not giving a signal that this work should be done. And so in the rich world, problems like baldness get funded with billions, whereas the things that really kill lots of people, like malaria and TB, used to get basically nothing. Those are what we're going after in health."

He adds, "Once you improve health in a country, it really changes everything, because parents don't need to have as many children to be sure that someone will support them in their old age. Population growth goes down, you can feed, you can educate, you can provide jobs. And the virtuous cycle that we've seen, fortunately, in most places in the world can be extended to these other countries."

### *Addressing Critics*

Critics say the Gates Foundation tries to use its deep pockets to influence global health policy, while sometimes failing to consult people with long-term experience in areas such as malaria and tuberculosis control or HIV prevention. Bill Gates says the foundation has supported the World Health Organization with more than \$1 billion in grants, and he stresses that WHO remains the policy-making organization.

"They do not have in their budget money for drug research, so the really sad thing is that hardly anything was being spent on malaria research, hardly anything was being spent on TB research or an AIDS vaccine," Bill Gates says. That created an opening for the foundation "to really highlight that more needs to be spent on these things" and to work "together with the organizations that were already there."

The foundation has responded to criticisms by seeking feedback from people intimately involved with the governments it works with. It has set up advisory panels for issues regarding the U.S., global development and global health.

"Strong outside voices are people we're listening to," Melinda Gates says. "They're helping us gather feedback from grantees on the ground. We want good criticism and good feedback, so we're doing better as an organization. We take that very, very seriously."

## 8. POLITICS AND POLICY

### "Initial treatment for HIV infection - an embarrassment of riches"

**Author(s):** Bernard Hirschel, Alexandra Calmy

**Source:** *N Engl J Med.* 2008 May 15;358(20):2170-72. Editorial.

<http://content.nejm.org/cgi/content/full/358/20/2170>

Drugs that are used to treat patients with human immunodeficiency virus (HIV) infection are classified according to their target. The first ones to be developed were nucleoside reverse-transcriptase inhibitors (NRTIs), which lead to premature termination of the nascent DNA chain, and nonnucleoside reverse-transcriptase inhibitors (NNRTIs), which bind and inhibit reverse transcriptase. The viral protease inhibitors were next. NRTIs, NNRTIs, and protease inhibitors remain the staples of highly active antiretroviral therapy, but other targets, such as the CCR5 receptor, the fusion peptide, and viral integrase, have recently yielded promising molecules.

At this time, eradication of HIV is impossible. Rebound inevitably follows cessation of therapy, and therapy must therefore be lifelong. With more than 20 drugs to choose from, there is an embarrassment of riches. Possible combinations are almost endless, as are the possibilities of side effects, either beneficial or damaging drug interactions, and the development of viral resistance.

Early in the antiretroviral-therapy era, the combination of indinavir (a protease inhibitor) and zidovudine and lamivudine (both NRTIs) predominated as the reference treatment. In 1999, the NNRTI efavirenz, in combination with zidovudine and lamivudine, proved to be more effective in diminishing the plasma concentration of HIV type 1 (HIV-1) RNA (the "viral load") than the reference treatment.<sup>1</sup> Indinavir has since been largely replaced by atazanavir or lopinavir combined with a small dose of ritonavir to boost absorption and plasma levels.

Current guidelines recommend initiating antiretroviral therapy with two NRTIs in combination with either an NNRTI or a protease inhibitor.<sup>2</sup> So the first question is, Which NRTIs and which protease inhibitor do we choose? And the second question is, Which is better, an NNRTI or a protease inhibitor? Phase 4 studies that compare treatment strategies are desirable, but they are difficult to do. In a rapidly moving field such as HIV therapy, what is the "reference treatment"? Trials have to be large and continue for a long time, and patients may vote with their feet and refuse to continue with a therapy that they judge, rightly or wrongly, to be inferior to the latest miracle drug. And large trials that continue for a long time are expensive. Drug companies have little to gain, and much to lose, from comparing one of their already marketed drugs with another that may be better. The National Institutes of Health, through the Clinical Trials Network, have very properly undertaken trials such as the Strategies for Management of Antiretroviral Therapy (SMART; ClinicalTrials.gov number, NCT00027352 [ClinicalTrials.gov]),<sup>3</sup> which showed that intermittent treatment was inferior to continuous treatment for patients with HIV infection.

In this issue of the Journal, Riddler et al.<sup>4</sup> report on the AIDS Clinical Trials Group Study A5142, which compared three drug combinations in the initial therapy of 753 patients with HIV infection: efavirenz plus two NRTIs (efavirenz group), lopinavir-ritonavir plus two NRTIs (lopinavir-ritonavir group), and lopinavir-ritonavir plus efavirenz (NRTI-sparing group). As previously noted, the first two regimens were popular and widely prescribed. The third is theoretically attractive, since it avoids the use of NRTIs, which are suspected of contributing to side effects. An uncontrolled study of 86 patients showed that this combination would be effective, although it was not well tolerated: after 48 weeks, 24% of patients either discontinued the study regimen because of adverse events or were lost to follow-up.<sup>5</sup> A study by Boyd et al. looked at efavirenz with ritonavir-boosted indinavir as an

NRTI-sparing option, with similar conclusions.<sup>6</sup>

The results of the study by Riddler et al. are difficult to put in a nutshell. We want regimens that win in all categories: suppression of HIV-1 RNA, an increase in the CD4 cell count, a lack of emergence of resistance, low toxicity, and simplicity. However, the study by Riddler et al. yields a split decision. When the regimens were ranked according to suppression of HIV-1 RNA, the efavirenz group had the best results, closely followed by the NRTI-sparing group and the lopinavir-ritonavir group, although the difference between the efavirenz group and the NRTI-sparing group was not significant. When the regimens were ranked according to the emergence of drug resistance, the winner was the lopinavir-ritonavir group, followed by the efavirenz group and the NRTI-sparing group, and again the difference between the lopinavir-ritonavir group and the efavirenz group was not significant. Finally, as measured by the proportion of patients who discontinued or changed their treatment, all three groups had similar rates of adverse events.

Patients who participate in clinical trials differ from the majority who do not participate - one reason why clinical practice often cannot reproduce published results. Efavirenz causes side effects involving the central nervous system, including sleep disturbances with vivid dreams, dizziness, and daytime drowsiness.<sup>7</sup> Such symptoms are frequent and troublesome early on; they largely disappear after a few weeks of therapy. Nonetheless, in all studies we are aware of, a sizable percentage of patients discontinued efavirenz because of these effects; the proportion was particularly high among patients who acquired HIV through illicit drug use, partly because efavirenz interferes with methadone. We are struck by the fact that Riddler et al. did not record much of this type of discontinuation in their study. This suggests that their patients were greatly motivated to continue their prescribed regimen, perhaps through their repeated and close contact with the investigators - a type of Hawthorne effect<sup>8</sup> that is difficult to duplicate in routine practice.

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**EDITOR'S NOTE:** *The full text of this article, including references, is available with a subscription at the above website. It refers to another article in the same issue of NEJM by Riddler, et. al., entitled Class sparing regimens for initial treatment of HIV-1 infection, also available with a subscription to NEJM.*

[Return to Table of Contents](#)

### "Moral scales in the Senate"

**Author(s):** Michael Gerson

**Date:** 14 May 2008

**Source:** *The Washington Post, Op-Ed page*

<http://www.washingtonpost.com/wp-dyn/content/article/2008/05/13/AR2008051302305.html?hpid=opinionsbox1>

How much do seven members of the U.S. Senate weigh?

Eyeing them -- Tom Coburn, Jim DeMint, Jeff Sessions, Saxby Chambliss, David Vitter, Jim Bunning, Richard Burr -- I'd guess they probably come in at about 1,300 pounds. These are the Republicans who have signed a hold letter, preventing action on the reauthorization of the President's Emergency Plan for AIDS Relief (PEPFAR).

Now, how much do 3 million HIV-AIDS-infected people -- the treatment goal of a reauthorized PEPFAR -- weigh? This is a more difficult calculation. Adults with advanced forms of the disease can weigh about 60 pounds.

Children with AIDS are like shadows falling on a scale. Maintaining weight becomes difficult with vomiting and diarrhea, with tuberculosis and fungal infections, with cancers such as Kaposi's sarcoma and lymphoma.

Even so, you'd think that a few million of these wasting bodies would weigh more on the moral balance than seven senators. But so far, you'd be wrong.

It is the nature of the Senate that the smallest of minorities can impede the work of the majority. But it takes a conscious choice -- an act of tremendous will and pride -- for members to employ these powers against an AIDS bill with overwhelming bipartisan support.

The seven, led by Coburn, complain that the reauthorization is too costly. They object to "mission creep" -- the funding of "food, water, treatment of other infectious diseases, gender empowerment programs, poverty alleviation programs" -- as though people surviving on AIDS treatment do not need to eat, work or get their TB treated. And the senators are concerned that AIDS funds might be used for things such as abortion referrals and needle distribution, though the legislation doesn't mention these possibilities. So they are pushing for the extension of a superfluous spending mandate requiring that at least 55 percent of PEPFAR resources be used for treatment, on the theory that this will starve "feckless or morally dubious" prevention programs.

For all of conservatism's evident virtues, it can have one furtive, seedy vice: A justified suspicion of government can degenerate into an anti-government ideology -- rigid, stingy and indifferent to human suffering. Conservative concerns on family planning and abstinence in the PEPFAR reauthorization are not imaginary, but they could be resolved through good-faith negotiations, as they were in the House of Representatives. A generalized hostility toward AIDS prevention, however, is destructive. Given that there are about 2.5 new HIV infections for every person starting on AIDS drugs, there is no way to control the pandemic through treatment alone. And because treatment is less expensive than it used to be, PEPFAR is meeting its treatment goal for less money. The 55 percent treatment floor would force the program to waste money in pursuit of an arbitrary, nonsensical spending target -- the worst kind of congressional earmark.

Other members of the Senate Republican conference seem content to stand by and watch Coburn undermine the bill, since they have their own, quiet concerns about PEPFAR's price tag. But the legislation is an authorization, not the appropriation (which comes later), so the \$50 billion figure means little. These Republicans are objecting to a placeholder, taking a baseball bat to a vapor.

President Bush has yet to push for PEPFAR's reauthorization as his top legislative priority, so Majority Leader Harry Reid and Minority Leader Mitch McConnell feel little pressure to roll over Coburn's objections -- which they could do, since there are more than 60 "yes" votes.

Reid supports the legislation but seems uninterested in scheduling floor time without assurances from Republicans that the debate will be short and the number of amendments limited. If it passes, after all, Bush will get much of the credit. The political calculation must be tempting: Why not allow seven white Republicans to discredit their party by blocking a lifesaving bill for Africa? And there is a bonus: Coburn is an adviser on health issues to John McCain.

Given these obstacles, supporters of the PEPFAR reauthorization now estimate a 50 percent chance it will be shelved until next year. Without a five-year U.S. commitment on AIDS funding, other countries would be reluctant to put new people on treatment. And lives would be lost.

Each of the Coburn Seven counts himself pro-life. If a bill came to the Senate floor that would save millions of unborn children, one assumes that pro-life members would push to improve it, accept a few necessary compromises and then enthusiastically support the legislation.

It is difficult to imagine why pro-life legislation involving millions of Africans should be viewed differently.

[Return to Table of Contents](#)

**"Communicating the results of clinical research to participants: attitudes, practices, and future directions"**

**Author(s):** David I. Shalowitz, Franklin G. Miller

**Source:** *PLoS Med.* 2008 May 13;5(5):e91. *Guidelines and Guidance.*

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0050091&ct=1>

Recent commentaries advocate routinely offering study results to research participants [1,2]. However, debate continues over the scope and limits of investigators' responsibilities in this regard. A 2006 review identified 30 national and international policies and guidelines concerning the duty to return research results [3], of which 21 were published in the last decade. Worldwide interest in this complex issue will likely continue to rise in light of the increasing relevance of the results of biomedical research to participants' health and well-being.

Unfortunately, many policies and commentaries on communication of results either do not adequately take into account relevant available data, or fail to recognize the lack thereof. For example, existing data on participant desire and investigator support for communication of research results have not been synthesized, nor have the data on potential positive and negative consequences that communication of results may have for both participants and researchers.

The results of clinical research may be classified as either aggregate study results, representing synthesized data and conclusions drawn from groups of research participants, or individual results, representing distinct items of data collected from or about individual participants. In this article, we present a narrative review of available data on the effects of communicating aggregate and individual research results on participants, investigators, and the research enterprise. We also present available data on disclosure practices and the attitudes of investigators and participants towards communication of research results. Our aim is not to provide definitive analyses of any of these domains; rather, it is to highlight trends in the literature as well as areas that require further investigation.

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

[Return to Table of Contents](#)

## 9. PREVENTION AND BEHAVIOR

**"What's a girl to do?"**

**Author(s):** Regan Hofmann

**Date:** May 2008

**Source:** *Poz Magazine*

[http://www.poz.com/articles/US\\_stigma\\_women\\_2176\\_14344.shtml](http://www.poz.com/articles/US_stigma_women_2176_14344.shtml)

As new HIV infections among U.S. women keep rising, a new study probes America's attitudes toward positive ladies. And the findings ain't pretty.

In the United States, women now account for more than a third of new HIV infections and a quarter of new AIDS cases. The proportion of AIDS diagnoses among women has tripled since 1985. And recently released statistics from a Centers for Disease Control and Prevention (CDC) study indicate that one in four female Americans between the ages of 14 and 19 has at least one sexually transmitted disease (though, for some reason, HIV was not one of the diseases studied). Unless things change, it looks like the United States is headed in the direction of the developing world, where closer to 50 percent of all those living with HIV are women and where the odds for the ladies are getting worse all the time.

So why women and why now? Given the lag time between when women get infected and when they are diagnosed, and the secondary lag between those diagnoses and when that data are made public by the CDC and similar groups, it's important to note that what seems like a recent spate of new infections among women likely represents infections that happened anywhere from three to 20-plus years ago. The truth is that women have always contracted HIV but that the numbers announced publicly have only recently gotten high enough to cause alarm.

Recognizing the fact that more women are living with HIV in the United States than ever before, the Foundation for AIDS Research (amfAR) hired the research firm Harris Interactive to chart the public's opinions of HIV-positive women. The goal was to identify and eventually correct any misconceptions that could be leading to the swell of new infections among women and girls. Polling a wide cross section of more than 4,800 Americans, amfAR flushed out a truth that I, an HIV-positive woman, have long suspected: The stigma surrounding women and HIV is particularly severe.

The study confirmed my belief, for instance, that how a woman contracts the virus colors people's perceptions of her. Nearly 60 percent of the respondents said they have a "very negative opinion" of a woman who contracted HIV through exchanging sex for drugs or money, 30 percent said they would look down on a positive woman who got the virus from "having multiple sexual partners," 14 percent said they would scorn a woman who had sex without a condom, 12 percent were uncomfortable if a woman became positive as a result of not knowing the HIV status of her sexual partner. Even women who contract HIV via a rape or blood transfusion weren't spared: About 5 percent of respondents said they would have a "very negative opinion" of them.

The idea that people who "do bad things" get HIV and that people who get HIV are bad sits at the core of our struggle to prevent a disease that is almost always preventable. Until we can convince people that the virus has no moral preference, some people will believe that their ideology, not actual sexual and other precautions, will protect them. True, certain acts are riskier than others, but a female prostitute who has unprotected sex with a client and a married woman who has unprotected sex with her husband after he cheats on her may experience the same risk. People's opinions on the relative morality of those two circumstances may differ, but the virus is unaware of that distinction and will affect both people equally.

The Harris Interactive study does not attempt to conclude why women are prone to disproportionate levels of HIV infection. But in revealing Americans' deep stigmatization of HIV-positive women, it suggests an endless cycle of cause and effect: The stigma stifles discussion of prevention and testing; the lack of awareness and testing increases infection; women who do test positive are made to think they are bad and should have known better, so they are driven underground, becoming invisible, further increasing stigma. And when HIV-positive women are afraid to come forward, suffering silently with their scarlet A, the public continues to think that women are not at risk, even as the numbers climb ever higher.

To truly understand the depth of people's distaste for women with HIV, consider the study's other findings. A mere 14 percent of people said women with HIV should have kids. Meanwhile, 59 percent said women with cancer should have kids, 47 percent said depressed women should bear children, 37 percent said women with multiple sclerosis should have kids, 20 percent said those with hepatitis C should conceive, 19 percent said women with

Down syndrome should get pregnant and 17 percent said women with schizophrenia should have kids. If an HIV-positive woman decided to have a child, one third of Americans would not support her decision at all. I can only surmise that this speaks to the widespread ignorance of the fact that it is possible to prevent mother-to-child HIV transmission; that many HIV women will live long full lives and be able to care for their children; and that being pregnant has been proven to bolster the health of HIV-positive women.

Now that amfAR has identified how painfully our society can treat women living with HIV, perhaps our next step should be to focus on properly teaching girls and young women how to avoid HIV - and other STDs - and to work to diminish the devastating stigma that keeps women in hiding, thus perpetuating the myth that they are not increasingly affected by AIDS.

[Return to Table of Contents](#)

### "Taking care of business"

**Author(s):** Lucile Scott

**Date:** May 2008

**Source:** *Poz Magazine*

[http://www.poz.com/articles/prevention\\_sexworkers\\_India\\_2176\\_14361.shtml](http://www.poz.com/articles/prevention_sexworkers_India_2176_14361.shtml)

*HIV infections keep rising in India. But they have fallen drastically among one group: the country's sex workers. These global prevention leaders are teaching squeamish governments - including America's - how to get the job done.*

Budhwar Peth, the largest red-light district in the Indian city of Pune, seems like any other neighborhood there. Vendors hawk everything from grain to knockoff designer handbags; they compete for space with an ever-moving mass of pedestrians, bicyclists, cars, carts, rickshaws and cows. But peer behind the bustle, and you'll see dozens of women lining each block. They stand in front of ramshackle, two-story brothels with dirt floors and chipping pastel paint, a Hindu temple popping up above them. Men ranging from university students to soldiers and businessmen mill about and appraise the stationary women, who return their lingering glances. As the night wears on, music will blast, booze will flow and more and more women will emerge from the brothels. There they will earn from 10 rupees (40 RS equals \$1) to, in a very few cases, 5,000 rupees a night, depending on their look and their employer.

This afternoon, one veteran of the sex trade, Shanti, 48, weaves through the dusty sidewalks. Wearing a sari of muted green, she makes her way to the neighborhood health clinic, where she works as a peer educator. Like many of India's estimated 4 million female sex workers, Shanti arrived from a poor rural village. She was 18, her parents had just died and she had three young brothers to support. Facing a job market with few options for lower-class women, she turned to the brothels, where women without a good education can make far more than they can in other fields. She says her husband, whom she married as a teenager, "was of no use. He was a drunkard and he beat me up and we didn't have enough food."

Shanti shares another characteristic with many Indian sex workers: She is HIV positive. When she was diagnosed, in 2003, about 54 percent of female sex workers in the city of Pune (population: 5 million) were estimated to be positive. There were few programs designed to combat HIV in sex workers. What's more, the failure of world governments - including those of India and the United States - to address the issue stigmatized the women of Budhwar Peth and sex workers around the globe, confining them to shadows of society. They had little knowledge

of HIV or condoms as the epidemic spread not only through their community but to their clients, other sexual partners and the population at large. But all that has begun to change. The HIV rate among the area's female sex workers has dropped to around 20 percent. "We didn't know anything about condoms before," says Shanti, with a grin. "And now there are too many." Indeed, the country's progress in combating HIV among sex workers is being recognized globally as a model for prevention among marginalized social groups. The sex workers of Budhwar Peth have much to teach the world about sexual safety and solidarity. And in that arena, their services are absolutely free.

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

[Return to Table of Contents](#)

**"Men's condom use in higher-risk sex: trends and determinants in five sub-saharan countries"**

**Author(s):** Tim Adair, Macro International Inc.

**Date:** April 2008

**Source:** *Demographic and Health Surveys (DHS)*

[http://www.measuredhs.com/pubs/pub\\_details.cfm?id=766&srchTp=home](http://www.measuredhs.com/pubs/pub_details.cfm?id=766&srchTp=home)

This paper examines men's condom use at last higher-risk sex (i.e., nonmarital, noncohabiting partner) in five sub-Saharan countries: Burkina Faso, Cameroon, Kenya, Tanzania, and Zambia. The two most recent Demographic and Health Surveys (DHS) in each country are analyzed to show trends in various indicators. Condom use is an important way to prevent the transmission of HIV, the virus that causes AIDS. Encouragingly, use of condoms has increased substantially in Burkina Faso, Cameroon, and Tanzania, with smaller increases in Kenya and Zambia. At the same time, levels of higher-risk sex have declined in four of the five countries, although use of a condom at last higher-risk sex remains below 50 percent in Kenya and Zambia. Multivariate analysis shows that higher education is a consistently strong, positive predictor of condom use at last higher-risk sex, whereas higher wealth status is not significant in most surveys. Knowledge that use of condoms can reduce the risk of HIV transmission is a consistently strong, positive predictor of condom use, but urban-rural residence and region are significant only in some surveys. Comparing the two most recent DHS surveys in each of the five countries, there are no clear patterns of change in the predictive strength of explanatory variables. However, there is evidence of widening gaps in condom use by level of education in Cameroon and by urban-rural residence in Kenya. One important policy finding that emerged from this study is that low wealth status is not a barrier to condom use in most countries, but lack of education is.

[Return to Table of Contents](#)

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