

HIV Trends and Women's Sexual Health

March 2009

A women-centred focus on HIV, sexually transmitted infections, prevention and treatment issues

New hope for microbicides:

High-dose tenofovir microbicide completely protects monkeys

An animal study has found that a single dose of a microbicide gel containing tenofovir and FTC completely protected six out of six monkeys given a twice-weekly vaginal challenge of a combined human/monkey virus called SHIV. No monkeys were infected after 20 challenges with the virus whereas monkeys not given the microbicide were infected after an average of four challenges.

Unexpectedly, however, the study also found that a gel containing tenofovir alone was just as effective and also protected all the monkeys. This contrasts with previous studies, which have found lower rates of efficacy for single-drug microbicides.

To test the effectiveness of the 1% tenofovir intravaginal microbicide gel and a combination gel including 5% FTC and 1% tenofovir, the investigators designed a four-arm study including a total of 21 pigtail macaques.

In order to simulate human sexual exposure more accurately than other studies, the investigators gave lower doses of SHIV than in previous studies, but gave them more frequently – twice rather than once a week. In addition, the monkeys were not treated with progesterone. Previous studies have dosed monkeys with this hormone because it stops the animals' menstrual cycle, which is monthly like the human cycle, and keeps the vaginal wall thin, creating a state where the monkeys are permanently at their most vulnerable point of the cycle to infection. This study left

continued

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614-1033 Davie Street, Vancouver, BC, V6E1M7 Phone: 604.692.3000 Toll free in BC: 1.866.692.3001

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Tenofovir Microbicide success (continued)

the monkeys to menstruate and more accurately imitates women's changes in vulnerability. Protection was measured over ten weeks or two complete menstrual cycles.

The study used gels containing high doses of antiretrovirals. In particular there was 30mg of tenofovir in each dose compared with 40mg in microbicide trials that are currently taking place in humans - weight-for-weight a much larger dose.

Presenter Charles Dobard of the Centers for Disease Control said that trials with lower doses were being contemplated, saying that "we wanted to aim high and scale back."

There were eleven controls, nine of whom received a placebo gel and two no gel. The 1% tenofovir and 1% tenofovir/5% FTC arms contained six monkeys each. The gels were applied intravaginally 30 minutes before exposure to SHIV. Infection with SHIV was checked using both antibody and viral load tests. The investigators also measured drug absorption 30 minutes after administration.

Of the eleven macaques in the control arm, ten were infected with SHIV after a median of four exposures to the virus. Both of the animals that received no gel became infected.

After 20 exposures to SHIV, none of the macaques that were treated with either the tenofovir gel or the FTC/tenofovir gel were infected. The investigators comment that this demonstrates that "both tenofovir alone and when combined with FTC provided very significant protection ($p < 0.005$)."

Drug-level monitoring demonstrated that low levels of FTC (median, 67ng/ml) or tenofovir (median, 22ng/ml) were consistently detected in blood after these drugs were administered. It was estimated that this represented just 0.029% of the total tenofovir dose and 0.026% of the FTC.

Reference

Dobard, C. et al. Complete protection against repeated vaginal seminal HIV exposures in macaques by a topical gel containing tenofovir alone or with emtricitabine. Sixteenth Conference on Retrovirus and Opportunistic Infections, Montreal, abstract 46, 2009.

Source: Gus Cairns & Michael Carter, AIDSMap.com report on Sixteenth Conference on Retroviruses and Opportunistic Infections (February 10th 2009)



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Other Microbicides News

Sexuality, HIV Risk and Potential Acceptability of Involving Adolescent Girls in Microbicide Research in Kisumu, Kenya

Females under age 18 have high rates of HIV acquisition and thus represent an important population for the clinical research of microbicides. Microbicide trials, however, primarily enroll adult participants. In the current study, the authors “sought to understand the individual, family, and community-level factors that may influence the acceptability of microbicide use and research involving adolescent girls.”

In Kisumu, Kenya, the researchers conducted 30 interviews with girls ages 14-17, as well as nine focus groups with adolescent girls, their parents, and community leaders. Discussion topics included adolescent sexuality, HIV prevention methods, perceptions about the use of microbicides, and views about microbicide research involving adolescent girls.

The results found that while adolescent sexuality is stigmatized, it is also “acknowledged to be a natural part of the ‘adolescent stage.’ Desperation to stop the spread of HIV among youth and support for female-initiated HIV prevention methods led to enthusiasm about microbicides and future microbicide research.”

However, participants raised numerous concerns about microbicides, including: the difficulty of using such a product in a timely fashion “due to the rushed, unplanned nature of adolescent sex”; the fear of experimental products; concerns about product efficacy; and parents’ worries “that supporting microbicide use in youth would defy societal pressures that denounce adolescent sexual activity.”

“Microbicide acceptability for youth in sub-Saharan Africa may be bolstered by desperation for

new methods to stop the spread of HIV, yet hindered by misgivings about experimental HIV prevention methods for youth,” the authors concluded. “Understanding and addressing the microbicide’s perceived benefits and shortcomings, as well as the broader context of adolescent sexuality and HIV prevention, may facilitate future research and promotion of microbicides in this high-risk group.”

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 01/30/2009
Original Source: Sexual Health Vol. 5; No. 4; P. 339-346 (11..08)::
Michele Montandon; Nuriye Nalan Sahin-Hodoglugil; Elizabeth Bukusi;
Kawango Agot; Brigid Boland; Craig R. Cohen



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HIV Hardens the Arteries

People with HIV seem to be at increased risk of developing serious illnesses such as heart disease and stroke.

There has been debate about the reasons for this. Treatment with some anti-HIV drugs can increase levels of blood fats, a risk factor for heart disease. But some researchers have suggested that HIV infection itself increases the risk of heart disease.

A US study has found evidence supporting the theory that HIV itself is a major risk factor for heart disease.

Researchers from the FRAM study showed that HIV infection increased the severity of hardening of the arteries (atherosclerosis) as much as smoking and diabetes.

They measured the thickness of the carotid artery in the neck of 433 people with HIV and over 5700 HIV-negative individuals.

Results showed that the carotid artery was significantly thicker in the people with HIV.

This was still the case when the researchers took into account factors such as age, sex, ethnicity and traditional risk factors for heart and lung disease such as smoking, diabetes and high blood pressure.

HIV-positive women seemed to have a greater risk of having a hardening of the carotid artery than HIV-positive men.

The researchers estimated that HIV infection independently increased the extent of hardening of the arteries by about the same amount as well-established risk factors for heart disease like smoking and diabetes.

Although the researchers think that a

HIV-positive women seemed to have a greater risk of having a hardening of the carotid artery than HIV-positive men.

number of factors are associated with the risk of heart disease for people with HIV, they think that the effect of HIV itself is “very large” and much greater than any effect associated with anti-HIV drugs.

It's recommended that HIV treatment should be started when a person's CD4 cell count is around 350 cells/mm³ - one of the reasons for this was that research showed patients with a CD4 cell count of this level and above had a lower risk of heart disease than patients with lower CD4 cells counts.

Source: AIDSMap.com report on Sixteenth Conference on Retroviruses and Opportunistic Infections



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Treatment as Prevention

One of the hottest topics in the HIV field over the past year has been the infectiousness (or otherwise) of people taking HIV treatment and who have an undetectable viral load. The issue was thrust into the spotlight by what's become known as the "Swiss Statement", that said people who were fully adherent to their HIV treatment, who had an undetectable viral load and did not have any sexually transmitted infections were not able to transmit HIV to their heterosexual partners. Few have publicly backed the Swiss, but there is a general consensus that HIV treatment can significantly reduce the risk of HIV transmission.

Two studies have been presented to CROI demonstrating that there is a lower risk of HIV transmission in serodiscordant heterosexual couples when the HIV-positive partner is on treatment. The first study was conducted in Rakai, Uganda and involved serodiscordant heterosexual couples. It found that there were no cases of HIV transmission in couples where the HIV-positive partner was on treatment. In contrast, an HIV incidence rate of 9 per 100 person years was seen in couples where the HIV-positive partner was not on treatment. But the Rakai study was limited by the small study sample (205 couples) and its short duration (one year).

A larger and longer study conducted in Rwanda and Zambia was also presented to the conference. This study included just under 3000 couples and lasted from 2002 to 2008. There was a total of 175 HIV transmissions, and 171 of these were in couples where the HIV-positive partner was not taking HIV treatment. This meant that the risk of HIV transmission was three to fivefold lower in serodiscordant heterosexual couples when the HIV-positive partner was taking HIV treatment. The

researchers did not have any information on the viral load of the individuals who transmitted HIV to their partners.

Source: AIDS MAP.com Daily New Update from Sixteenth Conference on Retroviruses and Opportunistic Infections, February 11th 2009

Many Maternal HIV Transmissions May be Due to Infection During or After Pregnancy

About 40% of cases of mother-to-child HIV transmission could be because the mother became infected with HIV during pregnancy or when breastfeeding, researchers told CROI. The study was conducted in Botswana in 2007 and involved 644 women on maternity wards or attending child immunisation clinics.

They found that HIV prevalence was 1.3% amongst the women on maternity wards, but 3% amongst women attending immunisation clinics.

The researchers therefore believe that many women are infected with HIV later in pregnancy or in the first year after giving birth when they are still breastfeeding.

They used their findings to calculate the proportion of HIV transmissions that were due to women becoming infected during pregnancy or after delivery and cautiously estimated this to be 43%. Routine re-testing of HIV-negative women during pregnancy was recommended by the researchers.

Source: AIDS MAP.com summaries of Sixteenth Conference on Retroviruses and Opportunistic Infections, February 11th 2009



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United States

Premarital Abstinence Pledges Ineffective, Study Finds

Teenagers who pledge to remain sexually abstinent until marriage are just as likely to have premarital sex as their non-pledging peers and are significantly less likely to use condoms and other forms of birth control once sexually active, a new analysis of data from a large federal study shows.

“Taking a pledge doesn’t seem to make any difference at all in any sexual behavior,” said report author Janet E. Rosenbaum of the Johns Hopkins Bloomberg School of Public Health.

The analysis included data from the National Longitudinal Study of Adolescent Health, which compiled detailed information from a representative sample of approximately 11,000 students in grades seven through 12 in 1995, 1996, and 2001. While researchers have previously used the data to examine abstinence education programs, the new study is the first to account for other factors that may influence the teen’s behavior, including their attitudes about sex, their parents’ attitudes about sex, and their perception of their friends’ attitudes about sex and birth control.

Rosenbaum studied roughly 3,400 students who said in 1995 they had neither had sex nor taken a virginity pledge. She

compared 289 students who subsequently took a pledge in 1996 with 645 otherwise similar non-pledgers.

The study found that by 2001, 82 percent of pledgers had broken their promise. For both groups, there was no significant difference in the proportion of students who had engaged in any type of sex, including oral and vaginal sex, the age at sexual debut, or the number of sex partners.

While there was no difference in the rate of STDs in the two groups, the percentage of students who reported

condom use was lower for those who had taken a pledge - 24 percent compared to 34 percent for non-pledgers.

“There’s been a lot of work that has found that teenagers who take part in abstinence-only education have more negative views about condoms. They tend not to give accurate information about condoms and birth control,” said Rosenbaum.

The study, “Patient Teenagers? A Comparison of the Sexual Behavior of Virginity Pledgers and Matched Non-Pledgers,” was published in *Pediatrics* (2009;123(1):e110-e120).

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 01/05/2009
Original Source: Washington Post (01.29.09):: Rob Stein

Teenagers who pledge to remain sexually abstinent until marriage are just as likely to have premarital sex... and are significantly less likely to use condoms and other forms of birth control.



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Skiping Doctor Visits Risky for HIV Patients

The death rate for HIV patients who miss scheduled clinic appointments during their first year of treatment is more than double that for patients with perfect attendance, according to a recent study.

Dr. Michael J. Mugavero and colleagues at the University of Alabama-Birmingham studied 543 patients who began outpatient HIV care at the school's 1917 HIV/AIDS Clinic between 2000 and 2005. Of the patients, 60 percent missed an office visit in the first year of treatment. Even after controlling for immune system function at the outset and HIV drug therapy in that first year, the mortality rate for patients who made all scheduled visits was one per 100 persons per year, compared to 2.3 per 100 person-years in those who missed appointments. Furthermore, the increased risk of death was similar when patients missed only one, or two or more visits.

"Considering tens of thousands of individuals are newly diagnosed with HIV infection in the United States annually, and the high frequency of missed visits in the first year of care - which was associated with over a two-fold increase in mortality in our study - extrapolation of our findings to the general population level has profound public health implications," said Mugavero.

"For HIV care providers, missed visits shortly after establishing outpatient care serve as a marker identifying patients at higher risk for poor clinical outcomes - patients who may require closer monitoring," Mugavero added.

The study, "Missed Visits and Mortality Among Patients Establishing Initial Outpatient HIV Treatment," was published in *Clinical Infectious Diseases* (2009;48(2):248-256).

Canada: Most Grade Five Girls Given HPV Vaccine

Preliminary figures show approximately 65 percent of fifth-grade girls in Edmonton's public and Catholic schools have been vaccinated against human papillomavirus (HPV). Firm provincial data are expected in late January or early February.

Alberta Health committed \$10 million annually to provide the Gardasil vaccine for free to grade five girls beginning in September of last year. Gardasil protects against four strains of HPV linked to 70 percent of cervical cancers and 90 percent of genital warts.

However, some Catholic leaders in the province opposed the vaccination program, fearing it could send "a message that early sexual intercourse is allowed, as long as one uses protection," Calgary Bishop Frederick Henry and other Alberta bishops wrote in a position statement.

The Edmonton Catholic School Board decided to offer the free vaccine, while other Catholic districts including Calgary, Elk Island, Grande Prairie, St. Thomas Aquinas, and Lakeland opted out. In Calgary Catholic schools, just 18.9 percent of targeted students were vaccinated against HPV at community clinics following the district's decision not to let public health nurses give the shots on school property.

Dr. Barbara Romanowski, a University of Alberta professor specializing in infectious diseases, called the Calgary Catholic school results "very, very disappointing." "I think they're a reflection of

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 02/12/2009
Original source: Reuters Health (02.11.09): David Douglas

continued



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HPV Vaccine (continued)

misinformation and inappropriate interference of the church in the health of the girls. Eighty or 82 percent of girls have absolutely no protection when they choose to become sexually active, which is very sad," she said.

Dr. Marcia Johnson, deputy medical health officer for Alberta Health Services Edmonton region, said she suspects many Catholic parents in Calgary were too busy to book vaccination appointments for their daughters outside school. "It's my assumption the low uptake may be related to convenience factors and not just lack of interest in the vaccine," she said.

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 01/14/2009
Original Source: Edmonton Journal (01.13.09): Jodie Sinnema

California: One in Four Teens Got Cervical Cancer Vaccine in '07

A report released Tuesday by the University of California-Los Angeles' Center for Health Policy Research finds high levels of awareness and acceptance of the human papillomavirus vaccine Gardasil among Californians.

In 2007, Gardasil's first full year of distribution, one in four teenage girls in the state - roughly 378,000 - received at least one dose of the vaccine, according to the survey. Gardasil is administered in three shots over a period of six months. And among those who had not started the series, a majority of teens, young adult women, and their parents expressed support for the vaccine.

Gardasil protects against strains of the STD linked to the majority of cervical cancer and genital wart cases. When it was approved in June 2006, critics argued it was too new for its long-term effectiveness and safety to be known; that it was too expensive; that it was unnecessary because Pap smears already look for cervical cancer; and that it could be viewed as tacit approval of premarital sex. In 2007, CDC recommended the vaccine for girls ages 11-12 and as well as other females up to age 26.

The study is the first to examine Gardasil vaccination rates within a single state. Researchers used a large database, the California Health Interview Survey, in which more than 50,000 residents are periodically interviewed via telephone.

Sociologist David Grant, the survey's director, said preliminary results showed little difference in acceptance by race, ethnicity or economic status. The researchers plan to release additional data on how different ethnic and socioeconomic groups have complied with CDC's recommendation.

Grant said the team was surprised to find widespread acceptance of Gardasil, which is attributed in part to aggressive marketing by its maker, Merck & Co. "It's hard to open a magazine targeted to young women and not see an ad for Gardasil," he said.

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 02/19/2009
Original Source: Los Angeles Times (02.18.09): Mary Engel



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Kenya: Adult Male Circumcision: Effects on Sexual Function and Sexual Satisfaction

While male circumcision is being promoted as an HIV prevention tool in high-risk heterosexual populations, there is concern about the procedure's effect on sexual function. The researchers undertook the current study to assess how adult male circumcision impacts male sexual function and pleasure.

The subjects were participants in a controlled trial of circumcision to reduce HIV incidence in Kisumu, Kenya. The men were uncircumcised, HIV-negative, sexually active, ages 18 to 24, with a hemoglobin of 9.0 mmol/L or greater. Exclusion criteria included having a foreskin covering less than half the glans, which might unduly increase surgical risks, or a medical indication for circumcision. The participants were randomized 1:1 to receive immediate circumcision (circumcision group) or delayed circumcision after two years (control group). Detailed evaluations were conducted at one, three, six, 12, 18, and 24 months. The main outcome measures were sexual function between circumcised and uncircumcised men; and sexual satisfaction and pleasure over time following circumcision.

From February 2002 to September 2005, 2,784 men were randomized, including 100 excluded from analysis because they crossed over; were not circumcised within 30 days of randomization; did not complete baseline interviews; or were outside the age range.

From baseline to month 24, rates of any reported sexual dysfunction decreased from 23.6 percent to 6.2 percent for the circumcised group,

and from 25.9 percent to 5.8 percent for the uncircumcised group. "Changes over time were not associated with circumcision status," the authors noted. Sixty-four percent of the circumcised men rated their penis as "much more sensitive" after the operation, and 54.5 percent rated their ease of reaching orgasm as "much more" at month 24.

"Adult male circumcision was not associated with sexual dysfunction," the authors concluded. "Circumcised men reported increased penile sensitivity and enhanced ease of reaching orgasm. These data indicate that integration of male circumcision into programs to reduce HIV risk is unlikely to adversely effect male sexual function."

Source: Journal of Sexual Medicine Vol. 5: P. 2610-2622 (11..08):: John N. Krieger, MD; Supriya D. Mehta, PhD, MHS; Robert C. Bailey, PhD, MPH; Kawango Agot, PhD, MPH; Jeckoniah O. Ndinya-Achola, MD; Corrette Parker, PhD; Stephen Moses, MD
Original Source: Journal of Sexual Medicine Vol. 5: P. 2610-2622 (11..08):: John N. Krieger, MD; Supriya D. Mehta, PhD, MHS; Robert C. Bailey, PhD, MPH; Kawango Agot, PhD, MPH; Jeckoniah O. Ndinya-Achola, MD; Corrette Parker, PhD; Stephen Moses, MD



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United States: New Cream Disables Herpes Virus

Noting that “a vaginal microbicide able to protect against [herpes simplex virus-type 2] transmission could contribute significantly to controlling sexually transmitted diseases,” researchers say they have developed a cream that may protect against the virus for up to one week.

Herpes viruses - HSV-2, which causes genital herpes; herpes simplex virus-type 1, which causes cold sores; and varicella, which causes chicken pox and shingles - target nerve cells. The viruses stay latent in the host person or animal, often causing periodic outbreaks. Acyclovir and similar drugs can suppress symptoms and are available as both creams or pills. However, these treatments have not been shown to prevent infection.

Deborah Palliser of Harvard Medical School and Albert Einstein College of Medicine and colleagues worked with Alynam Pharmaceuticals Inc. to develop the cream using small interfering RNAs (siRNAs). These molecules can silence microRNAs, tiny strands of ribonucleic acid, that help to turn genes into proteins. The cream targets a gene called nectin-1; mice engineered to lack this gene are less likely to be infected with HSV-2.

However, the researchers found that the cream took one day or so to “silence” nectin-1. Attacking a second gene, UL29, which is found in the herpes virus itself, provided immediate protection, they noted. Incorporating both genes into the cream provided protection for approximately one week, they said. A type of cholesterol was employed to help carry the siRNAs, and the cream did not irritate the mice’s vagina.

While stressing that the cream is still in development and more research is needed, the

researchers concluded that “topically applied siRNAs might be useful to treat and prevent reactivation and sexual transmission of clinically latent HSV-2 infection.”

The study, “Durable Protection from Herpes Simplex Virus-2 Transmission Following Intravaginal Application of siRNAs Targeting Both a Viral and Host Gene,” was published in the journal *Cell Host & Microbe* (2009;5(1):84-94).

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 01/26/2009
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(janetm@pwn.bc.ca)

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