

HIV Trends and Women's Sexual Health

June 2009

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

Increasing Risk of HIV Among Older People, Doctors Failing to Diagnose Cases in Population, WHO Study Says

People ages 50 and older are more likely to have unprotected sex than younger groups, increasing their risk for HIV and other sexually transmitted infections, according to a recently released World Health Organization study, Reuters UK reports. According to the WHO Bulletin report, "The Unexplored Story of HIV and Aging," physicians are failing to diagnose new HIV cases in this population because the virus still is considered to affect mostly younger populations. Older generations are "assumed not to be at risk," but HIV prevalence and incidence in people ages 50 and older "seem surprisingly high, and the risk factors are totally unexplored," the study said.

According to Reuters UK, the most likely mode of HIV transmission among older people is sexual activity, with the increasing use of impotence treatments a possible explanation for the "increase in frequency." The study said that erectile dysfunction drugs "have been extending the sex life of many older individuals" since 1998 and "may be extending the HIV epidemic into older age groups." The use of such medications "in industrialized countries has been associated with risky safety practices," the study said (MacInnis, Reuters UK, 3/3).

George Schmid, one of the study's nine authors and a researcher with WHO's HIV/AIDS department, said it is "certainly true" that a majority of

continued

CONTENTS

Increasing Risk of HIV Among Older People	1
Study Shows Decreased Risk of Death From Opportunistic Infections With Earlier Antiretroviral Treatment	3
Combined Effect of Modern Highly Active Antiretroviral Therapy Regimens and Adherence on Mortality over Time	4
Antibodies Present in Long-Term HIV Survivors Could Contribute to Vaccine Development	5
Protein Grown in Tobacco Could Result in Low-Cost Microbicide	6
First Hint of Microbicide Efficacy	7
FDA Approves New Female Condom	8
Abnormal Cells in Cervix Raise Cancer Risk	9
Immigrant Parents Deal with the Forbidden Word	10



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Increased Risk of HIV Among Older People (continued)

the attention given to HIV/AIDS screening and prevention has been on younger generations "because those are the ones who are at most risk." However, "it doesn't mean that people who are 50 and older are at no risk, and we think there is an underappreciated number of individuals in that age group who are becoming infected," he said. Experts said that a larger focus needs to be placed on early HIV diagnosis among older people, and the study reports that there is not enough discussion of HIV even at the patient-care level. Schmid said, "Physicians don't think the (over-50s) are at risk, so they don't ask, or else they may be a bit uncomfortable asking." In addition, patients are "somewhat uncomfortable talking about these things," he said (Edwards, Canwest News Service/Ottawa Citizen, 3/4). Schmid also said that few HIV/AIDS surveys collect data about people ages 50 and older and primarily focus on people between ages 15 and 49.

Schmid said that the researchers "have been a bit surprised" by the "somewhat surprisingly high proportion" of older people living with HIV, which is about "one-quarter to one-third of the younger age groups" (VOA News, 3/3). Schmid said the "frequency" of HIV in older people is "worrying." He also said, "We need to understand why and when these people are becoming infected so that public health campaigns can be better targeted to prevent such infections" (AFP/Morningstar.com, 3/3).

... older women may be at increased risk for HIV transmission from unprotected sex because of thinning of the vaginal mucous membrane.

According to the Canwest/Ottawa Citizen, separate studies have shown that older people are less likely to practice safer sex than their younger counterparts, which can lead to increased risk of HIV (Canwest News Service/Ottawa Citizen, 3/4). Reuters UK reports that older women may be at a higher risk for HIV transmission from unprotected sex because of thinning of the vaginal mucous membrane ~ which gives natural lubrication ~ that comes with aging.

According to the study, the life expectancy for people who contract HIV at age 65 or older is four years, despite antiretroviral drugs that can extend life expectancies for some people. The authors said that "[w]aning immunity with age" could be the reason for the decline in life expectancy (Reuters UK, 3/3). The report said that erectile dysfunction and medicine to treat it is "common" and "widely available," but "no study has been done of their possible impact on the HIV epidemic" (Reuters UK, 3/3).

Source: Kaiser Daily HIV/AIDS Report: March 4, 2009



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Treatment

Study Shows Decreased Risk of Death From Opportunistic Infections With Earlier Antiretroviral Treatment

HIV-positive people with opportunistic infections who receive earlier antiretroviral treatment lower their risk of death compared with people who delay treatment, according to a new study conducted by the Stanford University School of Medicine and published in PLoS One, the San Jose Mercury News reports. The findings could lead to changes in recommendations for antiretroviral treatment protocol, specifically for patients diagnosed with HIV at an advanced stage, the Mercury News reports.

The study included 262 HIV-positive participants at 39 health care sites across the U.S., and 20 participants in South Africa. During the yearlong study, the researchers found that among the participants who were treated promptly after developing an opportunistic infection, 14% died or developed another infection. The researchers also found that 24% of participants who deferred treatment for an average of 45 days died or had a decrease in health outcomes.

According to the Mercury News, the question of when to start HIV-positive people on antiretroviral treatment remains unclear because of issues such as the high cost of medicines, side effects, and drug interactions or resistance. Andrew Zolopa, head of Stanford University School of Medicine's division of infectious diseases and lead investigator of the study, said that physicians often treat HIV-positive people for an "acute crisis, then follow up later

with treatment for HIV." He continues, "But that answer is wrong. The study shows very clearly that there is no safety downside to doing this ~ and the benefit is quite substantial, reducing death by 50%."

"Even in San Francisco, one of the first epicenters of HIV in the United States, we still find that many people present late in the course of their illness with an opportunistic infection," Mitch Katz, director of San Francisco's Department of Health who was not involved in the study, said. He added, "This study shows that it is

Physicians often treat HIV-positive people for an "acute crisis, then follow up later with treatment for HIV [...] But that answer is wrong"

lifesaving to treat those persons with antiretroviral drugs while they are still in the hospital." Katz said that the results could lead to changes in HIV/AIDS practices worldwide. The International AIDS Society, CDC and the British AIDS Society have developed guidelines recommending that early antiretroviral treatment be considered in patients with opportunistic infections, Zolopa said. In addition, NIH is considering an international study to examine earlier initiation of antiretroviral treatment involving more than 9,000 people from both developed and developing countries (Krieger, San Jose Mercury News, 5/15).

Source: Kaiser daily HIV/AIDS Report, May 19, 2009



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Treatment

The Combined Effect of Modern Highly Active Antiretroviral Therapy Regimens and Adherence on Mortality over Time

The current longitudinal study characterized the impact of adherence on survival in treatment-naïve patients initiating currently recommended highly active antiretroviral therapy (HAART) regimens.

The study focused on 903 patients who had initiated HAART between January 2000 and November 2004, following them until November 2005. The HAART regimens contained efavirenz, nevirapine, or ritonavir-boosted atazanavir or lopinavir.

Among the study participants, all-cause mortality was 11 percent, and individual adherence significantly decreased over the study period. The mean adherence level declined from 79 percent within the first six months after initiating HAART to 72 percent in the 24- to 30-month period (P value < 0.01). Over time, non-adherence (<95 percent) was strongly associated with higher mortality risk (hazard ratio: 3.13; 95 percent confidence interval [CI]: 1.95-5.05). Non-adherent patients taking nonnucleoside reverse transcriptase inhibitor (NNRTI)-based and boosted protease inhibitor-based regimens were, respectively, 3.61 times (95 percent CI: 2.15-6.06) and 3.25 times (95 percent CI: 1.63-6.49) more likely to die compared with patients who adhered to their regimens. Within the cohort taking NNRTI-based regimens, non-adherent patients on efavirenz were at a higher risk of mortality.

"Incomplete adherence to modern HAART over time was strongly associated with increased mortal-

ity, and patients on efavirenz-based NNRTI therapies were particularly at a higher risk if non-adherent," the study authors concluded. "These results highlight the need to develop further strategies to help sustain high levels of adherence on a long-term basis."

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 03/31/2009
Original Source: JAIDS Vol. 50; No. 5: P. 529-536 (04.09):: Viviane D. Lima, PhD; Richard Harrigan, PhD; David R. Bangsberg, MD, MPH; Robert S. Hogg, PhD; Robert Gross, MD, MSCE; Benita Yip, BSc (Pharm); Julio S.G. Montaner, MD, FRCPC, FCCP



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Vaccine Update

Antibodies Present in Long-Term HIV Survivors Could Contribute to Vaccine Development, Study Says

HIV-positive people who do not develop AIDS and do not require antiretroviral medication could provide insight for new strategies in vaccine development, according to a study published Sunday in the journal *Nature*, London's *Independent* reports. Michel Nussenzweig ~ head of Rockefeller University's Laboratory of Molecular Immunology and author of the study ~ said his research aimed to harness natural mechanisms to target HIV rather than use synthetically produced antibodies, some of which have failed in earlier HIV vaccine trials.

For the study, Rockefeller University researchers examined antibodies present in the blood of six long-term HIV survivors who appeared to have a degree of natural immunity to the virus (*Connor, Independent*, 3/16). The researchers isolated 433 antibodies from the patients, all of which targeted HIV's protective outer coating, or "envelope." The researchers then cloned the antibodies and observed which elements of the envelope each antibody targeted and how effectively it neutralized HIV. During the research, Johannes Scheid, a doctoral student at Rockefeller University, identified a new structure on the HIV envelope that scientists previously had not recognized as an antibody target. Although the researchers determined that each antibody individually had a weak effect on HIV, they also found that the antibodies as a group effectively targeted the virus (*PA/Google.com*, 3/15). In addition, the researchers determined that a prototype vaccine developed from several of the antibodies can prevent the growth of HIV in human cells in a test tube.

Nussenzweig said the study identified "many different antibodies that individually have limited neutralizing ability but together are quite powerful." According to Nussenzweig, only about one in every 1,000 HIV-positive people produces the neutralizing antibodies. He said the research attempts a new approach to HIV vaccine development by "copying what exists in nature and that we know can work because of the long-term survivors." He added, "Instead of inventing something that doesn't exist, it's trying to copy something that does exist." Nussenzweig said the study's results "should make people think about what an effective vaccine should look like." According to the *Independent*, the researchers next plan to conduct further trials of vaccine candidates on laboratory animals and human volunteers.

The *Independent* also profiled Kai Brothers, a San Francisco man who has been living with HIV for 28 years without developing AIDS or requiring antiretroviral medications. The *Independent* reports that Brothers, who did not participate in the new study, might be one of "a few ~ perhaps as few as one in 5,000" ~ HIV-positive people who have natural immunity to the virus. Brothers said he has participated in HIV research for 10 years, adding, "I feel dedicated to giving back something because of my good fortune" (*Independent*, 3/16).

Source: Kaiser Daily HIV/AIDS Report, March 17, 2009



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Microbicide News

Protein Grown in Tobacco Could Result in Low-Cost Microbicide, Study Says

Researchers on Monday announced that tobacco plants in Kentucky have been used in a study to develop a low-cost drug that inhibits HIV, providing hope for the eventual development of a vaginal microbicide, the Louisville Courier-Journal reports (Kenning, Louisville Courier-Journal, 3/31). The study, published Tuesday in the Proceedings of the National Academy of Sciences, was a collaborative effort between scientists at the Owensboro Cancer Research Program; the National Cancer Institute; Kentucky-based biotech companies Intrucept Biomedicine and Kentucky Bioprocessing; and researchers at Duke University and the University of London (Adkins, Business First of Louisville, 3/30).

According to the Courier-Journal, the researchers used a manufacturing process that utilized an existing protein called Giffithsin, which can inhibit HIV transmission during sexual activity. Kenneth Palmer, lead researcher and senior scientist at the University of Louisville, said that he used a method to grow large amounts of the protein in a relative of the tobacco plant at a low cost, producing 500,000 doses from a 5,000 square-foot greenhouse, the Courier-Journal reports. Palmer said the process resulted in a product that could be more effective than previous microbicide efforts.

According to Palmer, many scientists are pursuing HIV prevention methods, mostly in gel forms that attack the virus, but some have had side effects and were expensive to produce. The Courier-Journal reports that Palmer's product did not

appear to cause inflammation in users and that a vaginal gel made through the process "could potentially cost just a few cents." Palmer said that the end-product, likely a gel, could be available as early as 2015 if clinical trials are successful (Louisville Courier-Journal, 3/31). He estimated that "tens of millions" of dollars would be needed to continue the project through the third phase of clinical testing. Donald Miller, director of the James Graham Brown Cancer Center, said that international donors might be interested in assisting in funding the research. Miller said the new study is a "very important piece of work." He added, "We think this is a validation of our belief that this is going to be a very viable, cost-effective way to produce new drugs" (Business First of Louisville, 3/30). According to Palmer, condoms are the only product currently available and "they're obviously not enthusiastically embraced by all users." He added that there is "a big need for an effective, female-controlled intervention to protect from HIV" (Louisville Courier-Journal, 3/31).

Source: Kaiser Daily HIV/AIDS Report, April 1, 2009



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Other Microbicide News

First Hint of Microbicide Efficacy

Some of the more encouraging data at the 16th Conference on Retroviruses and Opportunistic Infections (CROI) – which was held this year from February 8-11 in Montreal – came from a triumvirate of clinical and nonhuman primate studies with new HIV prevention strategies. The first study, known as HPTN 035, evaluated the safety and efficacy of the microbicide candidate PRO 2000, a topical gel composed of 0.5% of a synthetic polyanionic polymer that non-specifically acts to block attachment of HIV to host cells.

This Phase IIb study enrolled 3,099 women at seven clinical trial centers in Africa and the US and evaluated the efficacy of PRO 2000, as well as a second topical microbicide called BufferGel, which contains an agent designed to boost the natural acidity of the vagina in the presence of seminal fluid.

The study also had two control arms—one received a placebo gel and the other, which was unblinded, received only condoms and no gel. A no-gel arm was included in the trial over concerns that the placebo might have antimicrobial properties that could protect against HIV.

The results of this study showed that women who were randomly selected to receive both PRO 2000 gel along with condoms had 30% fewer HIV infections than those who received the placebo gel and condoms. At the conclusion of this three-year trial, there were 36 HIV infections among women in the PRO 2000 group, compared to 54 in the

BufferGel group, 51 in the placebo gel group, and 53 in the no-gel group.

However, Salim Abdool Karim, a clinical infectious disease specialist who led the PRO 2000 study, cautioned that the results were not statistically significant compared to either the placebo gel or no-gel groups. “This could be a chance finding,” he said, adding that additional evidence would be necessary to “conclusively determine whether PRO 2000 is an effective microbicide.”

When researchers analyzed the data based on adherence, they found that women who reported using the gel at the last coital act at least 85% of the time, had an overall 44% reduction in HIV infection compared to women who received the placebo gel. And in women who reported using the gel that often without regularly using condoms, there was a 78% reduction in HIV infection compared to the placebo group.

There was a palpable level of excitement following Karim’s presentation, with many audience members rushing to the microphones to congratulate the researchers on the conduct and results of the trial. Karim said this excitement was understandable given the recent results from two trials of other microbicide candidates. Carraguard, made from a seaweed derivative, was found last year not to reduce the risk of HIV acquisition in a three-year, Phase III study of 3,200 women in South Africa. And a Phase III trial of cellulose sulfate that had enrolled 1,333 women was discontinued in Decem-

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First Hint of Microbicide Efficacy (continued)

ber 2007 after early data suggested that the microbicide candidate might be contributing to an increased risk of HIV infection.

"We are at the end of a series of disappointments," Karim said. "We need something that gives us hope. The HPTN 035 trial results represent that hope." A Phase III study of PRO 2000 conducted by the Microbicide Development Programme in the

UK is nearing completion in South Africa, Tanzania, Uganda, and Zambia. This trial has enrolled 9,000 women, and results, which are expected in late 2009, will provide additional data on whether PRO 2000 is effective at blocking HIV transmission.

Source: 'Canvassing CROI', IAVIReport 13/1, January-February, 2009: Kristen Jill Kresge & Regina McEnergy

Prevention

FDA Approves New Female Condom

The Female Health Company on Wednesday announced that FDA has approved its FC2 Female Condom to help prevent pregnancy and sexually transmitted infections such as HIV, the AP/Forbes reports. With the approval, the lower-cost, new version of the female condom now will be available in the U.S. In addition, USAID now can procure the condoms and distribute them through HIV/AIDS programs worldwide (AP/Forbes, 3/11).

The new female condom is made of synthetic rubber instead of polyurethane and is less expensive than the original version. According to the Chicago Tribune's "Triage," both the new version and older version are equally effective. The new version likely will cost about 30% less than the older version, making it more affordable for individuals and public health groups, Mary Ann Leeper, strategic adviser to FHC, said (Graham, "Triage," Chicago

Tribune, 3/11). The new version also is manufactured through a less-expensive process, which FHC said should allow health groups to distribute larger quantities to women in Africa and other areas heavily affected by HIV/AIDS. The FDA approval is an "important development in efforts to deliver affordable access to woman-initiated HIV prevention in the United States and around the world," Leeper said (Reuters India, 3/11).

The World Health Organization in 2006 approved the new version of the female condom for purchase by United Nations agencies, according to FHC. More than 23 million FC2 condoms have been distributed in 77 countries since then (AP/Forbes, 3/11).

Source: Kaiser Daily HIV/AIDS Report, March 12, 2009



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Cervical Cancer News

Abnormal Cells in Cervix Raise Cancer Risk: Study

Whether abnormal changes in cervical cells - known as cervical intraepithelial neoplasia (CIN) - return or develop into cervical cancer depends in part on a woman's age and the type of treatment she receives, a new study finds.

CIN is mainly caused by human papillomavirus (HPV), a common STD. The condition is grouped into three stages: mild or grade 1, with just a few abnormal cells; grade 2; and severe or grade 3, in which precancerous cells are found in the top layer of the cervix. Pap smears sample the cervix for evidence of CIN.

Joy Melnikow of the University of California-Davis and colleagues studied more than 37,000 women from Canada's British Columbia Cancer Agency who were treated for CIN from 1986 to 2000. These women were compared to a group of more than 71,000 who had no history of abnormal cervical cells. Both groups were followed through 2004.

According to the researchers, the risk of cervical cancer and recurrence of grade 2 or 3 CIN was highest for women over age 40, those previously treated for grade 3 abnormal cells, and those whose cells were frozen via cryotherapy. Women who underwent cone biopsy, whereby cells are surgically removed, were the least likely to have recurrent CIN.

Melnikow added that in general, most recurrences of CIN happened in the first six years of treatment. Women who have been treated for CIN have "a low, but higher-than-average risk of invasive cancer, so they need regular screening over an extended period of time," she said.

In addition, women treated surgically have a higher risk of bleeding and preterm labor when they become pregnant, said Melnikow. "Younger women planning later pregnancies may prefer cryotherapy; their risk of recurrence is lower and a recurrence can be treated again," she said.

The study could not assess whether women experiencing recurrence had HPV infections that caused their original abnormal cells to return, the researchers noted.

The study, "Cervical Intraepithelial Neoplasia Outcomes After Treatment: Long-Term Follow-Up from the British Columbia Cohort Study," was published online in the Journal of the National Cancer Institute (2009;doi:10.1093/jnci/djp089).

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 05/21/2009
Original Source: Reuters (05.12.09):: Julie Steenhuyzen

Women who have been treated for CIN have "a low, but higher-than-average risk of invasive cancer, so they need regular screening over an extended period of time"



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Canada

Immigrant Parents Deal with the Forbidden Word

Recently, 106 parents from the area's diverse immigrant communities graduated from a Toronto Public Health program that promotes family sex education and parent-child communication. Many of the parents had little exposure to sex education, and for some even talking about sex would typically be considered taboo. The TPH outreach, "Raising Sexually Healthy Children: Peer-Parent Leadership Training Program," consists of three weekly, 90-minute sessions.

On a recent Saturday at a Mandarin-speaking workshop, Julie Wang spoke without embarrassment to seven men and women about penises, erections, and masturbation. "Regardless of age, is it normal for children to play with their sexual organ?" Wang read from a list of questions for the parents. "Not when they are under five, right?" a woman whispered.

"Masturbation is actually quite normal, but it's supposed to be done privately," Wang said. "But for religion or other reasons, kids are shamed [by adults] and feel guilty of doing it." Wang distinguished "filth by hand," a Chinese term for masturbation, from the more neutral "self-comfort" phrase.

"These parents get a letter about sex education at their child's school, and they don't know what the teachers are going to tell their kids," said Anda Li, a TPH sexual health educator and peer education program administrator. "And it is so difficult for them to ask because sex is such a taboo in their

own culture." "Raising sexually healthy kids can reduce [STDs], unwanted pregnancy, and even gay bashing," Li noted.

First launched in 1996 by TPH and a coalition of community groups, the program now has peer leaders for the Bengali, Chinese, Korean, Portuguese, Spanish, Tamil, and Vietnamese communities. The parent-trainees are supported in delivering 52 workshops through funding from the Ontario Trillium Foundation.

Source: CDC HIV/Hepatitis/STD/TB Prevention News Update 05/05/2009
Original Source: Toronto Star (04.30.09):: Nicholas Keung

HIV Trends and Women's Sexual Health is published quarterly. Archived copies can be found on our website:
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