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FOR IMMEDIATE RELEASE

Use of lubricants with anal sex could increase risk of HIV New Research Presented at International Microbicides Conference

PITTSBURGH, May 23 – The risk of acquiring HIV through unprotected anal sex is at least 20 times greater than with unprotected vaginal sex and increases if other infections are already present in the rectal lining. Could the use of lubricants – at least certain kinds – be another risk factor among men and women who engage in receptive anal intercourse? Two studies presented today at the International Microbicides Conference in Pittsburgh, suggest the answer is yes.

In one study involving nearly 900 men and women in Baltimore and Los Angeles, the researchers found that those who used lubricants were three times more likely to have rectal sexually transmitted infections (STIs). Another study that subjected popular over-the-counter and mail-order lubricants to rigorous laboratory tests discovered that many of the products were toxic to cells and rectal tissue. If in humans, these products have the same effect, the cells might be rendered more vulnerable targets for HIV infection than they already are.

In the United States alone, receptive anal intercourse is practiced in up to 90 percent of gay and other men who have sex with men, according to International Rectal Microbicides Advocates. Moreover, the practice is not limited to men. U.S. estimates and surveys in the United Kingdom indicate between 10 to 35 percent of heterosexual women have engaged in anal sex at least once. Globally, estimates suggest 5 to 10 percent of sexually active women are having anal sex. While condoms are generally effective for protecting against HIV and other STIs, most acts of anal sex go unprotected.

Microbicides – substances applied topically on the inside of the rectum or vagina – could potentially help prevent the rectal transmission of HIV, and some are being tested in early Phase I safety studies. Another approach called oral pre-exposure prophylaxis (PrEP) involves the use of antiretroviral drugs to reduce the risk of HIV in HIV-negative people. A large Phase III trial of PrEP involving men who have sex with men in South America, Africa and the United States is expected to report results by early next year. Yet, if either of these approaches is found effective in clinical trials, they will do no good if those most at risk don't use them. Other research presented today sheds light on this issue. Summaries of all three studies are provided below.

M2010 is taking place May 22-25 at Pittsburgh's David L. Lawrence Convention Center. Nearly 1,000 participants from 47 different countries are attending the meeting to hear about the latest developments in HIV prevention research.

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Use of lubricants with anal sex associated with more rectal STIs

Lubricants are typically used before and during receptive anal intercourse, but their use could increase the risk of rectal sexually transmitted infections (STIs), a study involving nearly 900 men and women in Baltimore and Los Angeles has found. Even after controlling for gender, HIV status, city, condom use, and number of sex partners in the past month, the association between lubricant use before receptive rectal intercourse and rectal STIs remained strong, reported Pamina Gorbach, Dr.PH, from the School of Public Health and the David Geffen School of Medicine at the University of California, Los Angeles, who led the study. According to the study's statistical analysis that considered the HIV status, gender, condom use and study site, participants who used lubricants before receptive anal intercourse were three times more likely to have a rectal STI. Although the analysis didn't consider the specific lubricants being used, it may be that certain types of products are more irritating to the lining of the rectum than others, which could increase men and women's vulnerability to rectal STIs, the researchers suggest.

The study, which was conducted between October 2006 and December 2008, examined the rectal health and behaviors of 879 men and women. Participants in the study were tested for gonorrhea and Chlamydia and asked about their sexual and hygiene practices in private computer-based interviews. Of the 879 participants, 421 reported having receptive anal intercourse in the past month (229 men) or in the past year (192 women) and of these 421, 302 provided the researchers with additional information about their use of lubricants. About half, or 147 (52.7 percent) said they used a lubricant when they last engaged in anal sex.

Of the 302 included in the analysis, 25 (8.3 percent) tested positive for a bacterial rectal STI (5.6 percent of women and 10.2 percent of men). But among those who said they recently used a lubricant, the number of STIs was higher. With STI test results available for 145 of the 147 recent users, the researchers found that 17 (11.7 percent) tested positive for a rectal STI compared to just seven (5.1 percent) of the 156 who said they did not use a lubricant. A higher percentage of African Americans (61 percent) reported using lubricants than did Hispanics (40.4 percent) and whites (23.2 percent). A higher percentage of HIV-positive participants (56 percent) were more likely to report using lubricants than were HIV-negative participants (43.7 percent). Most of the participants who reported using lubricants said they used a water-based lubricant (76 percent); 28 percent used silicon-based products, 17 percent oil-based lubricants and 6 percent said they had used numbing lubricants. More research will be needed to understand exactly how lubricants facilitate transmission of STIs, including HIV, the researchers say.

Study is first to evaluate safety of lubricants used in anal sex

A laboratory study that compared over-the-counter and mail-order lubricants commonly used with receptive anal intercourse found many of the products contain higher amounts of dissolved salts and sugars compared to what's normally found in a cell. As a result, the products had toxic effects on the cells and rectal tissue studied. Some of the lubricants caused significant portions of the epithelium – the layer of cells that serves as a protective barrier inside the rectum – to be stripped away. Conclusions cannot be made based on this study alone, though the results are compelling enough to wonder if these lubricants might have the same effect in people and thereby increase susceptibility to HIV, commented Charlene Dezzutti, Ph.D., from the University of Pittsburgh and Magee-Womens Research Institute, who led the study for the Microbicide Trials Network. The study, which was conducted in collaboration with International Rectal Microbicides Advocates (IRMA), was undertaken because little is known about the safety of lubricants even though they are frequently used during anal sex.

Six products were studied. Five (Astroglide, Elbow Grease, ID Glide, KY Jelly and Wet Platinum) were selected because they had been identified as those most commonly used by the more than 6,300 respondents to an IRMA survey. The sixth product (PRÉ) was selected to serve as a control because it is isomolar. Osmolarity refers to the concentration of dissolved particles (salts and sugars) found inside a cell relative to the outside. A product that is isomolar has the same concentration of particles as inside the cell, whereas a product that is hyperosmolar has a higher concentration of salts and sugars relative to the cell. To correct this imbalance, a cell forces water out but then it becomes withered and dies. Most of the lubricants studied were water-based, except for Wet Platinum, which is a condom-compatible silicone-based product. The researchers characterized each product according to

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its osmolarity, pH and viscosity – or slipperiness. Studies then were conducted to determine the effect of each lubricant on different cell types, rectal and cervical tissue and on bacteria (microorganisms that are important to the health of the rectum). Based on the tests performed, PRÉ and Wet Platinum were shown to be safest, while Astroglide was the most toxic to cells and tissues, and KY Jelly had the worst effect on the good bacteria, essentially wiping out an entire colony. PRÉ was the only water-based lubricant that was not hyperosmolar and did not disrupt the epithelium. None of the lubricants had measurable anti-HIV activity. In future studies, the researchers hope to determine the effect that different lubricants have on susceptibility to HIV infection in tissues.

The bad news: Boston survey finds awareness about PrEP poor among MSM;

The good news: MSM likely to use PrEP and microbicides for prevention

Despite being representative of one of the highest at-risk populations for HIV, a large number of HIV-uninfected men who have sex with men (MSM) surveyed as part of a study had never heard of pre-exposure prophylaxis (PrEP), the use of antiretroviral (ARV) drugs by HIV-negative individuals for preventing HIV. PrEP is being evaluated in several trials in different at-risk populations, including MSM. The study, which was conducted in the Boston area, involved 105 MSM who reported having unprotected receptive anal intercourse at least once in the prior year with a partner they knew was HIV positive or didn't know for sure whether or not they were infected. The participants had been enrolled in a study to determine the acceptability of rectally administered placebo gels and suppositories. The survey was conducted at the time of enrollment to help understand the demographic and behavioral factors that may increase men's likelihood for using a microbicide or oral PrEP, reported Kenneth Mayer, M.D., of the Fenway Institute in Boston and Brown University in Providence, R.I. The average participant's age was 39; 70.5 percent had at least a high school education; 24 percent were African-American and 8.6 percent were Latino. Participants reported having an average of more than four sex partners in the two months prior to their enrolling in the study.

While 44.8 percent of the participants had heard of post-exposure prophylaxis (PEP) for preventing HIV, whereby anti-HIV drugs are administered within 72 hours of an exposure, such as through unprotected sex or an occupational needle-stick injury, only 20 percent had heard of PrEP. However, once participants were informed about both approaches, as well as about rectal microbicides, nearly 60 percent indicated they would likely use PEP, 40 percent said they would use PrEP, and half said they would likely use a rectal gel for prevention. The responses did not differ by demographic characteristics. Men who indicated they were most likely to use rectal microbicides were also more likely to use PrEP. While the study was small, the results are instructive to efforts for raising awareness and understanding about the HIV prevention approaches that are currently in clinical trials. This in turn may help facilitate adherence to and improve effectiveness of these approaches if they become widely introduced, say the researchers.

More than 33 million people are living with HIV, more than two thirds of them in sub-Saharan Africa, according to UNAIDS. The number of new infections continues to outstrip advances in treatment: For every two people who begin treatment, five are newly infected. Globally, women account for half of all HIV infections, and in sub-Saharan Africa, women comprise 60 percent of all infected adults. Young women are especially vulnerable. In southern Africa women aged 15 to 24 are at least three times more likely than their male peers to be infected with HIV. Meanwhile, men who have sex with men (MSM) bear the burden of the epidemic in the United States and in other parts of the world, such as Europe, Latin America, Australia and New Zealand. According to the U.S. Centers for Disease Control and Prevention, MSM of all races is the only risk group in the United States in which new HIV infections are increasing. Black heterosexual women represent the third highest risk group in the United States, after white MSM and black MSM, respectively.

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M2010 is the sixth biennial meeting of the International Microbicides Conference and marks the first meeting in the United States since the 2000 inaugural gathering in Washington, D.C. Other previous meetings have been in Antwerp, Belgium; London, England; Cape Town, South Africa; and New Delhi, India. Co-chairs of this year's conference are Sharon Hillier, Ph.D., and Ian McGowan, M.D., Ph.D., both of the University of Pittsburgh; and Gita Ramjee, Ph.D., of the Medical Research Council of South Africa.

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NOTE TO EDITORS: Drs. Pamina Gorbach, Charlene Dezzutti and Kenneth Mayer will discuss the results of their research during a **press briefing on Tuesday, May 25 at 1:15 p.m., ET** that will be moderated by Dr. Ian McGowan. For information on how to participate by teleconference, contact Ian Temple at itemple@globalhealthstrategies.com. (Journalists in countries for which there is not a toll-free dial-in number can be called by the teleconference operator.) Abstracts and lay summaries being discussed in this press briefing will be posted at <http://www.microbicides2010.org/media> between 9:30-11 a.m., the morning of the briefing. Journalists may also request scientific abstracts or lay summaries of research being featured in press briefings by contacting Lisa Rossi at rossil@upmc.edu or +1-412-916-3315 (mobile), or between May 22-25, at +1 (412) 325-6063/6064. The on-site press room for registered media is located in Room 309 of the Convention Center. Hours of operation are 7 a.m. to 7 p.m. (ET), Saturday, May 22 through Tuesday, May 25. Press room staff can be reached during this time at +1 (412) 325-6063/6064. The scientific program and other information about the meeting can be found at www.microbicides2010.org.