Pregnancy doubles HIV risk in men; first trial of a microbicide in pregnant women

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Young women of reproductive-age are among those at greatest risk of acquiring HIV, and several studies have suggested that during pregnancy women are even more susceptible to infection. Now, a new study finds that pregnancy is a time when men also are at greater risk. In fact, their risk doubles if their partner is both HIV-infected and pregnant.

The results were presented today at the International Microbicides Conference (M2010) in Pittsburgh, along with findings of a pivotal study that is the first to ask whether using a microbicide during pregnancy is safe for women and their babies.

Between 70 and 90 percent of all HIV infections in women are acquired through heterosexual intercourse, and women are twice as likely as their male partners to acquire HIV during sex, due in part to biological factors that make them more susceptible. Many women remain sexually active during pregnancy. Although correct and consistent use of male condoms has been shown to prevent HIV infection, women often cannot or do not wish to negotiate condom use with their male partners. And for many women, especially those who wish to become pregnant, abstinence is not an option they can consider. Microbicides -- substances designed to be applied topically on the inside of the rectum or vagina - are under active investigation as a method for women to use to protect against HIV.

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. Summaries of the two pregnancy-related studies are provided below.

Pregnancy doubles HIV risk in men, study finds

While a number of studies have shown that during pregnancy women are at increased risk of acquiring HIV from an infected partner, a new study has found pregnancy is a time when men also are at greater risk - double the risk, in fact. The study, which involved 3,321 couples in which one partner was HIV-infected and the other not, is the first to show that a man in a relationship with an HIV-positive woman has a greater chance of becoming infected while she is pregnant than when she is not.

Even after accounting for behavioral and other factors that usually contribute to HIV risk, the increased risk associated with pregnancy remained. Biological changes that occur during pregnancy may make women more infectious than they would be otherwise, explains Nelly Mugo, M.D., M.P.H., of the University of Nairobi & Kenyatta National Hospital in Nairobi and the University of Washington in Seattle, who presented results of the study on behalf of the Partners in Prevention HSV/HIV Transmission Study team. The study was conducted in Botswana, Kenya, Rwanda, South Africa, Tanzania, Uganda and Zambia.

The researchers followed for up to two years 1,085 couples in which the male was infected and 2,236 couples in which the female was infected to understand the different circumstances and determinants that may contribute to HIV risk. During this time, 823 pregnancies took place, which allowed the researchers to look more closely at the particular risk factors for HIV that occur during pregnancy and not. In their analysis, they found that pregnancy was associated with increased risk of both female-to-male and male-to-female HIV transmission. But for women with an HIV- infected partner, the study found that factors other than

pregnancy also likely contributed to this increased risk, such as sexual behavior. In men, however, the link between pregnancy and HIV risk was much clearer, even after considering whether or not they had engaged in unprotected sex or were circumcised. Measures of viral load and CD4 counts of the infected partner also had no bearing. Increased female-to-male transmission of HIV during pregnancy may be due to physiological and immunological changes that occur with pregnancy, the authors conclude, but more research will be needed to confirm this hypothesis.

Microbicide study in pregnant women takes a giant baby step for HIV prevention research

Results of the first study of a vaginal microbicide tested in pregnant women found only small amounts of drug are absorbed into the bloodstream, amniotic fluid and umbilical cord blood. The study, which involved applying a single dose of tenofovir gel hours before women gave birth by cesarean delivery, was conducted as a first step toward determining if use of a vaginal microbicide during pregnancy is safe for women and their babies. The findings support continuing with further studies of tenofovir gel in pregnant women, said Richard Beigi, M.D, MSc., of the University of Pittsburgh and Magee-Womens Hospital of UPMC, who led the study for the Microbicide Trials Network.

The active ingredient in tenofovir gel is an antiretroviral that is approved as an oral drug and used as part of the standard HIV treatment regimen. Both research and clinical experience with the oral drug have indicated its use is safe in HIV-infected women during pregnancy. In previous studies looking at the use of oral tenofovir for the prevention of mother-to-child transmission of HIV, researchers found that low amounts of drug pass to the baby. In the current trial, which involved healthy, uninfected pregnant women, the amount of drug found in umbilical cord

blood was 40-times lower than cord blood levels noted in these other studies after oral dosing, and the amount that got absorbed into the maternal blood was at levels 50- to 100-times lower.

Young women of reproductive-age are among those who are at greatest risk of acquiring HIV. Pregnancy is a time when they may be even more susceptible. Because no information has been available to know whether using a candidate microbicide during pregnancy is safe, women who participate in clinical trials must use contraception, and if women become pregnant, they must stop using study product- at a time when protection may be needed the most. In this study, gel containing a single dose (40 mg) of tenofovir gel was applied in 16 healthy HIV-negative women approximately two hours before they gave birth by scheduled caesarean delivery. Researchers took maternal blood samples before and up to 24 hours after the gel was applied and collected samples of the amniotic fluid surrounding the baby, umbilical cord blood, placental tissue and uterine tissue. In addition to finding very low levels of drug, the researchers also reported there were no serious side effects attributed to the gel in either the mothers or their newborns. Based on these results, researchers now plan to conduct a larger study of tenofovir gel in both pregnant and breastfeeding women.

Provided by International Conference on Microbicides