

# Philadelphia Story: 93% Finish HIV Vaccine Trial

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Contributing Writer

MEXICO CITY — Retention strategies helped ensure that about 93% of high-risk, drug-using women in Philadelphia participating in the HIV vaccine trial completed the trial and 90% received all vaccinations.

"In Philadelphia, we were a site for the STEP [HIV vaccine] trial," David S. Metzger, Ph.D, said at the International AIDS Conference. "That gave us the opportunity to examine the timeliness of vaccinations that participants received as well as factors that may predict or relate to loss to follow-up."

The majority of people becoming infected with HIV in the city are heterosexual black women, according to Dr. Metzger, an investigator with the HIV

**The 124 women in the study had high levels of sexual risk behaviors and drug use; in the prior 3 months, 52% had had at least five sexual partners.**

Prevention Research Division of the University of Pennsylvania, Philadelphia. For the trial, he and his colleagues selected as their target population sexually active women who had multiple male partners, had recently used

crack cocaine, lived in neighborhoods with high HIV prevalence, and were willing to participate. A mobile unit was used for recruitment.

In all, 124 HIV-negative women were enrolled in the trial, Dr. Metzger reported. They were 37 years old, on average, and 91% were black. Forty-eight percent had not completed high school, and 20% had unstable living arrangements.

The women had high levels of sexual risk behaviors and drug use, he noted. For example, in the prior 3 months, 52% had had at least five sexual partners, 21% had had unprotected sex with an injection drug user, and 94% had exchanged sex for drugs or money.

Meanwhile, 75% had used crack cocaine at least 20 times, 38% had used alcohol that many times, and 13% had snorted cocaine that many times.

"We had a number of structured retention strategies that we used during our trial to help women maintain their scheduled appointments for vaccinations and follow-up," Dr. Metzger explained.

For example, all appointments were scheduled at enrollment, a database was used to maintain contact information, and participants were assigned to a retention team and were given transportation tokens or van service.

"All of our retention efforts were designed to protect confidentiality and done with permission of the participant," he commented. "We tried to demonstrate respect in all of our activities."

The women were given \$25 for each visit, he said, an amount that was small enough to make it unlikely that they were

participating primarily for the money.

During the 1-year trial, most of the women indeed were vaccinated and stayed on the trial, Dr. Metzger reported. More than 90% received all three vaccinations and more than 93% had 1-year follow-up.

Overall, 66% of the women received all vaccinations on time, while 34% did not (25% received at least one vaccination late and 9% missed at least one vaccination). Compared with their counterparts who were always vaccinated on time, women

who were not vaccinated did not differ with respect to race, education, distance from the clinic, moving during the trial, and prior sexual risk behavior and drug use. "This is important because obviously in a vaccine trial, if women who were more risky were less likely to complete vaccination or complete the study, it would bias the interpretation of the results," Dr. Metzger commented.

"We can conclude that heterosexual, drug-using women can be recruited and

retained at high levels that are acceptable for clinical trials of HIV preventive vaccines," he said.

"Retention on trials is particularly critical when unexpected findings occur. "We need to follow up [with] these women in order to get a complete picture of the data," Dr. Metzger added. Only two women in the cohort have become HIV positive, he noted.

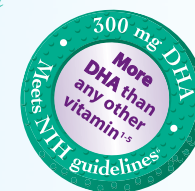
Dr. Metzger reported that he had no conflicts of interest related to the study. ■

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