

HIV Vaccine Trials Network
HVTN 505 Site CAB Members, Seeking Input on iPrEx Results Conference Call
Tuesday, Dec. 14, 2010, 5pm Pacific

Attendees:

Jim, St. Louis
John, Denver
Kathleen, San Francisco
Louie, Denver
Ross, Dallas
Sam, Orlando
Victoria, Seattle
Ya, Chicago

Margaret Wecker, HVTN Core
Magda Sobieszczyk, Columbia University
Niles Eaton, HVTN Core
Sarah Alexander, HVTN Core
Scott Hammer, Columbia University
Susan Buchbinder, SFDPH

Minutes:

Niles Eaton: Thank you to everyone for joining the call. We are keenly interested in hearing about how HVTN 505 site Community Advisory Board (CAB) members feel about these results. We are taking detailed notes, and will be placing those notes on the public HVTN website, so that others can provide comments. Magda will be presenting information about the iPrEx study, and asking some questions about how these results affect you and your communities.

Magda Sobieszczyk presented the slides.

Ya, Chicago: were there any differences in iPrEx among different races? Were there any genetic differences in how Truvada worked?

Magda: The study done predominantly in South America, only 2 sites in the US enrolled into this study. Susan, do you have anything to add:

Susan Buchbinder: The overall racial/ethnic mix was 9% African American, and 69% identified as mixed race or other. The largest population came from Peru & Brazil, and a lot people there identified as mixed race. The analyses aren't really powered to detect differences in races. But there was an analysis of efficacy between those in the Andean region versus other regions, and there was no difference. The genetic testing has not been done, but there are many planned analyses.

Sam, Orlando: 18 partners over 90 days, and on average 5 drinks per day?

Magda: About half reported having ~5 drinks per day, yes.

Sam, Orlando: The iPrEx participants reported 18 partners over the past 90 days, correct? And on average, 5 drinks per day? From my own experience with HIV testing & counseling, I haven't heard the counseling message that lowering drinking decreases risk of HIV. Was that part of this study?

Magda: As part of counseling, participants were counseled about substance use. Susan, do you want to comment?

Susan: The average number of drinks per day was much lower in SF, but the South American sites had a much higher drinking rate. In the study, the goal was comprehensive counseling, including substance use, and referral for services.

Sam, Orlando: So is this a temporary tool, a stopgap, until we have a vaccine? There's been a lot of chatter on Facebook about it, and I know a lot of my friends are excited about it.

Magda: Ideally, an individual would be able to choose between a menu of options: a pill, a gel, or a vaccine. The ideal will be a vaccine that is safe & effective & easy to take, but we may not find one that is 100% effective. People who can be monitored & tested frequently may choose a pill to prevent HIV infection. But people should be able to choose, and we need to give people options. This is exciting, but there may be others who can't take a pill, and we need to keep going toward a vaccine.

Ross, Dallas: Community is very involved and very tight knit. There's a lot of concern about accessibility to the drugs. I've been a volunteer at the STD clinic for some years and there is a lot of excitement. We have this great new opportunity, but I don't think we're taking account of logistical issues for implementation. Texas is a very conservative state, and there are no protections for sexual orientation, so an employer finding out about a employee on this drug could fire him.

Magda: You're absolutely right. There are still a lot of questions about how this could be implemented.

Ya: We need to make sure that this stays in the medical, public health model, and that it's no different than taking a birth control pill, or one for diabetes, high cholesterol.

Jim, St. Louis: Adherence is obviously a big deal. Is there any information from iPrEx that could tell us about potential adherence in those who were most motivated? Sex workers, maybe? It seems we're still a long way from this being fully implementable. Is there a risk of self-medicating, and what are the implications for vaccine studies? What about a black market for these pills, or through friends, etc?

Magda: In the broad strokes, we know that adherence was being monitored, but it was hard to measure how taking the pills would affect efficacy. There are other studies that will look at whether taking it at different timepoints, such as before/after sex, rather than every day, will affect efficacy. There are also animal studies.

Jim, St. Louis: is there any information about which demographic groups would have high adherence?

Magda: Most of the data is going to be derived from South America. Susan?

Susan: Adherence was measured in a number of different ways, and they don't always line up. So it's really hard to say whether people were taking their pills consistently. A small subgroup had blood levels measured, and it looked like that people were either taking it every day, or not at all. There will be a much larger analysis of blood levels, but those analyses are not done yet.

Jim, St. Louis: What about the black market question?

Magda: If individuals were to use PREP and participants were to use PREP, it would probably change the number of infections, and that will probably change the sample size, duration of the study. I think we will need to counsel participants about the study results and what they mean. We will also need to take

information about their use of PREP. We will need to make sure that they are educated about these results and the implications to themselves or their communities.

Scott Hammer: Hopefully we'll have trust relationships with our participants so they'll feel comfortable telling us about their PREP use. We will certainly want to educate them about the results and counsel them about its use and need for monitoring. If there is widespread use, it will likely lower the number of infections, but the DSMB will be monitoring that, and will be able to advise us.

Louis, Denver: How are you going to monitor blood levels?

Susan: In iPrEx, the blood levels were monitored among a very small group of those who became HIV infected, at the visit at which HIV infection was first detected, and compared to a control, which means a group of people who looked like the people who were infected. What needs to be done is monitoring the blood levels at the visit just prior to infection. But we will never be able to know how much of the drug was in their system at the time they were exposed. For the people who became infected, only three had drug in their system at the visit at which infection was first detected. To summarize, what we can say is that people who took the drug more regularly seemed to be more protected.