

HIV Vaccine Trials Network
NHVREI Partners Conference Call, Seeking Input on iPrEx Results Conference Call
Wednesday, Dec. 15, 2010, 10:30am Pacific

Attendees:

Stacey Little	Elizabeth Jean ("EJ") Dean	Michelle Simek
Sean Khalepari	Michelle at the AIDS	Niles Eaton
Jamal Hill*	Institute, on behalf of	Scott Hammer
Kia from the AIDS Alliance*	Michael Ruppel	Shelly Karuna
Luis Fernando Ramirez	Sterling Washington	Adam Sherwat
Katherine Heffernan*	Saúl Martinez	Magda Sobieszczyk
Kayce Matthews	Sherry LaCoke*	Mark Mulligan*
Kianna Scott*	Tom Kennedy	Brian Green
Shanebrae Price	Rona Siskind	Vaughn Taylor
Michael Robinson*	Katharine Kripke	Rudy Carn
Anne Marie Borrego	Ronald Johnson	Gary Daffin
Patricia Canessa	Erin Marzoli*	Brian Risley
Gail Broder	Rev. Doris Green	

Minutes:

Scott Hammer: Thanks for having us on this call. We had some slides but since we're short on time, I won't go through them, but I am happy to answer questions about iPrEX. HVTN 505 is a study of MSM & Transgender women who have sex with men in the US, and the HVTN 505 study team is going through a consultation with various community groups, trying to learn what the iPrEx results mean to these groups. We are interested in your impressions of iPrEx as a prevention modality. What does this group feel are the implications on HVTN 505? We will passively monitor PREP use in HVTN 505, relying on our trust relationships with participants to honestly report it. We will also consider whether PREP should be formally incorporated into the trial. We have received cautious opinions from other groups; we're interested in hearing from you about your thoughts about these questions. To start with each question individually, what are your impressions of the iPrEx results?

Stacey Little, AED: I've been participating in the HIV Prevention Leadership Summit in Washington, DC this week, and there is a lot of discussion about moving forward with PREP as an intervention. Interesting, given that it's only one study. We need to think about how we prepare communities, cost issues, and how this will work on the community level.

Sterling, IFBP: This is a great finding, & very promising, but I'm not sure about the practical applications. Will insurance companies pay for the drug as prevention?

Ronald Johnson: I've been startled at the workshops that I attended at HPLS, how much a given PREP is becoming based on one trial. It seems that the prevailing view is that this is given, and let's move forward with implementation.

Reverend Green, AIC: I've been trying to keep up with the information. I've been happy to know that another tool to add to the kit, but what do we do with states that have ADAP waiting lists? Are we looking into the finance question? How would we do this?

Scott: I can't answer these questions, but these issues have certainly been part of our team discussions. We anticipate that CDC will come out with an interim statement, probably by the end of February, then will work on a longer consultation process. The CDC will likely have to walk a fine line about these results, that these are exciting results, but that in the practical application, there will be obstacles. It's unfortunate that that tension exists.

Ronald Johnson: Truvada is a legal drug. People with health insurance can already get it. So there are issues around cost, but also bioethics: it's available to those who have insurances, as opposed to those uninsured who need treatment. There are a slew of ethical & policy issues.

Scott: So to my second question, how should these results affect our vaccine trial? As a reminder, we will monitor the use passively, to see if participants are using the drug.

Shanebrae Price: When we talk about how expensive they will be, I want to be sure not to let the cost of it enter into these discussions. When treatment first became available, the word was that it was too expensive, but there were ways around that eventually, with generics, etc.

Katherine Heffernen: Not sure budget is something we can just leap over. A pill may not help an entire community, but a vaccine may be a broader-based response.

Tom Kennedy from San Francisco: If everyone is taking PREP, and we know it's 70% effective, how we would be able to tell if the vaccine were working?

Scott: Should we just monitor uptake, or incorporate PREP into the study?

Brian Green from Philadelphia: I'm not sure I see the sense of incorporating iPrEx, given the timeline for enrollment of 505 –there's not that much time left. Just because these results are out there, some people may take it. But it's going to take some time for PREP to become available and the cost will be prohibitive. No agency is going to make this available right away to the everyone for HIV prevention. 505 was not powered to take this into account, so it makes sense to watch for the use for participants.

Tom: PREP should be optional. I was a participant in a trial, and if it had been required to take a pill, I wouldn't have taken it. This news is an opportunity to get our message out, to do community education about vaccine trials and their importance.

Scott: In our discussions, in our thought processes about how to adapt the trial, we have tried to incorporate PREP use only as optional.

Katherine: A couple of points: I don't think people will be able to get Truvada on insurance, companies will likely balk at that. So people will need a prescription and also probably will need to pay for the drug. I don't think we can assume that uptake will happen broadly.

Vaughn in NY: What we've heard from our people is that they understand these results as: this is a condom that you can swallow. Most of new infections are people in relationships who don't know their status, and we can't get people to use condoms.

Scott: I know our time on your call is coming to a close, so I just want to offer that if anyone has any questions, you can email any of us on this call. Thanks for letting us have this time with you.

Niles Eaton: there is an email address for receiving these comments: 505iprexcomments@hvtn.org.