

Case Study: HIV Vaccine Trials Network (HVTN) 505

Developing a standard HIV prevention package becomes more complex when new evidence for additional prevention strategies emerges. In 2010, the iPrEx trial results showed efficacy of using the ARV Truvada[®] as Pre-Exposure Prophylaxis (PrEP) to prevent HIV among men and transgender women who have sex with men. HVTN 505, a vaccine efficacy trial with these same populations in the U.S., was among the first to grapple with incorporating these PrEP results.

Shortly after favorable results were announced from iPrEx, and even before the US FDA announced its approval of Truvada[®] for use as prevention in 2012, HVTN 505 trial investigators acknowledged that PrEP was an important prevention option for participants and decided to review their protocol.

Post-iPrEx, HVTN 505 participants were surveyed about their understanding of PrEP and their intent to use PrEP. Consultations were held with Global Community Advisory Board members representing all Network sites. Additional consultations were held with a wider group of community stakeholders including scientists, local leaders, advocacy groups, and others to discuss the iPrEx results and standards of HIV prevention. Input was sought on the advisability of providing PrEP for trial participants interested in using it, and on the mechanisms of that provision. Post-FDA approval, a second set of consultations was held regarding implementation of such a plan.

The decision was made to include discussion of PrEP and education materials about this prevention option in trial-provided risk reduction counseling, and to make referrals to local healthcare providers who could prescribe and provide the primary care needed for people interested in taking PrEP. The size of the trial was increased in response to developments in the HIV vaccine field, as well as to account for up to 20% of trial participants using PrEP, and to explore how PrEP might affect behavior and the rates of HIV infection in the population. Information was collected from trial participants about their voluntary use of PrEP. The research team was also able to negotiate an agreement with Gilead Sciences, Inc., maker of Truvada[®], to make the medication available at no charge through a mail order pharmacy to participants who were interested in using PrEP to reduce their risk for HIV infection.

The actions taken in HVTN 505 provide an example of mindful implementation of GPP, lessons learned for adapting to a changing standard of HIV prevention, and how to involve stakeholders in decision-making during an ongoing clinical trial.