ABSTRACT.

Background: Dissemination of research results to study participants and stakeholders and provision of proven effective products in the immediate post-trial period are core elements of the conduct of biomedical HIV prevention clinical trials. Few biomedical HIV prevention trials have demonstrated HIV protection with novel interventions, and thus, communication of positive trial results and provision of an effective product have not been tested in many situations. Methods: In July 2011, the independent Data and Safety Monitoring Board of the Partners PrEP Study, a randomized, placebo-controlled efficacy trial of daily oral antiretroviral preexposure prophylaxis (PrEP) for HIV prevention among 4747 African heterosexual HIV serodiscordant couples, recommended discontinuation of the trial's placebo arm due to demonstration of PrEP efficacy. We describe dissemination of results, discontinuation of the placebo arm, and provision of active PrEP to participants' formerly assigned placebo. Results: Within 72 hours, of the Data and Safety Monitoring Board meeting the study results were publicly released and disseminated to stakeholders and study participants. Within 3 months, the study protocol was modified to permit participants initially assigned to the study's placebo arm to be offered active PrEP. Of the 1418 participants initially randomized to placebo who were clinically eligible to receive PrEP, 89.1% (1264/1418) consented. Conclusions: Prompt dissemination of a positive HIV prevention trial result and subsequent provision of effective product to research participants was feasible and efficient for >4700 HIV serodiscordant couples in East Africa. The extent to which study sponsors can assure continued product access to research participants remains a subject of discussion for future HIV prevention clinical trials.