GPP Case Study
MTN-017: Global civil society consultations

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MTN-017 is a Phase II safety and adherence study of a reformulated version of Tenofovir gel as well as oral Truvada®. It includes approximately 186 men who have sex with men (MSM) and transgender (TG) women in the U.S., Peru, South Africa and Thailand. It is sponsored and coordinated by the Microbicide Trials Network (MTN).

MTN-017 is a groundbreaking study in a number of ways. As the first Phase II study of a rectal microbicide, it was designed to give an indication of whether the product can be moved forward into an efficacy study. Rectal microbicide research is further behind in the pipeline of HIV prevention research than other modalities, but is extremely important since a large proportion of HIV transmission occurs through unprotected anal sex.

Additionally, MTN-017 is the first rectal microbicide trial outside the U.S. The trial involves sensitive issues that many people are uncomfortable with or not used to discussing. Participants in the trial need to undergo rectal exams and some biopsies. Additionally, populations that are highly stigmatized and vulnerable to HIV infection were recruited for participation.

As part of protocol development, the MTN, partnering with trial sites and advocacy organizations (including AVAC), undertook a series of civil society consultations at planned trial sites. Consultations took place in Cape Town, South Africa in October 2011; Pittsburgh, Pennsylvania in December 2011; Bangkok and Chiang Mai, Thailand in January 2012; and Lima, Peru in March 2012.

At the time of the Thai consultations, investigators were still questioning whether to enroll TG women in addition to MSM. Researchers were uncertain whether to focus on TG women given their status as a highly stigmatized group, which could hinder recruitment and retention in the study. However, civil society and other community representatives at both Thai consultations advocated strongly for their inclusion. The Thai community members informed the researchers that in Thai society, there is a great deal of fluidity between sexes. For instance, some MSM may become TG women, even during the course of the trial. Similarly, some individuals who identify as TG women may not have had gender reassignment surgery. They assured investigators that recruiting and retaining TG women in the trial would not be prohibitively challenging, and that many TG women would be willing to participate. Community stakeholder groups also identified ways in which potential harms to TG women could be mitigated. These groups also identified sources of social and legal support in the community that could offset the risks to TG women. Investigators listened and agreed to include TG women in the protocol.

This case shows the importance of the research team obtaining the unique insight of the community's social norms, practices, and perceptions to develop the protocol in a thoughtful way and, in the process, enhancing the efficiency of the overall trial.

It also highlights how research networks can embrace and implement GPP. Especially in the case of efficacy or larger-scale studies which involve multiple sites, protocols are most often developed at network or sponsor level and are received at trial sites in final form. No matter where a protocol is developed, the research group is responsible for considering and facilitating stakeholder input – whether that is on the entire trial design and protocol or on key aspects of the research.