**GPP Case Study:** Bangkok Tenofovir Study (BTS)

**Background**

The Bangkok Tenofovir Study (BTS) was launched in 2005 to determine if pre-exposure prophylaxis (PrEP) with an oral tablet of tenofovir (TDF) would reduce the risk of HIV infection among injecting drug users. The primary trial objectives were to determine if TDF prevented HIV infection among injection drug users and whether it safe in this population. Conducted in 17 drug treatment (methadone) clinics in the Bangkok area, the trial was sponsored by the Centers for Disease Control (CDC), in collaboration with the Bangkok Metropolitan Administration and the Thailand Ministry of Public Health.

From June 2005 through July 2010, more than 2400 HIV-negative male and female injection drug users were enrolled in BTS. Participants were recruited at drug treatment clinics, community outreach sites, and through a peer referral program. But starting in 2003, the Thai government waged a severe and widely publicized campaign against illegal drug use. This presented challenging policy and legal hurdles for trial staff seeking to implement safe and respectful research. In particular, Thailand's narcotics law prohibited the distribution of needles to inject illicit drugs, and as a result, clean needles could not be provided to individuals participating in BTS.

The trial sparked a heated dialogue among advocates and researchers about HIV prevention and support options that were not being offered to participants. Some advocacy organizations argued that by doing a prevention trial with drug users and failing to provide all participants with clean needles, the trial failed to meet its ethical obligation to provide the best possible prevention standards. The Thai Drug Users’ Network demanded a ‘halt or redesign’ of the trial. Other community groups, including the Thai National Network of People Living with HIV, and the Thai AIDS Treatment Action Group, expressed concern about unethical and coercive recruitment procedures, the fact that needle-exchange was not being offered despite half the participants being given a placebo, and the fact that, should the intervention prove effective, there was no guarantee of post-trial access.

As a result of this outcry, global and in-country meetings were convened with the trial sponsors, civil society groups, and other stakeholders to foster dialogue and discuss some of the ethical and operational challenges to BTS. Key issues of concern included stakeholder perceptions of inadequate standard of HIV prevention in the trial, lack of community stakeholder involvement or consultation in design and development of protocol, lack of clarity around the standard of care for seroconverters and HIV-positive individuals who were screened out, and lack of participant protection mechanisms within the volatile national context. Stakeholders’ requests for specific actions were acknowledged by the sponsors during consultations, but follow-up was perceived to be insufficient according to civil society groups.

BTS results in June 2013 revealed the first evidence of PrEP efficacy among injection drug users and generated global excitement. Researchers confirmed that trial participants would be offered access to PrEP for one year as part of a follow-on trial to assess PrEP use and effectiveness outside of a randomized, blinded trial. CDC pledged support to the Bangkok Metropolitan Administration and the Thailand Ministry of Public Health to determine how best to incorporate PrEP into local HIV prevention efforts.

Not mentioned as part of the official results dissemination, however, were the concerns raised by stakeholders through the course of the trial. Some advocates and other researchers also debated the legitimacy of the trial data, given the prevention package offered to participants. The lack of resolution left a rift between civil society and research entities, with uncertainty about stakeholder support for future steps with PrEP research and potential rollout in Thailand.