

Addressing Enrollment and Retention Challenges through Sociobehavioral Research in Cameroon's Tenofovir HIV Prevention Trial

T. Nyiama, N. Mack, K. MacQueen, G. Guest, E. Namey

Issues: Sociobehavioral research conducted in support of HIV prevention trials can be invaluable in preventing and solving enrollment and retention issues. Both planned and spontaneous sociobehavioral research activities are necessary.

Project Description: The Tenofovir HIV pre-exposure prophylaxis (PREP) trial with 400 high-risk women in Douala, Cameroon included sociobehavioral research consisting of: 1) pre-trial data collection, including an experts workshop, participant observation at 25 sites in 6 high transmission areas, 53 in-depth interviews and 5 focus groups with high-risk women, community members, PLWHA, and healthcare providers; 2) data collection during the trial, including trial site observation and 34 in-depth interviews with participants, discontinuers, seroconverters, and male partners of participants, regarding recruitment dynamics, trial participation, and referral to prevention and care; and 3) spontaneous research activities to address emerging issues.

Lessons learned: Information gained and community relationships built by the sociobehavioral research team during the pre-trial data collection phase proved critical to the ability of the clinical research team to meet enrollment targets. In the face of initially low enrollment, the sociobehavioral team contributed to problem solving through field assistance for recruitment outreach activities and monthly meetings with the clinical team. These strategies contributed to full trial enrollment (n=400 women) and a low rate of trial discontinuation. Subsequent controversies led to suspension and ultimate early closure of the trial. The sociobehavioral team drew on their knowledge of and relationships with community stakeholders to explore local responses to the controversy and early closure; to develop information, education & communication (IEC) strategies concerning the trial; and to communicate findings to community stakeholders.

Recommendations: Pre-trial and ongoing sociobehavioral research in support of prevention trials is critical for ensuring successful enrollment and community support of trials. Sociobehavioral research should be conducted to inform clinical activities in the areas of recruitment, retention, risk reduction, and mitigation of stigma. Unplanned research to address emerging concerns could include data to inform IEC strategies and community consultation processes, field support for recruitment and retention activities, and monitoring the effectiveness of participant support (e.g., health service referrals).