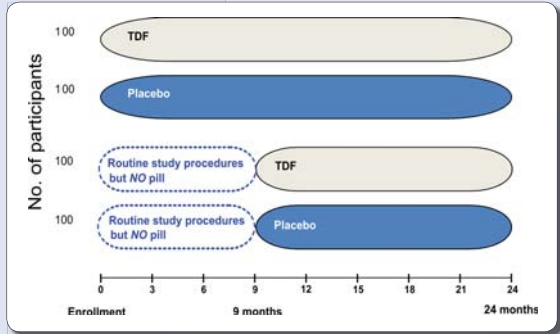


Recruitment Challenges and Strategies in the Phase II Extended Safety Trial of Tenofovir (TDF) HIV Chemoprophylaxis in Three US Cities among Men Who Have Sex with Men (MSM)

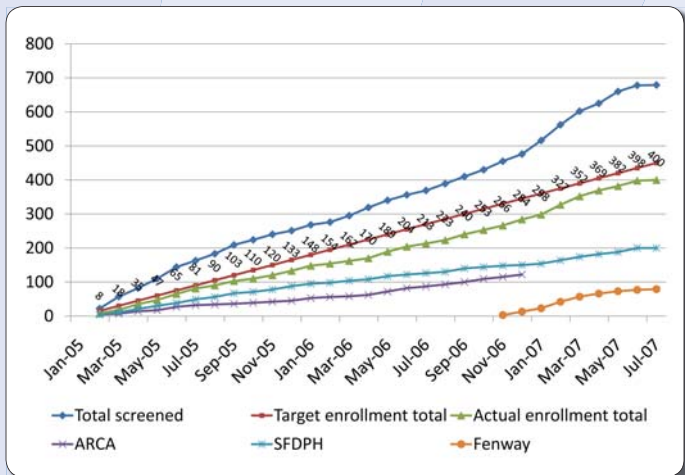
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Study Overview

- Randomized, double-blinded, placebo-controlled trial of once daily tenofovir PrEP among HIV-uninfected MSM
- N=400, including ≥ 25% men of color (Atlanta site had higher target)
- Participants followed for two years
 - Those who became HIV-infected during study followed for 1 year after seroconversion
- Quarterly study visits included:
 - Assessment of:
 - ◆ Medical signs/symptoms, adverse events, hematologic & blood chemistry studies, HIV testing
 - ◆ Sexual behavior, substance use, adherence by ACASI
 - ◆ Pill count, MEMS®
- Risk reduction & adherence counseling
- Reimbursement for time & transport
- Unique 4-arm design to assess relationships between sexual behavior & pill-taking (risk compensation)

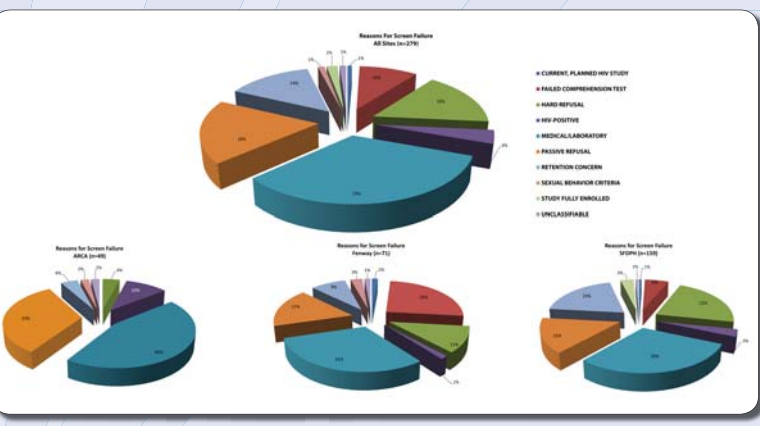


- **Trial sites:**
 - San Francisco Department of Public Health (SFDPH)
 - AIDS Research Consortium of Atlanta (ARCA)
 - Fenway Health, Boston
 - ◆ Added in late 2006
- **Major inclusion criteria:**
 - Born male, age 18 - 60 years of age at enrollment
 - HIV negative
 - Generally healthy, according to lab parameters & medical history
 - Report anal sex with another man in the last 12 months
 - ◆ Not intended to target those at highest risk
 - Able to understand key study concepts & requirements
 - Able to provide informed consent



Slower than Expected Recruitment

- **Led to critical assessment of:**
 - Recruitment methods & materials
 - Site differences & capacities
 - Sponsor limitations
 - Screening data
 - Possible changes given resource constraints
- **In response, the following was done:**
 - Evaluation of feasibility of adding additional site(s) (Fenway)
 - Regular calls among recruitment staff to share strategies
 - ARCA recruitment staff traveled to SFDPH to work with their recruitment staff
 - Development of creative, site-specific strategies
- Extensive pre-screening at sites (overall screen-to-enroll ratio low)



Overarching factors acted synergistically to complicate trial recruitment

- **Lack of familiarity with PrEP in target communities**, particularly early in the trial, likely affected the recruitment experiences of SF & Atlanta
- **Assumptions about PrEP based on experience with other prevention & treatment technologies/trials** led to initial overreliance on established recruitment methods & misperception of communities' receptivity to active recruitment methods/trial participation
- **As one of the first PrEP trials**, there were few specific resource, timeline, design, or implementation precedents
- **Differing site capacities/experience** exacerbated tensions inherent in multi-site trials between standardization & accommodation of site differences
- **Lengthy sponsor approval processes** undermined ability to adapt recruitment strategies to changing circumstances
- **Concern about potential political controversies** shaped low-profile trial rollout & recruitment methods, undermining community education & interest
- **Sponsor's relative lack of experience with internet & social media at the outset** diminished potential impact of these methods
- **Relatively modest resources** didn't allow for coordinated trial launch/media campaign & limited sociobehavioral research that may have facilitated recruitment

ARCA



Context/Barriers

- Concept of PrEP unfamiliar, difficult to understand
- Less cohesive MSM communities in Atlanta
- Street-outreach complicated by Atlanta's car-based culture
- Local clubs less experienced hosting HIV prevention activities
- Trial initially was perceived by some to be only for African-Americans
- Overreliance on passive recruitment strategies
- Fear of HIV medications by the HIV negative community, especially African-Americans
- MSM-specific internet chat sites commonly used by target populations, but recruitment through these sites limited by sponsor constraints

Strategies

- Hired recruitment coordinator experienced with HIV prevention in MSM communities of color
- Diverse recruitment team
- Focus groups informed development of culturally appropriate strategies for specific racial/ethnic groups
- Direct observation & skills- building with SFDPH recruitment staff
- Worked through community based organizations to disseminate study information



Fenway

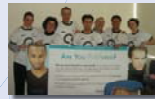


Context/Barriers

- Because recruitment started later:
 - Community more familiar with PrEP
 - Were able to build on lessons learned
- Extensive preparation of public health stakeholders

Strategies

- New venues such as:
 - Provincetown
 - Private parties
- Gregarious & creative recruitment team
- Targeted recruitment strategies based on venue, e.g., dressed appropriately for "leather-night" at bars



SFDPH



Context/Barriers

- Community initially unfamiliar with PrEP concept
 - Confusion between PEP & PrEP
- Concerns about using medication as prevention
- Fear/stigma around taking HIV medication
- Community/provider concerns about behavioral disinhibition & resistance
- Awareness/understanding of PrEP increased with community education

Strategies

- Extensive community engagement
 - Focus groups with community opinion leaders to refine recruitment materials
 - Ongoing community education of a variety of CBOs, clinics, providers
- Multi-pronged approach including:
 - Direct outreach around specific events (e.g., street parties, bars)
 - Internet (craigslist)
- Increased efficiency of screening process
 - Short field pre-screening instrument
 - Group screens
- Adapted messaging to address community concerns
- Reviewed effectiveness of strategies in regular team meetings



Key Changes

- Active recruitment predominant at all sites
- Increased use of real-time recruitment data
- CDC IRB approvals streamlined
- Front-line recruitment staff from different sites actively exchanged information

With the benefit of lessons learned & additional resources, we advise incorporating one or more of the following strategies:

- Sites strongly advocated for a coordinated, high-profile media launch & campaign
- Interactive & sophisticated internet methods
- Ability to rapidly adapt recruitment materials & strategies
- More opportunities for "train the trainer" & recruitment staff exchanges among sites
- More information gathering & analysis (e.g., GPS, market segmentation research)

We would like to acknowledge the study participants & dedicated staff at ARCA, Fenway, SFDPH, & CDC.