Reaching transgender women with home-based, self-HIV testing in San Francisco: a pilot acceptability and feasibility study

Abstract
Transgender women are the population most impacted by HIV in the United States, with infection rates approximately 40 times higher than the general population. Despite elevated risk, the rates of HIV antibody testing in the transgender community are particularly low. Alternative testing strategies are critical for the approximately 700,000 transwomen living in the U.S. HIV self-testing kits will likely be available over-the-counter in 2012 and have enormous potential to increase testing uptake and earlier diagnosis of HIV infection, leading to improved health and decreased transmission. We will explore feasibility, acceptability, and supportive materials needed to offer home-based self-administered HIV testing for transwomen in three phases. Two focus groups will be conducted during a formative research phase to inform development of instructional materials to support reliable self-administered HIV testing and supplemental educational materials to be included in the home-test kits. The pilot study includes following 40 HIV-negative transwomen in San Francisco in a 3-month study of home test kits. Rapid tests will be demonstrated at baseline; participants will self-test at home monthly and provide acceptability data at 1 and 3 months. At the third visit participants will perform the test in the presence of a clinician to evaluate adherence to instructions. The third post-pilot phase includes in-depth interviews (IDIs) of 20 participants, and analysis of pilot study data. Analysis of acceptability and feasibility will include descriptive statistics as well as qualitative analysis of IDI data. This mixed-methods study undertaken by an early career PI (PhD 2009 / Assistant Professor 2011) represents the first attempt to systematically examine acceptability, feasibility, preferences, and support for home-based rapid HIV testing in the U.S. transfemale community.

Aims
Transgender women (people who were assigned ‘male’ at birth but do not identify as male but rather as female and/or transgender) represent the population most impacted by HIV in the United States. Male to female transgenders have extremely elevated infection rates – with over a quarter of the population infected,1-3 and over 50% infected among transgender women of color.3,4 Despite elevated risk for HIV, the rates of HIV antibody testing among transgender women are significantly lower than other at-risk groups.5,6 Because testing is the gateway into HIV/AIDS care and treatment, the large U.S. transgender community, approximately 700,000 people,7 urgently needs alternative approaches to HIV testing and care services.

Among technologies that may facilitate access to testing for transwomen and other high risk groups, HIV self-testing kits have enormous potential to increase the proportion of people tested, increase testing frequency, and encourage earlier detection of HIV and thus earlier treatment. HIV home-testing kits may become available over the counter (OTC) in the U.S. in 2012; two companies have already filed with the FDA for OTC status. Currently, a number of prospective studies are underway to determine the acceptability and accuracy of home testing among MSM in the US. However, HIV education, prevention, and research efforts tailored for MSM are neither culturally appropriate for nor generalizable to transwomen, who face unique barriers to care and distinctive contextual vulnerabilities. The potential of home HIV tests remains unexplored in the trans community, as do strategies to ensure successful use and appropriate follow-up.

We propose to determine the feasibility, acceptability, and supportive materials and resources needed to optimize home-based self-administered HIV testing for transwomen. We will conduct a pilot study, following 40 HIV-negative transwomen in San Francisco, to clarify what is necessary to successfully and safely scale up distribution of home testing kits in this underserved and high risk population, including monitoring of potential social harms or unintended consequences of self-testing. This study can help chart a path to harness the promise of home testing for one of the most heavily impacted populations. Specific Aims include:

Specific Aim 1: Determine the acceptability and feasibility of self-conducted home-based HIV testing for transgender women. Overview: We will use focus groups and in-depth interviews, survey data, and testing logs to examine testing uptake, venue preference, ease of use, confidence in test result, and likelihood to test again or recommend home tests. We will document accurate performance of the test by direct observation.

Specific Aim 2: Examine the educational and support needs of transwomen to ensure accurate performance of self HIV testing and facilitate entry into care. Overview: We will use mixed methods to determine what educational, instructional, and support information or resources (e.g. hotlines, referrals) are needed to ensure
safe and proper use of home tests and to identify the community preferred mechanisms and necessary support for facilitating entry into care for participants, including monitoring of social harms from using home tests.

Twenty-five years of HIV prevention research, practice, and policy have not adequately produced evidence-based, effective prevention options for this population at disproportionately high risk for HIV. Although HIV testing is critical to prevention and care, almost no research has been conducted to support alternative testing strategies for transwomen. This mixed-methods study represents the first attempt to systematically examine acceptability, feasibility, preferences, and requirements for support and facilitated entry to care for provision of home-based HIV testing to transwomen in San Francisco, home to a large trans community.

This pilot study will leverage the partnerships between UCSF/CAPS and the San Francisco Department of Public Health (SFDPH), which has an exceptionally strong research platform to support this project, including an NIH-funded HPTN/HVTN/MTN clinical trial site that is easily accessible to the transgender community. In addition, this pilot study will support an early career investigator with experience designing home testing research (Dr. Lippman), supported by a strong collaborative team, including the co-PI of the Center of Excellence for Transgender Health (Dr. Sevelius) and the PI of the SFDPH trial site (Dr. Buchbinder), in a line of research that can have important clinical and public health implications. The proposed research will inform a future NIH grant proposal (R34/R01) to examine whether home test kits will increase testing rates, early diagnosis, and early treatment for transwomen as compared to clinic-based testing in a multi-site study.

**Literature Cited**