Evaluation of Rapid HIV Self- Testing Among Men who have Sex with Men (MSM) in High Prevalence Cities: The eSTAMP Project

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Background

With the approval of the OraQuick® In-Home HIV Test (*OraQuick)* rapid self-testing is now a reality in the United States. In addition, the manufacturer of the SURE CHECK® HIV 1/2 Assay (*Sure Check*) is seeking approval for its over-the-counter (OTC) use. The high prevalence of undiagnosed HIV infection among men who have sex with men (MSM) and the potential need for more frequent and timely testing suggests that MSM might benefit from an OTC rapid test.

Main Study Goal

To evaluate the use and impact of distributed rapid HIV tests (oral fluid and finger stick blood) for "at-home" use by men who have sex with men (MSM) recruited via the internet.

Primary Outcomes of Interest

The eSTAMP project will recruit MSM to:

- Assess the field performance of rapid HIV self-tests, testing frequency, and impact on risk behaviors.
- Evaluate the degree to which persons with a reactive rapid self-test result are linked to medical care.
- Evaluate the extent to which MSM distribute self-test kits within their social and sexual networks
- Assess test preference

Additional feasibility and operational objectives for each part are described under Methods – Project Design.

Methods

Recruitment

MSM will be recruited through banner advertisement from social networking (e.g. Facebook) and/or sex-seeking internet sites for all 4 sequential parts of the project.

Eligibility Criteria

- Male at birth and currently identify their sex as male
- ≥18 years old
- Report anal sex with at least one man in the past year
- English proficient
- Does not have a bleeding disorder
- Not part of an HIV vaccine trial
- Not taking antiretroviral medication for HIV

Methods

Project Design : This research project will be conducted in four sequential parts. Each part will be independent and will provide information to develop and implement the next part of the study. At the end of each part the data will be evaluated and adecision will be made about whether and how to proceed with subsequent parts based on pre-established criteria

	Part 1: Assessment of Materials	Part 2: User Proficiency Assessment	Part 3: Field Performance Evaluation	Part 4: Randomized Prevention Trial of Kit Distribution
Objectives	To obtain feedback about the study packaging and instructions for 2 self-test kits and DBS specimen collection To examine attitudes toward recruitment, participation, and retention in online studies, and participation in an online survey that includes questions about high-risk sexual behavior	To determine whether untrained MSM can use provided print and video instructions to correctly: • perform and interpret each rapid HIV self-test • collect and prepare DBS specimens for mailing To compare participant's self-test results to: • trained testing staff interpretation • IA conducted on DBS specimen	To determine the field performance of rapid HIV self-tests compared to an IA performed on DBS To pilot the test kit delivery and tracking system To pilot the study referral support system for participants who have difficulty with procedures, concerns after testing and want information on linkage to medical care provider	To evaluate the public health benefits (testing frequency, impact on sex risk behaviors) of rapid HIV self-tests among MSM To evaluate whether persons with a reactive rapid self-test result access supplemental testing and medical care To evaluate the extent to which MSM distribute self-test kits within their social and sexual networks
Locations	Atlanta and Chicago	Atlanta	Atlanta, Baltimore, Chicago, Dallas, the District of Columbia, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, and San Juan	
Design	Qualitative in-depth individual interviews (N =15 men) 5 focus groups, each with 8 men	N = 40 men (at least 10 HIV positive men)	N = 900 MSM of HIV-negative/unknown status	N = 3200 MSM with HIV negative/unknown status: 1. Randomized Controlled Trial Control Arm (n=1600) Intervention Arm (n=1600) 2. Focus groups (n=TBD) N=300 MSM with HIV positive status 1. Observational 2. Focus groups (n=TBD)
Procedures for Participants	Participants will consent to either a qualitative interview or one of 5 focus groups	1. Perform rapid tests and interpret results • Oral fluid – OraQuick • Whole blood finger stick – Sure Check 2. Collect own DBS sample 3. Prepare for mailing a mock DBS specimen card 4. Interpret pictorial examples of rapid test results	1. Report HIV status 2. Provide phone number, email address & mailing address 3. Report unprotected anal sex with at least one man in the past year 4. Complete online consent and survey 5. Receive a mailed package containing: 1 OraQuick, 1 Sure Check and 1 DBS collection kit 6. Perform collection & testing procedures within 48 hour window 7. Return DBS card by mail 8. Report rapid test results online or using secure smart phone app	1. Report HIV status 2. Provide phone number, email address & mailing address See tables 1 and 2 for further details.

Table 1. Procedures for HIV negative/unknown participants

	Intervention Arm	Control Arm
Assessments	Baseline, 3, 6, 9, 12 months	
First package mailed	2 *OraQuick* & 2 *Sure Check*	
Data collected (website or cell phone app)	1) HIV self-testing activities (including professional testing), test results & sexual behavior 2) Test distribution to social/sexual networks	1) HIV testing activities (including self-testing), test results & sexual behavior
Order replacements	Replace tests used or distributed after completing assessments @ 3, 6, 9 months	
Performance Evaluation (12 month)	All participants will be sent a Part 3 package and asked to mail back a DBS specimen and provide rapid test results	

Table 2. Procedures for HIV positive participants

Assessments	Baseline, 3, 6 months
First package mailed	Package with 2 *OraQuick* and 2 *Sure Check*
Data collected (website or smartphone app)	1) Sex behaviors 2) Kit distribution to social/sexual networks 3) Network HIV self-testing activities 4) Treatment /care
Order replacements	Replace tests distributed after completing follow-up @ 3 months

Discussion

An OTC rapid HIV test was approved based on modeling assumptions about its potential public health risks and benefits.

Better information is needed to document the use of OTC rapid HIV tests among populations for whom frequent testing is a high priority.

Data obtained through this project will inform policies to guide the optimal use of OTC rapid HIV tests for MSM.

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