

Title: Provision of HIV Self-Test Kit to Emergency Department Patients

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JHM IRB - eForm A – Protocol

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1. Abstract

- a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

The newest CDC guidelines advocate routine HIV testing in all healthcare settings, and provide explicit recognition of the importance of emergency departments (EDs) for engaging patients to be testing.¹ These recommendations are based on numerous studies which have demonstrated that EDs represent the most common health care sites of missed opportunity for identifying patients with unrecognized HIV infections,^{2,3} as well as the fact that EDs have over 130 million patients visits every year.⁴ Many EDs across the U.S. have since taken up HIV screening as part of their practice, using varied implementation strategies. However, rates of testing in EDs have fallen short of the recommended broad intended reach, with most ED programs testing approximately 20% of all eligible patients⁵ and overall rate of testing in U.S. ED is relatively low.⁶ Challenges in best practices regarding how to increase the penetration rate, efficiently identify undiagnosed infected patients, reduce costs, and better utilize currently available resources remain. Notably, one of the major gaps identified by our research⁷ as well as others^{8,9} is that even when universal non-targeted offering of HIV testing is made available to all patients, 50 to 60% still decline to be tested. Recent CDC data indicate that > 50% of Americans aged 18-64 years report having never been testing for HIV and that up to 50% of those who continue to engage in high risk behaviors are not tested on a regular basis, which is part of the recommended national strategy.

One approach to narrowing the testing gap is to offer HIV self-testing, which offers an alternative innovative approach outside of the traditional modes of engaging patients, with potential to reach difficult to reach populations. Self-testing at home decreases the stigma and privacy barriers associated with a conventional health professional-based testing model, and may significantly increase HIV testing uptake, thereby potentially decreasing the number of undiagnosed HIV.¹⁰ Many partners and peers of individuals at risk for HIV are also hard-to-reach population.¹¹ Network snowballing recruitment approach has successfully used to identify persons with undiagnosed HIV infection.¹²⁻¹⁶ This approach will significantly improve the participation and involvement of those hard-to-reach high risk populations.

First, we hypothesize that the provision of an HIV self-testing kit to ED patients who decline conventional ED-based HIV testing will be acceptable for these “refusers” and this approach will increase the uptake and engagement of overall HIV testing. Second, we hypothesize that the provision of an HIV self-testing kit to ED patients who are at increased risk for HIV will be acceptable and will increase the engagement of HIV testing at regular basis. We also hypothesize that partners and peers of the testing “refusers” or ED patients with increased risk for HIV will request an HIV self-testing kit for HIV testing if they are referred by their partners or friends.

2. Objectives (include all primary and secondary objectives)

The proposed pilot research has three aims: 1) to determine the feasibility and acceptability of provision of HIV self-testing kit (OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test) in order to increase uptake and engagement of HIV testing among ED patients who decline conventional ED health professional-based HIV testing and to increase the engagement of HIV testing at a regular basis for those with an increased risk for HIV (the index participants); 2) to determine the uptake and engagement of HIV testing by provision of HIV self-testing kit; and 3) to determine the feasibility and acceptability of HIV self-testing kit referral among partners or peers of the index participants through drug, sex, or social networks.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

HIV testing is recommended for all individuals aged 13-65 years.¹ Recent CDC data indicate that > 50% of Americans aged 18-64 years report never having been testing for HIV.^{17,18} They could be those who are unengaged with conventional health professional based testing at the medical care setting such as emergency departments (EDs) where the HIV testing decline rate is up to 50 - 60%.^{8,9} Or, they could be disfranchised hard-to-reach populations who are much less accessible to health care.

HIV seroprevalence in JHH ED patients increased from 5.2% in 1987 to 11% in the early 2000s and decreased to 7.8% in 2007 and 5.6% in 2013 (eIRB protocol NA_00027191, NA_00085477). An ED HIV testing program was implemented in the JHH ED in 2005, where it continues today (eIRB protocol - NA_00044965, *Rapid On-Site HIV Testing in the Emergency Department (ED)*). Currently, up to 50 to 60% of JHH ED patients decline to be tested when non-targeted offering of HIV testing is made available to all patients (IRB00051816).

In the past decade, we conducted a series of studies assessing various aspects of patient self-testing for HIV using rapid POC assays. First, we evaluated acceptability, accuracy and feasibility of having untrained patients perform HIV self-testing using existing POC tests, compared with the standard approach (trained HIV testing facilitators testing as part of the health care team) (NA_00016348). The majority of participants trusted their results – 94% of oral fluid testers (using OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test) reported trusting self-administered test result "very much."¹⁹ Furthermore, almost all participants would perform an HIV POC test at home, given the opportunity – 95.6% of the oral-fluid group would "probably" or "definitely" perform a test at home, if available. A subsequent study involved untrained patients being asked to self-perform oral-fluid HIV POC test (OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test) first, before they were tested by the standard health care professional method (NA_00016348). Again, self-test results were 100% concordant with the standard test results; the majority of participants trusted their results and would perform an HIV POC test at home, if available.²⁰ In addition, based on their experience, approximately 50% of patients preferred testing themselves over testing by health care professionals (47% vs. 40%); of note, if given a choice patients also indicated that they would prefer to be tested at home over a clinical setting (clinic or ED) (51% vs. 40%).

IWTK (www.iwantthekit.org) has been in operation in Maryland and Washington DC for recruiting participants to self-collect urogenital and/or rectal samples at home and to mail them to a laboratory for testing for sexually transmitted infections (STIs) since 2004.²¹⁻²³ Over 6,000 women and over 3500 men have been tested for chlamydia, gonorrhea, and trichomonas using self-obtained samples such as vaginal, penile-meatal, and rectal swabs from requested home collection kits. IWTK is now beginning to offer the ability for IWTK users who order an STI home kit to also order a free oral fluid POC test for HIV that the participant can perform at home with privacy and confidentiality (IRB00063291).

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Aim 1 & 2: (to determine the feasibility and acceptability take-home HIV self-testing kits (OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test) in order to increase uptake and engagement of HIV testing among ED patients who decline conventional ED health professional-based HIV testing and to increase the engagement of HIV testing at a regular basis for those with an increased risk for HIV (the index participants); 2) to determine the uptake and engagement of HIV testing by provision of HIV self-testing kit)

We will conduct a pilot randomized study at JHH ED on patients who decline routine HIV testing offer by triage nurses.

1. Recruitment

“Refusers” Cohort

Study staff will screen the ED tracking board (Epic) for patients who meet study enrollment criteria, which is done routinely as part of the ED HIV testing program. When an eligible patient is identified by the chart review (please see HIPAA form 4), the study staff will talk to the ED clinician regarding research opportunity for the potentially eligible patients. For all individuals who are not clinical patients of a study team member, the recruitment procedure will be that the patient's clinician will request and document in the chart the patient's permission to be contacted by the research staff.

“High Risk” Cohort

“The eligibility of “high-risk cohort” is ED patients who are offered an HIV test as the standard of care in the ED, accept the standard of care (SOC) HIV testing, and who have at increased risk for HIV. Study staff will screen the ED tracking board (Epic) for patients who are offered an HIV test at triage by the triage nurse, which is done routinely as part of the ED HIV testing program. When an eligible patient is identified by the chart review (please see HIPAA form 4), the study staff will talk to the ED clinician regarding research opportunity for the potentially eligible patients. For all individuals who are not clinical patients of a study team member, the recruitment procedure will be that the patient's clinician will request and document in the chart the patient's permission to be contacted by the research staff. In order to determine if the patient is at increased risk for HIV, the study staff will use of the Screening Question (three screening questions) that is uploaded in eIRB application section 20 (see section 20 for Screening_Question_05312016”). The three questions are as follows: 1) Have you been sexually active in the past 12 months, 2) have you ever used injection drugs in your life, and 3) (for men only), have you ever had sex with a man in your life time. If the patient responds “yes” to the question “Is any of your answer “Yes” (see section 20 for Screening_Question_05312016”)?, they will be considered eligible and will then go through the consent and enrollment procedures. **No identifiers will be collected for this screening step.**

2. Enrollment

The study staff will obtain verbal informed consent. The process will involve a description of the study as provided in the verbal consent form (OralConsentScript_for_HighRiskPatient_06012016.docx) with a chance to provide answers to any questions about the study. Justification for verbal consent is provided in the e-IRB application. Specifically, this study involves no bodily intervention and poses minimal risk to patients. The consent process will take between approximately 5-10 minutes, but as much time as needed will be provided to patients. Consented subjects will be given a copy of the oral

consent document for their information and records. In this consent, the patient will be asked for permission to review their medical charts at Johns Hopkins Hospital for the clinical information of their ED visit. Consented patients will be randomized to one of two groups, the Index Group (Group 1) or the Reference Group (Group 2). The index group or the HIV self-testing kit group will be provided a free FDA-approved HIV self-testing home kit (OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test) and the reference group will not receive the HIV self-testing kit. Consented patients in both groups will fill out a short survey regarding their socio-demographic information as well as their experience, attitudes, and perceptions regarding HIV testing. For patients who are in the HIV self-testing kit group, they will be asked if they would like to take a free FDA-approved HIV self-testing home kit home. If they agree, the research staff will make sure the patients will take the kit home when they are discharged. Participants in this group will also receive information regarding how to access the IWTK website to report the completion of HIV self-testing at home. Participants in this group will also be informed of a lottery-based monetary compensation with 1 in 10 chance to win an additional \$50 gift card for reporting the test results to the IWTK website. Participant who wins the \$50 gift card will be notified via text message, followed by a phone call while participant who does not win the gift card will be notified via text message (see section 20 for "Text Message Script for Lottery Incentive). For patients who are in the reference group, a standard pamphlet regarding the importance of HIV testing and HIV testing venues in Baltimore City used by current JHH ED-based HIV testing program will be provided to the patients.

3. Survey information:

- Patients will be consented and enrolled in the study prior to collecting data in the ED.
- After patient consent and enrollment by the study staff, each study participant will complete a survey questionnaire (see attached Index_Questionnaire.docx in Supplemental Study Documents) at the time of enrollment to indicate their social, demographic, and clinical characteristics. The survey is research (not part of routine care), but would not add to the patient's length of stay since it can be conducted during waiting time in a private setting. This survey will be clearly explained by and completed with the assistance of the study staff.
- All patients will be informed of our intent to contact them for a brief follow-up phone interview at one month and 3 months from the date of enrollment. This is one of the exclusion criteria.
- Following enrollment, a member of the research team will abstract chart data of the ED visits. The abstraction will focus on visit-specific clinical data (e.g. chief complaint, diagnosis, acuity level, and disposition (The full variable list can be found in section 20, Variable List).

4. Patient Follow-up

- Participants will receive a phone or text message reminder from the study team in order to remind that they are enrolled in the study within a week after the enrollment. The study team will make sure that the participant is the one who answers the phone before reminding the participant of this study. The text message will not contain the words of HIV or HIV testing. The participant will also receive text message reminder 1 week before each follow-up time (1 and 3 month time point). The text message will include the reminder of the phone follow-up as well as the \$10 gift card incentive that we would be providing to the participant upon completing the phone follow up (see section 20 for "Text reminder version 0.02).
- Consented patients will be contacted by the study team at one month and 3 months after enrollment. No more than five separate attempts to contact will be made during this time until deemed lost to follow up for the particular follow up time point.
- Follow-up questionnaires will ask the patient about their experience, attitudes, and perceptions regarding HIV testing since their index visit. Please see attached Phone_Script.docx
- A \$10.00 gift card will be mailed to the participant once he/she completes the follow-up survey by phone for each follow up time point.

5. HIV Self-testing at home

Instructions for performing the home test, with visual aids, will be included with the kit. For participants in the HIV self-testing kit group whose test result by HIV self-testing at home is interpreted as “reactive” or “indeterminate”, he or she can follow the instruction inside the kit to call a hotline to our JHH ED routine rapid HIV screening and LTC program staff that operates 16 hours a day, 7 days a week, OraQuick Consumer Support Center that operates 24 hours a day, or their primary physician for counseling. Patients with a reactive test result can either come to JHH ED or the Johns Hopkins HIV Women’s Program to receive confirmatory blood testing of the screening self-test. All participants with a positive or indeterminate screening result will have blood drawn and sent to the Maryland Department of Health and Mental Hygiene Laboratories Administration Central Laboratory where FREE confirmatory testing will be performed using the HIV-1 Western Blot Assay from BioRad Laboratories. (At MD DHMH Central Laboratory, indeterminate and negative HIV-1 Western Blot specimens are tested using the Multispot HIV-1/HIV-2 Rapid test as a differentiation assay to rule out HIV-2, and using in-house validated HIV-1 real time PCR assay to detect acute cases of HIV-1).

For participants in the HIV self-testing kit group, they will be asked to report their test result on to IWTK website using the access information provided in the HIV self-testing kit.

Aim 3: to determine the feasibility and acceptability of HIV self-testing kit referral among partners or peers of the index participants through drug, sex, or social network

When the participants (the index participants) in the HIV self-testing kit group in Aim 1 receive the self-testing kit, they will also be provided 5 referral cards to give to their partners and peers in the drug, sex, and social networks for them to request a free HIV self-testing kit from the IWTK website. On the referral card, a unique code number be used after the subject uses provided URL to land in IWTK website and create an IWTK user account. The unique code number will indicate the IWTK user is referred from an ED patient who is an index participant. The index participants would also be informed of a lottery-based monetary compensation to provide 1 in 10 chance to win an additional \$10 gift card for every IWTK user that is referred from an index participant of our study. Participant who wins the \$10 gift card will be notified via text message, followed by a phone call while participant who does not win the gift card will be notified via text message (see section 20 for "Text Message Script for Lottery Incentive). The confidential code numbers will allow determination of whether ED subjects and/or their referrals use the IWTK website but will not allow research team access to identity-linked test results (Please see data management section below regarding de-identification before data analysis). At the 1-month and 3-month phone follow-up, we will ask participants if they are able to give the referral cards to their partner(s) or friend(s), how many cards they are able to give out, how many cards they are able to give to their partner(s), how many cards they are able to give to their friend(s), and how likely it is that their partner(s) and/or friend(s) will request an HIV self-testing kit from the IWTK website. Finally, we will ask them how we can increase the likelihood of their partner(s) and/or friend(s) accessing the IWTK website and requesting an HIV self-testing kit.

Data management

IWTK website is an HIPAA compliant, secure website [please see IRB-approved protocol (IRB00063291)]. Drs. Hsieh and Gaydos, and Ms. Jett-Goheen are the research team members for the current eIRB protocol (IRB00090921) and IRB-approved protocol (IRB00063291). Ms. Jett-Goheen will manage the IWTK dataset according to the IRB-approved protocol (IRB00063291). All study data will be secured electronically on password-protected files in a password protected, encrypted drive on the departmental server with access password restricted to the study investigators and designated staff who have completed appropriate research training and are part of the study team. All data will be kept on Johns Hopkins School of Medicine servers and will not be transmitted or transferred outside of Johns Hopkins. Dr. Hsieh does not have access to IWTK dataset with identifiers. Ms. Jett-Goheen will de-identify the IWTK dataset and provide de-identified data to Dr. Hsieh for data analysis

Access Controls: Only Drs. Hsieh and Gaydos, Ms. Jett-Goheen, and the research coordinators who have completed appropriate research training and on the IRB protocol have the access to the data. The general data access controls are under Johns Hopkins School of Medicine IT and Department of Emergency Medicine. The data files will also be password-protected.

Access Log-in: There will be multi-level log-in control to access the study data. They include JHMI log-in, departmental server access, and data file password log-in.

Data Security: All study data will be secured electronically on password-protected files in a password protected, encrypted drive in the departmental server with access control and multi-level log-in control by Johns Hopkins School of Medicine IT and Departmental IT. All of the data will not be transferred or transmitted out from Johns Hopkins School of Medicine Server. For this research protocol, we will plan to destroy the participant's identifiers at the earliest opportunity – i.e. 3-6 months after the enrollment after we make sure that the participant completes the follow-up survey and receives the incentive that we mail.

- b. Study duration and number of study visits required of research participants.**
The study duration of this pilot study will be 1 year. Each consented participant will have their surveys completed during their ED visit, a phone or text message reminder within one week after the enrollment, and will have one follow up phone call at one-month and three-month time point after enrollment, respectively.
- c. Blinding, including justification for blinding or not blinding the trial, if applicable.**
N/A
- d. Justification of why participants will not receive routine care or will have current therapy stopped.**
N/A
- e. Justification for inclusion of a placebo or non-treatment group.**
N/A
- f. Definition of treatment failure or participant removal criteria.**
N/A
- g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.**
N/A

5. Inclusion/Exclusion Criteria

Inclusion Criteria for Aim 1 and 2 "Refusers" Cohort: ED patients who are 18-100 years old, able to provide informed consent for HIV testing, offered an HIV testing by the triage nurse but declined the testing offer.

"High Risk" Cohort; ED patients who are 18-100 years old, able to provide informed consent for HIV testing, who are at increased risk for HIV (i.e. sexually active in the past 12 months, ever injection drug in the lifetime, or men who have sex with men in the life time), those who accept the standard of care (SOC) HIV testing.

For Aim 3: partners or peers of study participants enrolled in the Aim 1.

Exclusion Criteria: Any person who is already known to be HIV positive. Patients with a chief complaint of sexual assault, patients with chief complaint of occupational exposure and patients who are otherwise ineligible to consent to an HIV test due to medical condition (e.g., severe illness, altered mental status). Any person who has previously enrolled in this study. Any person less than 18 years of age. Any person who is not able to provide contact information for follow-up survey. Any person who reports they are unable to access the internet.

6. Drugs/ Substances/ Devices

- a. The rationale for choosing the drug and dose or for choosing the device to be used.**
OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test as first FDA-approved HIV test, for which could be purchased over the counter in the US.
- b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.**
N/A.
- c. Justification and safety information if non-FDA approved drugs without an IND will be administered.**
N/A.

7. Study Statistics

a. Primary outcome variable.

The primary outcome variables include (1) the uptake of HIV self-testing kit among ED patients who decline conventional ED health professional-based HIV testing and to increase the perceived engagement of HIV testing at a regular basis for those with an increased risk for HIV (the index participants); (2) the relative engagement of HIV testing in one month among the index participants with provision of HIV self-testing kit as compared to those without HIV self-testing kit; (3) number of successful referrals for HIV self-testing kit request from the index participants to their partners or peers of their drug, sex, and social network.

b. Secondary outcome variables.

Participant's attitudes and perceptions on conventional health professional HIV testing in the ED as well as home self-testing. Participant's view on his/her partners and peers' attitudes and perceptions on conventional health professional HIV testing in the ED as well as home self-testing.

c. Statistical plan including sample size justification and interim data analysis.

Descriptive data analysis will be performed at the end of the study.

This is a pilot feasibility and acceptability study. We will plan to enroll a total of 200 ED patients (100 in the self-testing group and 100 in the reference group). For 100 participants in the self-testing group, each of them will refer up to 5 partners/peers to IWTK website to request STI screening kit/HIV self-testing kit. Sample size justification is not required. There will be no interim data analysis.

d. Early stopping rules.

N/A

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

The HIV self-testing kit is an FDA-approved home testing kit which is available over the counter. There should be no medical risks to the participants other than a potential psychological discomforts related to the survey, and if the patients has a positive test result.

b. Steps taken to minimize the risks.

There are no medical risks. Data will be maintained in secure data bases, only accessible to study personnel. Data will be secured in a password-protected electronic database. All study data will be secured electronically on a password protected, encrypted disk drive in departmental server with access available only to the study investigators and designated staff who have completed appropriate research training. After data abstraction and follow-up survey are complete, all identifying information will be removed and destroyed and only de-identified data will be kept for analysis.

c. Plan for reporting unanticipated problems or study deviations.

Any unanticipated problems or study deviations will be reported to the IRB.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There should be no legal risks associated with confidentiality as all study team members have signed certificates of confidentiality on file and have completed HIPAA training.

e. Financial risks to the participants.

There should be no financial risks to participants as the HIV screening tests are offered free.

9. Benefits

a. Description of the probable benefits for the participant and for society.

For HIV negative participants, there are no probable benefits to the participant except for a sense of knowing one's HIV status. For those participants whose HIV self-test is positive, a benefit will be the ability to be linked into HIV care if subsequent confirmatory HIV testing is positive. Results will help inform public health practices of how best to identify patients with undiagnosed HIV infection in EDs in the United States.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

The compensation will be a \$10 gift card to those (1) who are in the HIV self-testing group and (2) who are in the reference group and complete a phone survey at every phone follow up time point (1 and 3 month). We will use a lottery based monetary compensation (in gift card) to provide 1 in 10 chance of receiving a \$50 gift card for the Index participant who report their self-testing results on the IWTK website.

Index participant would also have a 1 in 10 chance to receive a \$10 gift card for every IWTK user that is referred from an index participant.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Study procedures for the home test will be paid for by the NIH funded Center for Point-of-Care Tests for Sexually Transmitted Diseases. Confirmatory testing through MD DHMH Laboratories Administration Central Laboratory is FREE. Enrollment into care and subsequent treatment for participants who are identified as HIV positive by confirmatory testing will be paid for by third party payers such as insurance, Medicare, medical assistance.

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