Home-based STI / HIV Screening

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Innovations in HIV CARE

www.iwantthekit.org
http://hopkinsmedicine.org/medicine/std
Disclosures

• I have received funding for research grants and/or have been a lecturer for Becton Dickinson, Gen-Probe Hologic, Abbott Molecular, Atlas, Cepheid, and Quidel
Objectives

1. To become familiar with the public health screening program called iwantthekit (IWTK)

2. To learn the acceptability of IWTK users for home HIV testing

3. To know about a novel ED program for self-testing for HIV at home

4. To be familiar with use of Dried Blood Spots (DBS)
   ✓ for 4th generation POC HIV test (p24 and Ab)
   ✓ for syphilis treponemal POC test
1. I Want the Kit (IWTK)

- Research lab based at JHU that provides STI self-testing kits to residents of Maryland, D.C., and Alaska, aged ≥14 yr.; Educational pages
- Kits allow individuals to collect for STIs in the comfort and privacy of their homes; mail; free
- Offer testing for trichomoniasis, gonorrhea, and chlamydia since 2004
- HIV study and home test kits introduced 2016
- Previous studies demonstrated high acceptability of home self-testing kits
IWTK: Methods

- Order a kit on line; & select Rx clinic
- Kit mailed to home
- Collect sample at home
- Mail kit to lab
- Text or Email sent for when results are ready
- Patient obtains results on line (HIPAA compliant)
- Attend a clinic for Rx
- Retest reminder for positives sent in 3 months

Residents of Maryland, Washington DC, and Alaska can order and receive test kits. These kits let you collect your own samples at the comfort and privacy of your home.

GET THE STI KIT!
Eligibility: 14 and over, any gender, living in Maryland, Washington DC or Alaska. Vaginal, Penile, and/or Rectal collection kit.

FREE HIV STUDY!
Eligibility: This Johns Hopkins University study is open to people 18 and over, any gender, living in Baltimore City or Baltimore, Harford.
Residents of Maryland, Washington DC, and Alaska can order and receive test kits. These kits let you collect your own samples in the comfort and privacy of your home.

If you are interested but not eligible, register here and we will contact you if a study becomes available.

INSTRUCTIONS

Residents of Maryland, Washington DC, and Alaska can order and receive a test kit.

Do NOT order a test kit to give to your sex partner(s). They must create an account and order their own test kit.
### Sexually Transmitted Infection (STI) Positives by Sex and Age, IWTK Specimens, Aug 2013-Dec 2016 (N= 3,191)

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Chlamydia^</th>
<th>Gonorrhea</th>
<th>Trichomonas^^</th>
<th>Any STI*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Females</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&lt;25</td>
<td>8.6%</td>
<td>0.8%</td>
<td>5.9%</td>
<td>13.7%</td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>4.5%</td>
<td>0.4%</td>
<td>5.9%</td>
<td>10.1%</td>
<td></td>
</tr>
<tr>
<td>35+</td>
<td>2.8%</td>
<td>0%</td>
<td>6.9%</td>
<td>8.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&lt;25</td>
<td>9.5%</td>
<td>2.4%</td>
<td>1.1%</td>
<td>11.8%</td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>8.9%</td>
<td>3.0%</td>
<td>0.2%</td>
<td>10.9%</td>
<td></td>
</tr>
<tr>
<td>35+</td>
<td>2.2%</td>
<td>0.9%</td>
<td>2.2%</td>
<td>5.3%</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25</td>
<td>8.9%</td>
<td>1.3%</td>
<td>4.3%</td>
<td>13.1%</td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>6.4%</td>
<td>1.5%</td>
<td>3.4%</td>
<td>10.4%</td>
<td></td>
</tr>
<tr>
<td>35+</td>
<td>2.5%</td>
<td>0.5%</td>
<td>4.2%</td>
<td>6.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td>6.5%</td>
<td>1.3%</td>
<td>3.9%</td>
<td><strong>10.7%</strong></td>
</tr>
</tbody>
</table>

^Differences in chlamydia+ by age were statistically significant for women and men (Pearson chi-square, p<0.01)

^^Differences in trichomonas+ by age were statistically significant for men (Pearson chi-square, p<0.01)

*Differences in overall STI+ by age were statistically significant for women and men (Pearson chi-square, p<0.01)
% Positive by STI and Race, IWTK Specimens, Aug 2013-Dec 2016 (N= 3,191)

<table>
<thead>
<tr>
<th></th>
<th>Black, Non-Hispanic</th>
<th>White, Non-Hispanic</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonorrhea</td>
<td>1.4</td>
<td>0.7</td>
<td>1.9</td>
</tr>
<tr>
<td>Trichomoniasis^</td>
<td>6.0</td>
<td>1.9</td>
<td>2.2</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>7.5</td>
<td>5.6</td>
<td>6.2</td>
</tr>
<tr>
<td>Any STI^</td>
<td>13.4</td>
<td>7.9</td>
<td>9.7</td>
</tr>
</tbody>
</table>

^Statistically significant (Pearson chi square)
STI Trends, IWTK Aug 2013 - Dec 2016

CT = *Chlamydia trachomatis*, TV = *Trichomonas vaginalis*, NG = *Neisseria gonorrhoeae*

^Statistically significant differences (Pearson chi-square, p<0.01)
## Risk Analysis: Sexually Transmitted Infection (STI) Positivity*

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>%Positive</th>
<th>OR (95% CI)^</th>
<th>AOR (95%CI)^^^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>11.4%</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Female</td>
<td>9.8%</td>
<td>0.84 (0.67-1.06)</td>
<td>1.10 (0.87-1.40)</td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>7.9%</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Black, Non-Hispanic</strong></td>
<td>13.4%</td>
<td>1.81 (1.39-2.36)</td>
<td>1.67 (1.27-2.20)</td>
</tr>
<tr>
<td>Other Race</td>
<td>9.6%</td>
<td>1.24 (0.88-1.74)</td>
<td>1.15 (0.81-1.62)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>--</td>
<td>0.96 (0.95-0.98)</td>
<td><strong>0.97 (0.96-0.99)</strong></td>
</tr>
<tr>
<td>2013</td>
<td>12.5%</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2014</td>
<td>12.9%</td>
<td>1.04 (0.76-1.43)</td>
<td>1.14 (0.82-1.59)</td>
</tr>
<tr>
<td>2015</td>
<td>8.9%</td>
<td>0.68 (0.47-0.98)</td>
<td>0.78 (0.54-1.14)</td>
</tr>
<tr>
<td>2016</td>
<td>8.3%</td>
<td>0.64 (0.44-0.92)</td>
<td>0.72 (0.49-1.06)</td>
</tr>
<tr>
<td>Prior STI (Y:N)^γ</td>
<td>14.4%:9.9%</td>
<td>1.53 (1.18-1.99)</td>
<td>1.26 (0.96-1.66)</td>
</tr>
<tr>
<td>Rectal sex (Y:N)</td>
<td>14.8%:9.1%</td>
<td>1.73 (1.37-2.18)</td>
<td><strong>1.81 (1.43-2.30)</strong></td>
</tr>
<tr>
<td>IWTK Risk Score^µ</td>
<td>--</td>
<td>1.17 (1.10-1.25)</td>
<td><strong>1.14 (1.07-1.22)</strong></td>
</tr>
<tr>
<td>Used IWTK Before (Y:N)</td>
<td>9.8%:11.5%</td>
<td>0.84 (0.67-1.05)</td>
<td>0.79 (0.62-1.00)</td>
</tr>
</tbody>
</table>

*Findings in red were statistically significant at the <0.05 alpha level; see summary for interpretation

^Odds Ratio (OR) estimates based on univariate logistic regression (N=3,191)

^^Adjusted Odds Ratio (AOR) estimates based on multivariate logistic regression with all risk factors listed included in the model (N=3,163); interactions between risk score and correlated covariates (Prior STI, or Rectal sex) were evaluated and removed from the model due to insignificance; the model fit was adequate (Hosmer and Lemeshow GOF, p=0.37)

^γPrior STI based on prior positives identified from IWTK testing where rescreening was completed

^µRisk Score derived from IWTK Risk Quiz; risk estimated on a 10 point scale based on age, number of partners, history of STIs, condom use, and other risk factors
IWTK STI Summary

- High STI specimen positivity (10.7%), indicates the IWTK reached a high-risk population for anonymous internet testing
- Race was significantly associated with overall STI & TV positivity
- STI positivity rates decreased in 2015 and 2016
- Risks consistent w/ literature; **black, young age, prior STI, & rectal sex**
- Except for prior STI, factors significant in multivariate analysis:
  - The odds of positivity were 67% higher for black users vs. white (p<0.01)
  - The odds of positivity decreased by 3% each year of increased age (p<0.01)
  - The odds of positivity increased by 14% for each 1 point increase on the 10 point risk score among IWTK users (p<0.01)
  - The odds of specimen positivity were 81% higher among IWTK users requesting rectal kits, a proxy for rectal sex (p<0.01)
  - The odds of positivity were 21% lower among prior IWTK users (p=0.05)
- The findings of the study further validate the IWTK risk scoring tool as a means of predicting STI probability.
2. Home IWTK testing for HIV

- Approximately 15% of HIV infected unaware of status
- Adolescents & young adults are less likely to know
- 44% of individuals 13-24 yr. are undiagnosed
- Young adults 20-29 yr. account for 37% of all new cases
- Between 2010 and 2014, annual infections decreased by 10%
- Declines in infection are inconsistent across
Adult/Adolescent New HIV Diagnoses by ZIP Code, Baltimore City, Maryland, 2016

Legend
New HIV Diagnoses (age 13+)
N = 278 cases
- 0
- 1 - 5
- 6 - 14
- 15 - 20
- 21 - 25
- ZIP Code < 1,000 residents

Source: Center for HIV Surveillance, Epidemiology, and Evaluation, Maryland Department of Health. Data reported through June 30, 2017. Patient residence based upon residence at HIV diagnosis. Data for ZIP Codes with less than 1,000 residents as reported in the 2016 US Census Bureau Population Estimates have been suppressed for privacy.
HIV Home Self Test Study

• Introduced study with online consent in Jan. 2016 to request home Oraquick oral fluid self-test kit with questionnaire

• Kits available to people ≥18 yr. of any gender in Baltimore Metropolitan Area (Baltimore City or Baltimore, Harford, Anne Arundel, Howard, or Montgomery Counties)

• Conducted a retrospective analysis of characteristics and perceptions of IWTK HIV test kit users

• Descriptive data analysis conducted for individuals using kits to identify characteristics of study population

• Multivariate logistic regression analysis conducted to elucidate which characteristics could be predictors of test kit usage
Dr. Charlotte Gaydos, Principal Investigator at Johns Hopkins University, is conducting a research study entitled “Evaluation of the acceptability and feasibility of home performance of a rapid point-of-care test for HIV by participants from the ‘I Want the Kit (IWTK)’ program.”

Would you like to participate?

- Please provide a phone number so that we may contact you about the HIV study.
  - Phone Number
  - Yes, I am interested in the study.
  - No Thanks.
    - I am not interested in the HIV study. Send me only the genital and/or rectal collection kit for STIs that I ordered.

Principal Investigator: Charlotte Gaydos, DrPH - 410-614-0932
Sr. Research Coordinator: Mathilda Barnes – 410-614-2044
Research Manager: Mary Jett-Goheen – 410-502-2694

Study Number: IRB00063291

Why is this research being done?

This research is being done to evaluate the acceptability and feasibility of performing a single-use, rapid point-of-care test for HIV at home by participants from the 'I Want the Kit' (IWTK) project.
Sign up

**STI Self-collected testing kit** – Residents of Maryland, Washington DC, and Alaska, 14 and over, any gender, can order and receive the kit.

**HIV Self-testing Study Kit** – This study is open to people 18 and over, any gender, living in Baltimore City or Baltimore, Harford, Anne Arundel, Howard or Montgomery Counties in Maryland.

- The kits allow you to collect your own sample(s) in the comfort and privacy of your home.
- The kits are easy to use and the results are reliable.
- They are mailed directly to you free of charge.

**ED Referral**

If you have a referral card, enter your code here. You may be eligible to receive study compensation.

**First name**

**Last name**

**Email**

**Email confirmation**

Check your spam settings to make sure you get our emails!
OraQuick HIV-1/2 Testing Instructions

**OraQuick Kit:**
- Open first
- Test Vial
- Open last
- Swab

1. Swab once around the gums, both top and bottom.
2. Make sure that the swab rubs against the base of the gums.
3. Insert device into Vial; then set timer for 20 minutes.

**Results:***
- **NEGATIVE RESULT:** Control Bar (C) and Test Bar (T) present.
- **POSITIVE RESULT:** Control Bar (C) and Test Bar (T) present along with two additional bands.
- **INVALID RESULT:** Control Bar (C) and Test Bar (T) not present.
Participants given the option to express interest via the website

Coordinator called participants to explain aim of the study, answer any questions

After consenting via website, test kits mailed

Testers collect own oral fluid samples and perform test

Participants complete questionnaire, answering questions concerning ease, perceptions, and acceptability of testing process

Testers interpret results
I Want The Kit: Will Individuals Order and Perform a Free On-line HIV Test?

As of 04/06/18, there were 1444 eligible persons accessing the site; **332 (23%)** expressed interest.

Coordinator was able to speak to **72.6%** persons; **90%** signed consent and were mailed a kit. (10 declined to participate after talking to coordinator; 12 never signed consent form)

**73.7% (160/217)** used the HIV home kit and entered the results.

None have been positive; **46** have not yet reported results/survey; 11 kits were returned, lost in mail, or not received.
Characteristics of Individuals Who Consented

Gender: Male - 63%, Female - 36%, Other - 1%

Age: 18-24 yr - 18%, 25-29 yr - 27%, 30-34 yr - 20%, ≥ 35 yr - 35%

Race: White - 47%, African-American - 34%, Other - 19%

Ethnicity: Hispanic - 12%, Not Hispanic - 88%

Risk Score: Low Risk - 30%, Intermediate risk - 9%, High Risk - 56%, Very High Risk - 5%

Previous Use: No - 55%, Yes - 45%
## Test Kit Completion Status by Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Completed %</th>
<th>Not Completed %</th>
<th>Pearson Chi² Test p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>18.7 (41/219)</td>
<td>8.2 (18/219)</td>
<td></td>
</tr>
<tr>
<td>25-29</td>
<td>25.1 (55/219)</td>
<td>10 (22/219)</td>
<td>0.717</td>
</tr>
<tr>
<td>30-34</td>
<td>15.5 (34/219)</td>
<td>4.1 (9/219)</td>
<td></td>
</tr>
<tr>
<td>≥ 35</td>
<td>13.7 (30/219)</td>
<td>4.6 (10/219)</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25.6 (56/219)</td>
<td>10.5 (23/219)</td>
<td>0.613</td>
</tr>
<tr>
<td>Female</td>
<td>46.6 (102/219)</td>
<td>16.4 (36/219)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1.0 (2/219)</td>
<td>0.0 (0)</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>25.6 (56/219)</td>
<td>8.7 (19/219)</td>
<td>0.343</td>
</tr>
<tr>
<td>Black</td>
<td>32.4 (71/219)</td>
<td>14.6 (32/219)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>15.1 (33/219)</td>
<td>3.7 (8/219)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>10.5 (23/219)</td>
<td>1.4 (3/219)</td>
<td><strong>0.047</strong></td>
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<tr>
<td><strong>Risk Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Risk (0-1 point)</td>
<td>3.2 (7/219)</td>
<td>1.4 (3/219)</td>
<td>0.913</td>
</tr>
<tr>
<td>Intermediate Risk (2-3 points)</td>
<td>6.4 (14/219)</td>
<td>2.3 (5/219)</td>
<td></td>
</tr>
<tr>
<td>High Risk (4-6 points)</td>
<td>42.0 (92/219)</td>
<td>14.2 (31/219)</td>
<td></td>
</tr>
<tr>
<td>Very High Risk</td>
<td>21.5 (47/219)</td>
<td>9.1 (20/219)</td>
<td></td>
</tr>
<tr>
<td><strong>Previous Use</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td><strong>45.2 (99/219)</strong></td>
<td>9.6 (21/219)</td>
<td><strong>0.001</strong></td>
</tr>
<tr>
<td>No</td>
<td><strong>27.9 (61/219)</strong></td>
<td>17.4 (38/219)</td>
<td></td>
</tr>
</tbody>
</table>

* Statistically significant
Multivariate logistic regression analysis: unadjusted association of age, gender, race, ethnicity, IWTK risk score, and previous use with usage of test kit

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Odds Ratio (95% CI, p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>1</td>
</tr>
<tr>
<td>25-29</td>
<td>1.1 (0.52-2.3, 0.81)</td>
</tr>
<tr>
<td>30-34</td>
<td>1.7 (0.67-4.2, 0.28)</td>
</tr>
<tr>
<td>≥ 35</td>
<td>1.3 (0.53-3.3, 0.55)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>0.86 (0.46-1.6, 0.63)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
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</tr>
<tr>
<td>White</td>
<td>1</td>
</tr>
<tr>
<td>Black</td>
<td>0.75 (0.39-1.5, 0.40)</td>
</tr>
<tr>
<td>Other</td>
<td>1.4 (0.55-3.6, 0.48)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>1.75 (0.65-4.7, 0.27)</td>
</tr>
<tr>
<td><strong>Risk Score</strong></td>
<td></td>
</tr>
<tr>
<td>Low Risk (0-1 point)</td>
<td>1</td>
</tr>
<tr>
<td>Intermediate Risk (2-3 points)</td>
<td>1.2 (0.22-6.5, 0.83)</td>
</tr>
<tr>
<td>High Risk (4-6 points)</td>
<td>1.3 (0.31-5.2, 0.74)</td>
</tr>
<tr>
<td><strong>Very High Risk</strong></td>
<td></td>
</tr>
<tr>
<td>Previous Use*</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2.94 (1.6-5.5, 0.001)</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
</tr>
</tbody>
</table>

* Statistically significant
I Want The Kit: Will Individuals Order and Perform a Free On-line HIV Test?

Questionnaire (n=160) results:

- easy to collect oral fluid: 95.6%
- easy to follow instructions: 90.6%
- easy to read and interpret results: 96.9%
- easy to perform test: 96.2%
- believe result is definitely correct: 80.6%
- or probably correct: 19.4%
- trust result very much: 79.4%
- or trust somewhat: 20.6%
- definitely recommend to a friend: 95.0%
- definitely test self again at home: 83.1%
- or probably test self again at home: 15.0%

Maximum price pay to purchase OTC

- $10: 24.4%
- $20: 42.5%
- $30: 15.6%
- $40: 15.0%

(Only 1 person incorrectly reported HIV positive)
Based on your experience, would you prefer to test yourself for HIV at home or would you prefer a healthcare provider/laboratory collect and perform your test?

1. Prefer self-testing 113 (70.6%)
2. Prefer healthcare provider/laboratory 17 (10.6%)
3. No Preference 30 (18.8%)

If you went to a clinic, doctor’s office, or emergency room to see a healthcare provider, which would you prefer?

1. To have the healthcare provider collect your sample and perform the test 71 (44.4%)
2. To collect the sample yourself and have the healthcare provider perform the test 20 (12.5%)
3. To collect the sample yourself and perform the test yourself in the clinic/doctor’s office/ER 26 (16.2%)
4. No Preference 43 (26.9%)
Summary

- Data demonstrates **high acceptability** of home testing among study participants
- Multivariate logistic regressions indicate **previous use** of the IWTK platform and STI test kits was the only statistically significant predictor of use of HIV test kit
- Easy to perform and private self-testing kits for HIV may increase the number of individuals who are **aware of their HIV status** and screen regularly

**Limitations**

- Potential for recall bias
- Selection bias

**Future Considerations**

- How to increase use of home test kits among individuals who may identify as trans* or MSM
3. Novel ED program for self-testing for HIV at home

Increasing HIV Testing through Provision of Home HIV Self-Testing Kits to Emergency Department Patients – A Pilot Randomization Study of a Novel ED Intervention


SAEM, 2017
CDC Recommends
- EDs as corner stone for HIV screening
- Individuals be screened once in lifetime for HIV and those with increased risk receive an HIV test at least annually

Emergency Departments (EDs) have been successful in identifying undiagnosed HIV infection

Up to 60% patients decline to an HIV test offer in EDs, including patients at increased risk for HIV
Objectives

- To determine increase in HIV testing rates through provision of HIV self-testing kit among two groups of ED patients, the “Decliners” and the “High Risk”

“Decliners” - ED patients who decline conventional HIV testing

“High Risk” - ED patients who accept conventional testing and are at increased risk for HIV
Methods

Study Setting
- Johns Hopkins Hospital ED, Baltimore, Maryland
- ~70k ED visits annually
  - 51% females
  - mean age 44 ±17 years
  - approx. 70% population is African American
- Prior reported HIV seroprevalence of 5.6%

- JHH ED HIV Screening Program:
  - Routine non-targeted opt-out HIV screening at triage
  - 0.2 - 0.4% newly diagnosed HIV patients
"Decliners"

Patients who declined an HIV test offer

- Consented and enrolled

Patients took a baseline survey

Randomization

- Intervention group
  - Phone follow-up at one month

- Control group
  - Phone follow-up at one month

Methods
**Methods**

**Intervention group**

**Control Group**

Analysis performed using chi-square test.
Index Arm:

- OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test with instruction sheets

- Patient instructed to submit test result on iwantthekit.org (IWTK)
"Decliners"

Study population demographics: (n=100)
- 66% females
- Mean age $40.2 \pm 12.7$ years
- 46% White, 43% African American

Baseline survey analysis:
- 43% participants did not test for HIV in last 12 months.
- 19% participants never tested for HIV in their lifetime.
- 40% perceived themselves as having no risk for HIV
“Decliners” Results

Medical Care Setting – Emergency Department

Patients Offered an HIV Test

- Patients Accepted HIV Testing
- Patients Declined HIV Testing (126)

Patients Declined to Participate (26)

100 Patients Enrolled

Randomization

Intervention Group (n=52)

- Follow-up (n=28)
- Having HIV Test (n=15, 54%)
  - Self-Testing: (n=12)
  - Non Self-Testing: (n=3)

Control Group (n=48)

- Follow-up (n=35)
- Having HIV Test (n=2, 6%)

Lost Follow-up (n=24) vs Lost Follow-up (n=13)

Provision of HIV self-testing kits attributes to **88.9%** increase in HIV testing in the Intervention group. RR **9.4** (95% CI: **2.3, 37.6**) for HIV testing in the Intervention group compared to the Control group.
“High Risk” Results

Study population demographics: (n=100)

- 57% females
- Mean age $32.9 \pm 11.6$ years
- 83% African American, 7% White

Baseline survey analysis:

- 23% participants did not test for HIV in last 12 months
- 2% participants never tested for HIV prior to index visit
“High Risk” Results:

Medical Care Settings - Emergency Department

Patients accepted an HIV test (133)

Patients without increased risk for HIV (23) → Patients Declined to Participate (10)

100 Patients with increased risk for HIV

Randomization

Intervention Group (n=50)

Follow-up (n=33, 66%)

Having HIV Test (n=20, 60%)
Self - Testing: 19 (95%)
Non Self - Testing: 1 (5%)

Control Group (n=50)

Follow-up (n=37, 74%)

Having HIV Test (n=7, 21.6%)

Lost follow-up (n=17)

Lost follow-up (n=13)

Provision of HIV self-testing kits attributes to 64% increase in HIV testing in the Intervention group. RR 3.2 (95% CI: 1.6, 6.6) for HIV testing in the Intervention group compared to the Control group.
Conclusions

Provision of HIV Self-Testing kits to ED patients:
- Increases overall HIV testing rates among ED patients who decline an HIV test offer and could promote frequent testing in high risk individuals
- Overcomes some of HIV testing barriers in the ED
- Could benefit other settings such as clinics, outpatient centers, community outreach
4. The Future for IWTK

Use of dried blood spots (DBS)

- Syphilis
- HIV 4\textsuperscript{th} generation POC tests
- HIV viral load
Evaluation And Performance Of Dried Blood Spots For HIV Point Of Care/Rapid Testing

Alere for HIV p-24 and antibody:
Accuracy – DBS compared to ZeptoMetrix panel 100% (40/40)
PPA and NPA – 100% (20/20); 100% (20/20)
Reproducibility – 100% (160/160)

Dize et al. CVS, 2016
Health Check for Syphilis:
Accuracy – DBS compared to serum samples 100% (40/40)
PPA and NPA – 100% (20/20); 100% (20/20)
Reproducibility – 99.3% (159/160)

<table>
<thead>
<tr>
<th>Comparison Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Check DBS</td>
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<tr>
<td>Positive</td>
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<tr>
<td>Negative</td>
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</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
<td>n=40</td>
</tr>
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</table>
Validation of DBS for HIV viral load

Qualitative detectability of the HemaSpot device was assessed between 3.7 log copies/mL and 2.8 log copies/mL

Concordance between plasma and HemaSpot ≥ 1000 cps/mL

- 100% agreement was observed between the two sample types with viral load ranging between 3-7 log copies/mL.

Concordance between plasma and HemaSpot <1000 cps/mL

- 86% agreement was observed between the two sample types with viral load <1000 cps/mL.

• Good correlation was observed between the HemaSpot device and plasma viral load with R²=0.965.
Summary

- STIs commonly detected by IWTK recruitment
- Home TV POC study published
- HIV Home test project ongoing
- Future plans are to add DBS for HIV & Syphilis
- Could Home testing be used for PREP patients?

CT, NG, TV

TV POC at home → Perform HIV POC at home
Collect DBS at home for HIV & Syphilis?
Acknowledgements

• Mary Jett-Goheen
• Mathilda Barnes
• Laura Dize
• Justin Hardick
• Jeff Holden
• Barbara Silver
• Yu-Hsaing Hsieh
• Anuj V. Patel
• Richard Rothman
• Perry Barnes
• Anne Rompalo

Questions?

It's QUESTION TIME!!
Evaluation And Performance Of Dried Blood Spots For HIV And Syphilis Point Of Care/Rapid Testing

• **DBS Processing**
  - Half of each HemaSpot DBS was eluted into 500uL of 0.5% PBST, vortexed and eluted overnight at 4°C

• **DBS Testing**
  - Eluates were tested for p24 Ag and/or HIV Ab by Alere Determine™ HIV-1/2 Antigen Antibody Combo (Alere) or Multispot HIV-1/HIV-2 Rapid Test (BioRad); and Treponemal antibodies for Syphilis by Syphilis Health Check (Trinity Biotech)

• Eluates were tested according to manufacturers’ instructions for serum specimens

Dize et al. CVS, 2016
Validation of DBS for HIV viral load

EVALUATION OF AN OPEN MODE PROTOCOL FOR HIV-1 RNA QUANTIFICATION IN DRIED BLOOD SPOTS ON THE ABBOTT m2000sp AND m2000rt PLATFORM

• Eighty microliters of whole blood was spotted on the HemaSpot devices and air dried overnight at room temperature (RT).

• HemaSpot samples were eluted for 45 minutes at RT in 1.3mL of Abbott DBS Elution Buffer and processed by using the m2000_1.0ml_HIV_DBS_Quant protocol.

• Analytical sensitivity (AS), measuring range (MR) and precision were evaluated across 3 different runs in order to evaluate the performance of HemaSpot device with the above open mode protocol.

• EDTA anti-coagulated whole blood from patients with known HIV-1 RNA viral load was used to develop accuracy panels; the HemaSpot device results were compared to plasma viral load results obtained by Cobas AmpliPrep/Cobas Taqman HIV-1 v2.0 (Roche Molecular, Indianapolis, IN). 5 replicates of each specimen (ranging in concentration from ≥2.0 log < 7.0 log) were tested.

• Specificity was evaluated with EDTA anti-coagulated whole blood from known seronegative patients.

Dize et al, CVS 2016
New HIV Diagnoses in the United States for the Most-Affected Subpopulations, 2016

- Black, Male-to-Male Sexual Contact: 10,223
- Hispanic/Latino, Male-to-Male Sexual Contact: 7,425
- White, Male-to-Male Sexual Contact: 7,390
- Black Women, Heterosexual Contact: 4,189
- Black Men, Heterosexual Contact: 1,926
- White Women, Heterosexual Contact: 1,032
- Hispanic/Latina Women, Heterosexual Contact: 1,025
# Lifetime Risk of HIV Diagnosis

## Highest Risk

<table>
<thead>
<tr>
<th>State</th>
<th>One in “n”</th>
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<tbody>
<tr>
<td>District of Columbia</td>
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<tr>
<td>Maryland</td>
<td>49</td>
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<tr>
<td>Georgia</td>
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</tr>
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<td>Florida</td>
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<td>New York</td>
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<td>Texas</td>
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<td>New Jersey</td>
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<td>Mississippi</td>
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<td>Arizona</td>
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<td>Missouri</td>
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<tr>
<td>Arkansas</td>
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</table>

## Lowest Risk

<table>
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<th>State</th>
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<tbody>
<tr>
<td>West Virginia</td>
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<td>Wisconsin</td>
<td>307</td>
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<tr>
<td>Iowa</td>
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<tr>
<td>Utah</td>
<td>366</td>
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<tr>
<td>Maine</td>
<td>373</td>
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<tr>
<td>Alaska</td>
<td>384</td>
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<td>South Dakota</td>
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<td>New Hampshire</td>
<td>411</td>
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<tr>
<td>Wyoming</td>
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<tr>
<td>Vermont</td>
<td>527</td>
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<tr>
<td>Idaho</td>
<td>547</td>
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<tr>
<td>Montana</td>
<td>578</td>
</tr>
<tr>
<td>North Dakota</td>
<td>670</td>
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</tbody>
</table>

*Source: CDC.GOV*
• In 2016, Maryland ranked 5th among states with highest rates of diagnoses for HIV and AIDS among adolescents and adults
• Baltimore City disproportionately accounts for a large number of these diagnoses
**IWTK Risk Score**

<table>
<thead>
<tr>
<th>Questions</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you ≤ 25 years old?</td>
<td>Yes = 1 point. No = 0 points.</td>
</tr>
<tr>
<td>2. Have you had a new sex partner, or multiple partners, in the last 90 days?</td>
<td>Yes = 1 point. No = 0 points.</td>
</tr>
<tr>
<td>3. Do you have more than one current sex partner at the present time?</td>
<td>Yes = 1 point. No = 0 points.</td>
</tr>
<tr>
<td>4. Have you ever been told you had, or been treated for, and STI in the past?</td>
<td>Yes = 1 point. No = 0 points.</td>
</tr>
<tr>
<td>5. How many sex partners have you had in the last 90 days?</td>
<td>10 or more = 3 points. 5-9 = 2 points. 2-4 = 1 point. 0-1 = 0 points.</td>
</tr>
<tr>
<td>6. When you have sex, do you use a condom?</td>
<td>Never = 3 points. Sometimes = 3 points. Always = 0 points.</td>
</tr>
</tbody>
</table>

Gaydos et al. IWTK Risk Score, Sex Transm Infect. 2016;92:44–48
Residents of Maryland, Washington DC, and Alaska can order and receive test kits. These kits let you collect your own samples in the comfort and privacy of your home.

GET THE STI KIT!  FREE HIV STUDY!  ENTER MY RESULTS

If you are interested but not eligible, register here and we will contact you if a study becomes available.

INSTRUCTIONS

Residents of Maryland, Washington DC, and Alaska can order and receive a test kit.

Do NOT order a test kit to give to your sex partner(s). They must create an account and order their own test kit.

VAGINAL  PENILE  RECTAL
Self-Collection of Rectal Swab

ATTENTION: Read ALL instructions before you begin!

STEP 1
Wash your hands thoroughly.

STEP 2
Unopened Swab
Either squat down, or lift one leg on a toilet, ledge, or chair (as shown). Pull underwear down or off.

STEP 3
Open the swab. DO NOT TOUCH THE TIP OF THE SWAB.
Twist first to break seal.
Then pull. The swab will stay attached to the red cap.
Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

STEP 4
With your dominant hand (right if you’re right-handed, left if you’re left-handed), grip the opened swab 1.5” away from the tip of the swab (just below the first notch). DO NOT TOUCH THE TIP OF THE SWAB.
Do NOT, at any point, use anything (soap, saliva, or any kind of lubricant) either on your body or on the swab.

STEP 5
With your other hand, position your bare buttock and lift one cheek for easy access to the rectum. (DO NOT use anything on your rectum or the swab.)

STEP 6
Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.

STEP 7
Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there, for stability. (The swab should stay where it is—only your fingers should move.)

STEP 8
Gently rub the swab in a circle, touching the walls of your rectum, to collect the specimen.

STEP 9
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

STEP 10
Place used swab back into the transport tube. Close tightly to prevent leakage.

STEP 11
Place closed tube into the red plastic zip-lock bag. Seal the bag.

STEP 12
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It’s already addressed and postage is paid, so you don’t need to do anything else.
Self-Collection of Penile Swab
ATTENTION: Read ALL instructions before you begin!

STEP 1
Take the sealed swab out of the package. Open the swab. Twist first to break seal.

STEP 2
Roll the swab just at the tip or inside the opening to the penis through which you pass urine (pee). Roll the swab completely around the opening to get the best specimen. It is not necessary to put the swab deep inside the hole (urethra opening).

STEP 3
Then pull. The swab will stay attached to the red cap.

STEP 4
Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

STEP 5
Roll the swab around the edges of the urethra opening. (The swab can touch the edges of the hole, but don't push it inside.)

STEP 7
Place used swab back into the transport tube. Close tightly to prevent leakage.

STEP 8
Place closed tube into the red plastic zip-lock bag. Seal the bag.

STEP 9
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It's already addressed and postage is paid, so you don't need to do anything else.
Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!

STEP 1
Wash your hands thoroughly.

STEP 2
Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina - such as sitting on the toilet, or standing with one foot on a chair, or any position that you would use to insert a tampon.

STEP 3
Take the sealed swab out of the package. Open the swab.
Twist first to break seal.
Then pull. The swab will stay attached to the red cap.
Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

STEP 4
Insert the white tip of the swab about one inch inside the opening of your vagina.

STEP 5
Rotate the swab for 15 seconds, making sure that the swab touches the walls of your vagina so that moisture is absorbed into the swab.

STEP 6
Remove the swab from your vagina. Don’t let the tip of the swab touch anything else.

STEP 7
Place used swab back into the transport tube. Close tightly to prevent leakage.

STEP 8
Place closed tube into the red plastic zip-lock bag. Seal the bag.

STEP 9
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It’s already addressed and postage is paid, so you don’t need to do anything else.

Peel off adhesive to reveal seal.