At-Home Testing Webinar

• **Audio Instructions**
  1. Dial: (202) 318-6999
  2. Enter passcode: **2236027#**
  3. Connect your voice ID: **dial *65*(your 4-digit audio pin number)** – you can locate your pin by clicking on the “i” in the upper righthand corner of your screen

• **Housekeeping**
  • **All attendees** are on **mute** to limit background noise and ensure clear audio
  • This webinar is being **recorded**

• **Reminders**
  • To **unmute** your line and speak, **press *# (star, pound)**
  • Please use the **chat feature** on the right when submitting questions
Christopher S. Hall, MD, MS, AAHIVS  
Chair, Clinic+ Clinical Advisory Committee, NCSD  
Medical Consultant,  
UCSF CA STD/HIV Prevention Training Center  
Former VP Medical Affairs, San Francisco AIDS Foundation & Medical Co-Director  
East Bay AIDS Center  

NOTE: Dr. Hall is a Senior Medical Advisor for Nurx.com. His work on this technical assistance initiative should not be construed as an endorsement of Nurx or its associated lab partners.
Webinar #3 Objectives

• Describe NCSD At-home STD testing technical assistance (TA) components
• Review TA brief + FAQ + other resources
• Understand details of Johns Hopkins University “I Want the Kit” Program
• Understand Oregon Health Authority’s efforts to work directly with a private lab to make at-home STD testing available
• Provide Q&A opportunity for attendees
Technical assistance components

- Webinar meeting (2 of 4 completed)
- Enduring materials - TA brief with FAQ
- External resources + bibliography
- Field reports
- Pointing to 3rd party commercial resources (KFF, other)
- Additional committee-driven efforts to meet NCSD Member needs in the at-home testing space *(to be announced)*
- Invite input as to direction & content
# Pathways to realizing at-home STD testing

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Description</th>
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</thead>
</table>
| 1 | **Homegrown At-home STD Testing Solution**  
Local PHL, in-house providers, and self-fulfillment of kits |
| 2 | **Third-party At-home Lab interface Solution**  
In-house providers, with 3rd party lab kit fulfillment |
| 3 | **Third-party End-to-end Digital Provider + Lab Solution**  
Both provider and lab functions outsourced |

**Other:** BHOC’s TakeMeHome Program
Technical assistance brief + FAQ

National Coalition of STD Directors

At-home Self-collection Lab Testing for Sexually Transmitted Infections

Technical Assistance Brief
Updated May 20, 2020

I. Background: Home-based STI Testing with Digital Health Support

Since the advent of COVID-19 in the U.S. in January 2020, STD facilities and program/clinic staff have been frequently repurposed and redeployed substantially in an effort to scale up SARS-CoV-2 testing, contact tracing, and build infrastructure and response to this expanding epidemic. Digital health platforms can work hand-in-hand with t breaking down access barriers to facilitate patient care.

II. Regulatory Overview: Home-based Testing

The Food and Drug Administration (FDA) reviews diagnostic devices for clearance and approval. Device manufacturers submit a 510(k) application to FDA to demonstrate that a device is at least as safe and effective as a legally marketed device that is not subject to premarket approval (PMA). In the case of diagnostic assays that are most commonly in use to test for sexually transmitted infections (STIs), assays are 510(k) cleared or PMA cleared; however, the alternative collection methodology of self-collection of
Technical assistance brief + FAQ

III. STI Home Testing Landscape

Presently in the U.S., a very few high complexity laboratories have emerged to provide lab-based testing on self-collected samples collected in the home, using 510(k) cleared / PMA cleared assays.

The largest commercial labs (LabCorp and Quest) have involvement in this arena limited by heavy investment in brick-and-mortar draw stations and related infrastructure. Pixel by LabCorp offers home collection of a urine sample to test for three trichomonas. QuestDirect offers home collection for hepatitis B and C, syphilis and HIV. Both serve to initiate fulfillment of respective test kits.

A Look at Online Platforms for Contraceptive and STI Services during the COVID-19 Pandemic

Britni Frederiksen, Ivette Gomez, and Alina Salganicoff
Published: Apr 23, 2020

Online Contraception and STI Service Platforms

<table>
<thead>
<tr>
<th>Services by Platform</th>
<th>Filter Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Click on a box to see more information about the platform.</td>
<td>State</td>
</tr>
<tr>
<td>Pill</td>
<td>Patch</td>
</tr>
<tr>
<td>AfterPill</td>
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</tr>
<tr>
<td>Alpha Medical</td>
<td></td>
</tr>
<tr>
<td>Binx Health</td>
<td></td>
</tr>
<tr>
<td>(All)</td>
<td>(All)</td>
</tr>
</tbody>
</table>
## Technical assistance brief + FAQ

### Figure 1: Comparing at-home STD integration options

<table>
<thead>
<tr>
<th></th>
<th>(1) In-house/ “Homegrown” Program</th>
<th>(2) Integration with a Lab Service</th>
<th>(3) Integration with a Digital Healthcare Provider</th>
<th>(4) Hybrid / other Solutions</th>
</tr>
</thead>
</table>
| **Examples**                  | JHH “I Want the Kit” (IWTKit)     | Program develops platform (API, other) to access at-home testing lab kits | Program integrates with digital healthcare provider to offer end-to-end care and testing solution to its patients  
                                 | Howard Brown Health               |                                                   | • Colorado Dept of Public Health & Environment |
| **Potential Benefits**        | Seamless patient experience and management  
                                 | In some settings, as straightforward as building a new lab integration (to supplement existing lab order options)  
                                 | Outsourced lab/specimen logistics, clinician ordering, and patient support  
                                 | • Building Healthy Online Communities (BHOC): TakeMeHome service                                      |
                                 | No loss of surveillance or disease investigation integration with care | • Outsources kitting, fulfillment, and specimen handling | • Least internal resources required for at-home test integration |
VI. Frequently-asked Questions (FAQ)

Regulatory questions

Q: For an at-home self-collect test to be “validated,” does the self/sample collection have to be validated specifically?
A: FDA-cleared tests are intended to be ordered by a clinician, with samples obtained for patients in a clinical setting or draw station. When tests are used outside the clinical setting, a validation study must be performed to make sure that accuracy is maintained, and that new aspects of the testing methodology (such as shipping of samples, stability of specimens in transport devices) do not affect the integrity of the test. Self-collection also relies on individuals’ understanding of collection instructions, and human behavior that contributes to accurate collection of a sample, especially when collected by oneself, which may be inherently challenging and may contribute to inadequate collection. Therefore, a laboratory-developed test (LDT) must be validated such that every methodologic step of its use (i.e., self-collection, collection in a non-clinical setting, etc.) that differs from the 510(k) cleared or PMA cleared version of the same test must be validated.

Laboratory questions

Q: How accurate are at-home tests?
A: Sensitivity and specificity and other test performance characteristics are generated and documented in the validation study of the laboratory-developed test. At minimum, basic accuracy information should
Technical assistance brief + FAQ

VII. Resources

(1) Laboratory Developed Test (LDT) Validation Resources

Food and Drug Administration
Laboratory Developed Tests
https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests

College of American Pathologists
Laboratory Developed Tests

American Association for Clinical Chemistry
The American Association for Clinical Chemistry (AACC) is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. Our leadership in education, advocacy and collaboration helps lab professionals adapt to change and do what they do best: provide vital insight and guidance so patients get the care they need.

American Journal of Clinical Pathology
Population of Laboratory Developed Tests: A Clinical Laboratory Perspective
Pathway #1: Colorado

Review JHU/ID + Baltimore City HD experience as useful example of Pathway #1: “homegrown” at-home STD testing solution
Considerations for developing a homegrown at-home STD/HIV self-collection testing program: Lessons from IWTK

Charlotte A. Gaydos, MS, MPH, DrPH
Professor
Division of Infectious Diseases
Johns Hopkins University

NCSD
June 1, 2020

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, Quidel, Binx, and Cepheid,
Objectives: Development of IWTK

1. Formulation of a home-collection Internet test for STIs 2004: Validation & History
2. New format for 2013 website: Patient obtains results, mobile friendly, password protected, HIPAA
3. Pre-CoVID and Post-CoVID changes
4. Evaluation website Risk Quizzes; Home TV POC test
5. IWTK HIV home POC test launched Jan, 2016
6. Lessons Learned
   ✓ for 4th generation POC HIV test (p24 and Ab)
   ✓ for syphilis treponemal POC test
   ✓ for HIV viral load
Establishment of Iwantthekit (IWTK)


*Internet-based screening for *Chlamydia trachomatis* to reach non-clinic populations with mailed self-administered vaginal swabs. Sex Transm Dis, 2006.

*Can e-technology through the Internet be used as a new tool to address the Chlamydia trachomatis epidemic by home sampling and vaginal swabs? Sex Transm Dis. 2009.

Plus 14 others, including use of a simple risk quiz to help users determine risk for STIs.

Gaydos CA, et al.
Validation Efforts Clinician Collected vs. Self-Collected Vaginal Swabs

<table>
<thead>
<tr>
<th>Collection Method</th>
<th>Sym</th>
<th>Asym</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician collected</td>
<td>92.5%</td>
<td>87.2%</td>
</tr>
<tr>
<td>Self-collected</td>
<td>94.7%</td>
<td>84.8%</td>
</tr>
</tbody>
</table>

Validation studies performed for self collection:
- penile-meatal swabs
- rectal swabs
- throat swabs
- mailing of DRY swabs

Internet Recruitment iwantthekit.org (IWTK)

**Methods**
- Order a kit online
- Kit mailed
- Collect sample at home
- Mail kit to lab
- Receive results
- Attend a clinic for Rx

**New features 2013**
- Secure password protected login
- Selection of clinic before ordering kit
- New instructions
- Text/email to notify user that kit received
- Results ready to be retrieved
- New information about STIs
At I Want The Kit (IWTK), our mission is to help stop the spread of sexually transmitted infections (STIs) by offering easy and confidential chlamydia and gonorrhea testing* to residents of Maryland, Washington DC, and Alaska. STIs are spread from person to person during sex and may cause serious health problems if not diagnosed and treated early. The IWTK process is easy, convenient, and private! Use this site to order a kit, receive the kit in the mail, collect your own samples at home using the instructions we include, mail your samples back to our Johns Hopkins University laboratory, and check your results online when we let you know they are ready. Our lab is licensed by the State of Maryland and certified by the College of American Pathologists (CAP). * HIV home testing kits are also now available for residents of Baltimore City.

**Please note that as of April 16th, we have temporarily suspended the option to order a swab for collecting a throat specimen. The suspension is due to swab shortages created by the COVID-19 pandemic. We will restart throat testing as soon as the supply situation improves. Please continue checking back for updates.**

Have you heard about PrEP?

PrEP, or pre-exposure prophylaxis, is a way to help prevent HIV by taking one pill once a day. Go to www.PREPMaryland.org for more information and to find a PrEP provider near you.

If you live outside of Baltimore City but are a resident of Virginia or Maryland, you could be eligible for a free, at-home HIV test through the Virginia Department of Health. Please visit https://www.vdh.virginia.gov/ for more information.
Newly Formated IWTK:

- 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
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.)

**Female Anatomy**

**Male Anatomy**

**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.

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

STEP 3
Twist first to break seal.

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

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

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 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.
**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.
1. Wash your hands.
2. Twist the red cap and take the swab out of the plastic tube.
3. The swab should remain attached to the cap during the collection process.
4. Do not touch the white tip of the swab to anything, including your fingers.
5. Open your mouth and use the mirror to look at your throat.
6. Use the gauze pad to hold your tongue down, if needed, with your other hand.
7. **Wipe the back of your throat and tonsils** with the white tip of the swab.
   (see the pink areas in the image below for the correct spots to wipe)
8. Gagging may be a side effect of correctly collecting a throat sample.
9. Place the swab back into the transport tube.
10. Close the tube tightly by pushing the cap into the tube.
11. Put the tube into the plastic zip-lock bag, along with your genital and/or rectal swabs.
12. Seal the top of the plastic bag, and place it into the white cardboard mailer.
Pre-CoVID and Post-CoVID Changes

- EHE $-Summer 2019: added Baltimore users to request free HIV, oral fluid self-tests
- Provided linkage for enrollment into PrEP programs
- CoVID shut down March 14, 2020,
- Reopened April 6 IWTK (stopped throat swabs) to provide testing for MD/Baltimore since City STD and county clinics closed
WWW.IWANTTHEKIT.ORG

Know your status for Gonorrhea & Chlamydia in the comfort of your own home.

No blood test required!
Uses genital, rectal, and/or oral swabs.

EASY. DISCREET. RELIABLE. FREE.

BECAUSE HONESTLY, IF WE DON'T TAKE CARE OF OURSELVES, WHO WILL?

#PeopleWhoLookLikeMe
WHAT IF THERE WERE A PILL THAT COULD HELP PREVENT HIV?

THERE IS.
PrEP (Pre-Exposure Prophylaxis) is a way to help prevent HIV by taking one pill daily.

Go to www.PrEPmaryland.org for more information and to find a PrEP provider near you.

- TAKE ONE PILL DAILY.
- PREVENT HIV.
- STOP WORRYING.
- START LOVING!
Other aspects of Home Collection/Testing via Online Outreach

- Acceptability surveys
- Data analysis
- Public Health surveillance and trends
- Geomapping
- Risk Assessment
- Reinfection
### Specimen Positivity by Anatomic Site & Sex

**IWTK Aug 2013-Dec 2016** *(N=3,191)*

<table>
<thead>
<tr>
<th></th>
<th>Chlamydia^</th>
<th>Gonorrhea^^</th>
<th>Trichomonas</th>
<th>Any STI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rectal</strong></td>
<td>N=907</td>
<td>N=907</td>
<td>N=908</td>
<td>N=906</td>
</tr>
<tr>
<td><strong>Urogenital</strong></td>
<td>N=3,166</td>
<td>N=3,165</td>
<td>N=3,167</td>
<td>N=3,166</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td>4.7%</td>
<td>0.2%</td>
<td>4.9%</td>
<td>9.2%</td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td>5.2%</td>
<td>5.9%</td>
<td>0.7%</td>
<td>9.8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5.0%</td>
<td>3.0%</td>
<td>2.9%</td>
<td>9.5%</td>
</tr>
</tbody>
</table>

**How did you learn about iwtk?**

<table>
<thead>
<tr>
<th></th>
<th>News</th>
<th>Other</th>
<th>Personal Contacts</th>
<th>Promotional Materials</th>
<th>Internet</th>
<th>Health Care Professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N=457</strong></td>
<td>2%</td>
<td>7%</td>
<td>31%</td>
<td>26%</td>
<td>24%</td>
<td>10%</td>
</tr>
</tbody>
</table>

**Willing to self collect Dried blood spots for syphilis or HIV testing?**

- No
- Not sure

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*Hogenson et al.* Analysis of User Survey Data for an Internet Program for Testing for STIs IWTK in Maryland and Washington D.C. Sex Transm Dis 46:768-770, 2019
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)
HIV Home Self Test Study

- Study with online consent in Jan. 2016 to request home Oraquick oral fluid self-test kit with questionnaire
- Kits available to people $\geq 18$ yr. of any gender in Baltimore Metropolitan Area
- 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 characteristics could be predictors of test kit usage
HIV Home Test Progress

OraQuick HIV Self-testing Study – results from questionnaire (n=200)

- easy to collect oral fluid: 95.5%
- easy to follow instructions: 91.5%
- easy to read and interpret results: 96.5%
- easy to perform test: 97.0%
- believe result is definitely correct: 82.0%
  - or probably correct: 18.0%
- trust result very much: 80.5%
  - or trust somewhat: 19.5%
- definitely recommend to a friend: 94.5%
- definitely test self again at home: 83.5%
  - or probably test self again at home: 14.5%

Maximum price pay to purchase OTC
- $10-24.0%, $20-42.5%
- $30-14.0%, $40-16.0%

Earlier data: Of 83 who also tested for STIs, 16.9% w/ one STI
More females (N=836) than males (N=558) provided voluntary risk scores. % of users submitted scores was 43.9%
<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>
Prevalence of STI among IWTK Male Users by Risk Score Category

Risk Score Required (N = 592)

<table>
<thead>
<tr>
<th>Risk Score Required</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3</td>
<td>6.2%</td>
</tr>
<tr>
<td>4-6</td>
<td>10.9%</td>
</tr>
<tr>
<td>7-10</td>
<td>14.3%</td>
</tr>
</tbody>
</table>

Overall STI prevalence 10.5%

Hsieh, et al.
Distribution of High Risk Score (≥ 7) / STI in IWTK Males, Baltimore Zip Code

52% STI + males were in 3 zip codes located in central and northeast of Baltimore City (higher risk score than others)
The Future for IWTK

Use of dried blood spots (DBS)

- Syphilis
- HIV 4th 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)

<table>
<thead>
<tr>
<th>Comparison Method</th>
<th>Clinical Sensitivity and Specificity (PPA and NPA)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Any DBS Positive</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Any DBS Negative</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Dize et al. CVS, 2016
Evaluation And Performance Of Dried Blood Spots For Syphilis Point Of Care/Rapid Testing

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></th>
<th>Comparison Method</th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Check DBS Positive</td>
<td>20</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>20</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
<td>40</td>
<td>n=40</td>
</tr>
</tbody>
</table>

Dize et al. CVS, 2016
Lessons Learned to Guide Implementation

- Decide on area of service
- Decide on who will be served
- Evaluate capabilities for web portals
- Decide on testing methodology
- Carefully perform tests that will be used and who will perform them
- Logistical issues related to CoVID
  - Staffing, supplies, costs
- Risk of thinking outside the box
Summary

• STDs commonly detected by internet recruitment

• High risk scores predicts STIs in women & men

• TV Home Test project possible

• HIV Home test project possible

• Future plans: DBS for HIV & Syphilis

• Could Home testing be used for PrEP patients?

CT, NG, TV

TV POC at home

CT, NG, TV

Perform home HIV POC?

Collect home DBS HIV & Syphilis?
Acknowledgements

• Mary Jett-Goheen
• Justin Hardick
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• Barbara Silver
• Yu-Hsaing Hsieh
• Anne Rompalo
Insights From the Field

Liz Gilliams
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I Want The Kit: COVID-19 clinic experience

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Bernard C. “Jack” Young
Mayor, Baltimore City
Letitia Dzirasa, M.D.
Commissioner of Health, Baltimore City
IWTK: Pre- COVID

• Palm cards distributed in clinic
• Particularly useful for partners unwilling/unlikely to come into clinic
  • Paired with EPT
  • Did not keep good documentation on distribution/use
IWTK COVID Workflow @ clinic

• In person appointments
  • Limited to:
    • new HIV and syphilis diagnoses & treatment
    • contacts to HIV and syphilis
    • Urgent HIV primary care/ PrEP visits

• All other symptomatic patients and screening visits
  • Telemedicine (audio-only)
  • IWTK testing
Patients accessing IWTK

- STI screening
- Patients with STI symptoms, not seen in clinic
- Routine PrEP follow up
  - Along with blood testing ordered at commercial lab service centers
- STI testing for HIV primary care
Bernard C. “Jack” Young, Mayor, Baltimore City
Letitia Dzirasa, M.D. Commissioner of Health, Baltimore City

IWTK COVID Workflow @ clinic

Patient calls clinic → Requests testing or telemedicine visit → Staff discusses how to sign up with IWTK

Patient completes specimen collection → IWTK completes testing. Posts results on website. Faxes/secure emails positive results to designated clinic, surveillance

Patient receives result, calls clinic for follow up → Clinician reaches out to patient to address result
IWTK Orders by Month

<table>
<thead>
<tr>
<th>Order Quantity</th>
<th>September</th>
<th>October</th>
<th>November</th>
<th>December</th>
<th>January</th>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May 1-27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baltimore City</td>
<td>29</td>
<td>26</td>
<td>20</td>
<td>18</td>
<td>54</td>
<td>31</td>
<td>21</td>
<td>133</td>
<td>150</td>
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<tr>
<td>Other MD/DC</td>
<td>71</td>
<td>69</td>
<td>59</td>
<td>55</td>
<td>74</td>
<td>65</td>
<td>38</td>
<td>88</td>
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<tr>
<td>Alaska</td>
<td>27</td>
<td>44</td>
<td>37</td>
<td>34</td>
<td>32</td>
<td>26</td>
<td>10</td>
<td>27</td>
<td>18</td>
</tr>
<tr>
<td>HCPSS</td>
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<td>4</td>
<td>9</td>
<td>5</td>
<td>6</td>
<td>1</td>
<td>0</td>
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</tbody>
</table>

* Credit: Kelci Reiss, IWTK
Order Quantity by Gender Identity -- Baltimore City

<table>
<thead>
<tr>
<th>Gender Identity</th>
<th>September</th>
<th>October</th>
<th>November</th>
<th>December</th>
<th>January</th>
<th>February</th>
<th>March</th>
<th>April</th>
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</thead>
<tbody>
<tr>
<td>Female</td>
<td>15</td>
<td>10</td>
<td>9</td>
<td>11</td>
<td>35</td>
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<td>11</td>
<td>45</td>
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<tr>
<td>Male</td>
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<td>13</td>
<td>11</td>
<td>6</td>
<td>19</td>
<td>11</td>
<td>10</td>
<td>87</td>
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</tbody>
</table>

* Credit: Kelci Reiss, IWTK
The graph illustrates the number of IWTK orders by racial identity from September to April in Baltimore City.

<table>
<thead>
<tr>
<th>Month</th>
<th>White</th>
<th>Black</th>
<th>Asian/Pacific Islander</th>
<th>Multiracial</th>
<th>Unknown</th>
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</thead>
<tbody>
<tr>
<td>September</td>
<td>10</td>
<td>11</td>
<td>2</td>
<td>4</td>
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<tr>
<td>October</td>
<td>6</td>
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<td>November</td>
<td>10</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>December</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>3</td>
<td>0</td>
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<td>January</td>
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<td>February</td>
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<tr>
<td>April</td>
<td>21</td>
<td>90</td>
<td>3</td>
<td>13</td>
<td>6</td>
</tr>
</tbody>
</table>

*Credit: Kelci Reiss, IWTK
Summary thoughts

• Specimen return rate: TBD in COVID
  • Previously 60%
• Positivity rate (GC/CT) by individual: ~5.5%
• May IWTK orders: 150
• Sexual health clinic average monthly visits pre-COVID: 960
• Unmet need remains
Next steps

• Reviewing/managing results
• Managing scarce testing resources
• Serving patients with barriers
  • Variable technology literacy
  • Non-English speakers
  • No fixed home address
• Balance of in-person vs telemedicine staffing

Bernard C. “Jack” Young, Mayor, Baltimore City
Letitia Dzirasa, M.D. Commissioner of Health, Baltimore City
Thank you!!

• JHU IWTK team & BCHD colleagues
  • Charlotte Gaydos
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  • Barbara Silver
  • Gretchen Armington
  • Adam Huebner
  • Matthew Hamill
  • Sexual Health Clinics Staff
Insights From the Field

Tim Menza

Oregon Health Authority
Public-private partnerships for sexual health: the Oregon experience

- Origin of OR public-private partnership with Molecular Testing Labs
  - [Outbreak of HIV, syphilis among PWID]

- Data-driven work to further options for HIV, STI, HCV testing in OR through public-private partnerships
  - [What our claims data tell us]

- Integration into the work of public health
  - [Streamlining services provided by private organization into public health operations]
Q & A
Closing/Action Items

- COVID-19 Command Center on NCSD website
- Making Contact: A Training for COVID-19 Contact Tracers
- Clinic+ COVID-19 Information Sharing Call Friday, June 5th from 2:15-3:15 ET
- STD TAC Billing Toolkit
- Clinic+ questions/comments? Contact Jenny Mahn, Associate Director of Clinical Programs, at jmahn@ncsddc.org or (248) 765-5522