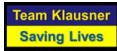


Advances in Self-Testing for HIV Infection and other STDs

Jeffrey D. Klausner, MD, MPH
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2017 Australasian HIV & AIDS Conference joint with 2017 Australasian Sexual Health Conference
Canberra, November 8, 2017



Disclosures

- In the past 12 months, I have received scientific advisory board fees from GSK and Cepheid
- I have received research grant funding from Gilead
- I serve on the WHO STI Treatment Guidelines work group
- I chair 2 NIH-funded FDA clinical studies on STI diagnostics
- Advisor to MyLabBox.com, SafeMovement and Healthvana

Outline

- What is self-testing?
- How is self-testing **adopted**?
- What is the **fidelity** of self-testing?
- Where can self-testing can be **disseminated**?

Self-Testing for HIV infection



- Only US FDA approved In-Home HIV Testing kit
- Used by over a million consumers
- Same device used by healthcare professionals
- Simple oral swab, no blood
- Results in 20 minutes
- 24 hour bilingual customer phone support and detailed product website offering information, referrals to care, product usage instructions and more
- High consumer satisfaction

Adoption

Self-testing adoption

- Influenced by user's perception of costs, benefits, personal need and convenience
- Users greatly prefer painless oral testing over fingerstick or venipuncture
 - Wood (2014) found 70% reported oral fluid testing acceptable
 - Highest (92%) in Malawi
 - Pai (2013) found 74-96% reported self-testing acceptable
 - Lippman (2015) found 88% use, 94% "easy" in SF Transgender persons
- Additional benefits include increased confidentiality, privacy and reduced social stigmatization

Estem KS, Catania J, Klausner JD, Curr HIV/AIDS Rep 2016.

Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial

Muhammad S Jamil, Garrett Prestage, Christopher K Fairley, Andrew E Grulich, Kirsty S Smith, Marcus Chen, Martin Holt, Anna M McNulty, Benjamin R Bavinton, Damian P Conway, Handan Wand, Phillip Keen, Jack Bradley, Johann Kolstee, Colin Batrouney, Darren Russell, Matthew Law, John M Kaldor, Rebecca J Guy

www.thelancet.com/hiv Vol 4 June 2017

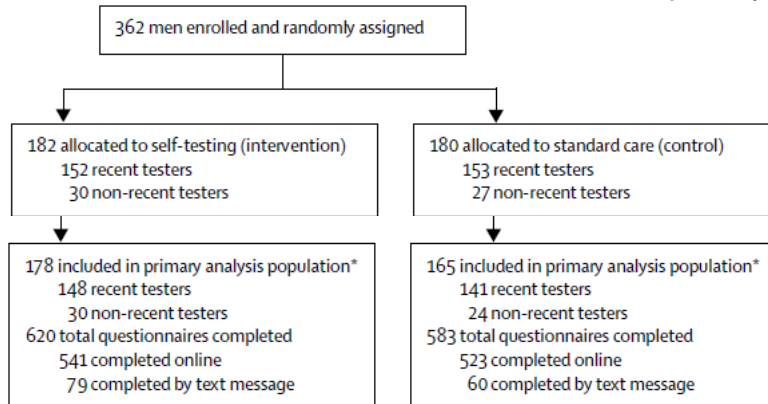
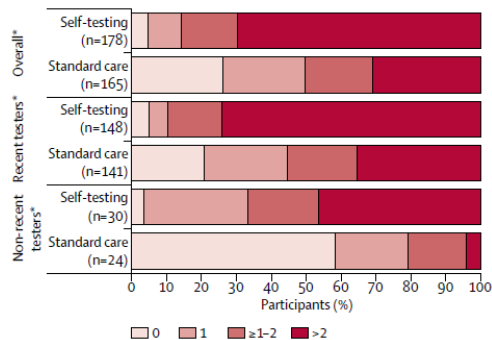


Figure 2: Number of HIV tests during follow-up

This analysis included all men who completed at least one follow-up questionnaire. Recent testers are men who had their last HIV test within the past 2 years. Non-recent testers are men who had their last HIV test more than 2 years ago or had never tested before. * $p < 0.0001$ (χ^2 test for difference in proportions between self-testing and standard care groups).



www.thelancet.com/hiv Vol 4 June 2017

Orasure Oraquick Number Cases Identified and Positivity among 1.2M tests sold, 2013-2017

The estimated prevalence rate between 1- 2%

Theoretical Projection of Total Number of Positives Identified Based on Consumer Support Center Activity			
	731 Positives* Identified via Consumer Support Center		
% of Positives Calling Support Center	1%	5%	10%
Projected Total Number of Positives	73,100	14,620	7310
Positives as Percent of Units Sold to date	6.1%	1.2%	.6%

*Positives captured launch through 6/30/17 Based on prelaunch research indicating that most (96%) consumers receiving positive result will contact their healthcare professional; ~1.2M units sold Jan 2013 through July 2017



Fidelity

Self-testing fidelity

- Original studies by manufacturer < 2% failure
 - Limited by use of select populations (MSM)
 - US adult vs. trained providers (sensitivity 92.9% vs. 99.3%)
- Singapore, error rate 0.6% (Ng, 2012)
- Atlanta, 9% error rate (MacGowan, 2017)
- China (non-Oraquick) 10% difficulty swabbing, 17.5% difficulty reading results (Marley, 2014)
- In NYC young MSM and transgender women reported concerns of anxiety, test correct use and instructions (Frye, 2015)

Estem KS, Catania J, Klausner JD, Curr HIV/AIDS Rep 2016.

Self-testing fidelity

AIDS Behav (2014) 18:5422–5432
DOI 10.1007/s10461-014-0818-8

ORIGINAL PAPER

What Should the Ideal HIV Self-Test Look Like? A Usability Study of Test Prototypes in Unsupervised HIV Self-Testing in Kenya, Malawi, and South Africa

Roger B. Peck · Jeanette M. Lim · Heidi van Rooyen · Wanjiru Mukoma ·
Lignet Chepkwa · Pooja Bansal · Lucia C. Knight · Nelly Muturi ·
Ellen Chirwa · Arthur M. Lee · Jeff D. Wellhausen · Olivia Tulloch ·
Miriam Taegtmeier

- 150 adults in Kenya, Malawi and South Africa
- Graphic and written instructions in English and local language
- 75% correctly performed each step
- 47% had multiple errors

“Further adaptation needed for low-literacy participants”

Peck R et al, 2014.

Dissemination

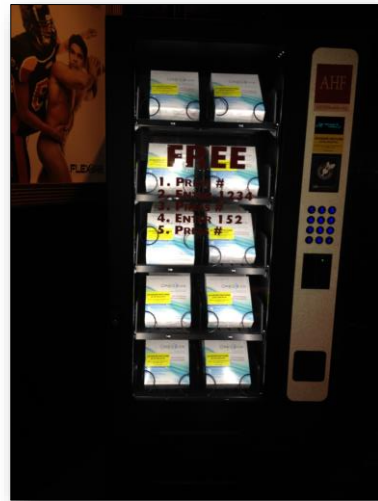
Self-testing dissemination-LA

- Vending machines
- Vouchers
- US mail
- Online



Vending Machines in sex clubs

- Self-contained unit
- Remote monitoring
- Instructions posted
- Private area



McGrath M et al, CROI pre-meeting, 2015

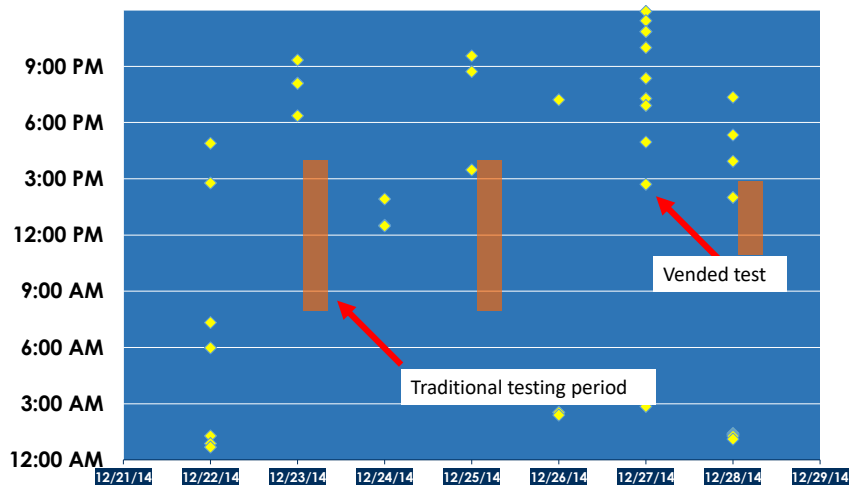
Initial Concerns

- Cost of HIV home test kits
- Emptying the vending machine
- Conflict with existing testing programs
- Home test kit window period
- Result anxiety

McGrath M et al, CROI pre-meeting, 2015

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Time/ date of vended tests vs. staff tests, LA



Results summary over 7 weeks, 2014

Vending machine

- 1,176 hours
- 312 tests

Traditional testers

- 64 hours
- 58 tests

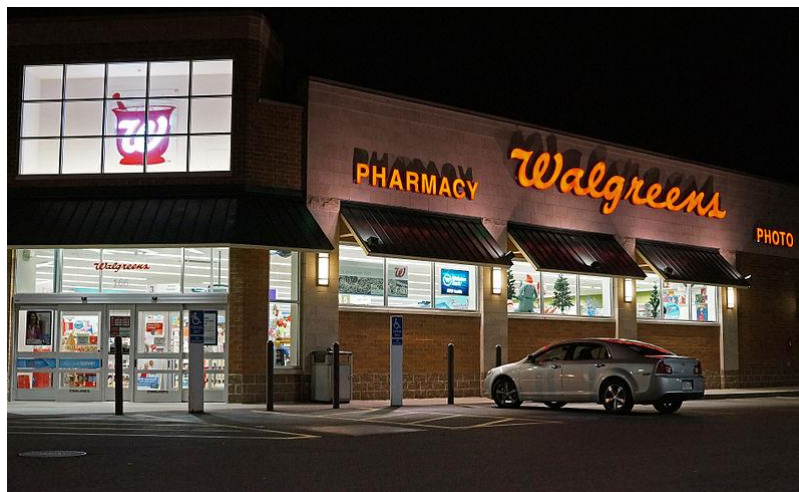
Voucher program, 2013



Marlin, BMC Public Health, 2014

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Voucher program, 2013



Marlin, BMC Public Health, 2014

20

RESEARCH ARTICLE

Open Access

Piloting an HIV self-test kit voucher program to raise serostatus awareness of high-risk African Americans, Los Angeles

Robert W Marlin^{1*}, Sean D Young², Claire C Bristow¹, Greg Wilson³, Jeffrey Rodriguez⁴, Jose Ortiz⁵, Rhea Mathew⁵ and Jeffrey D Klausner¹

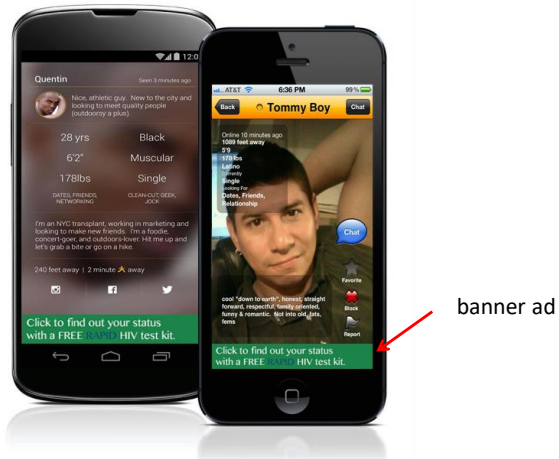
641 vouchers distributed to CBOs
274 went to clients
53 (19%) redeemed

3 (6%) reported new HIV+



Slide courtesy of Dr. Ian Holloway, UCLA

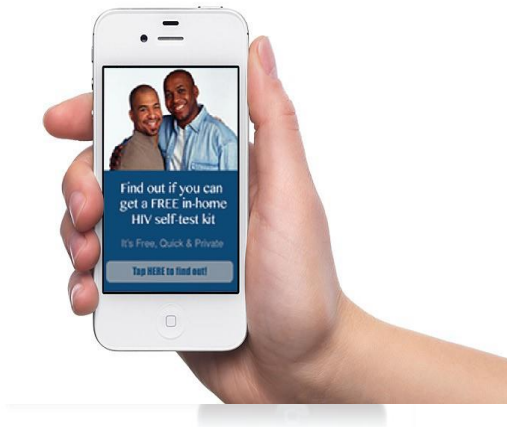
Social media promotion, 2014



Huang et al AIDS Edu Prev 2016

23

Social media promotion, 2014



Huang et al AIDS Edu Prev 2016

24



Huang, AIDS Edu Prev 2016

25

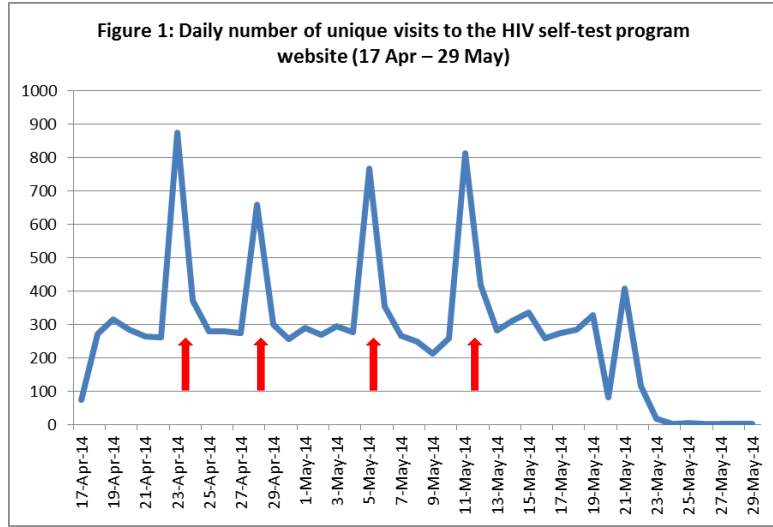
Three Choices



ISSTD 2015, P17.08; Huang et al AIDS Edu Prev 2016

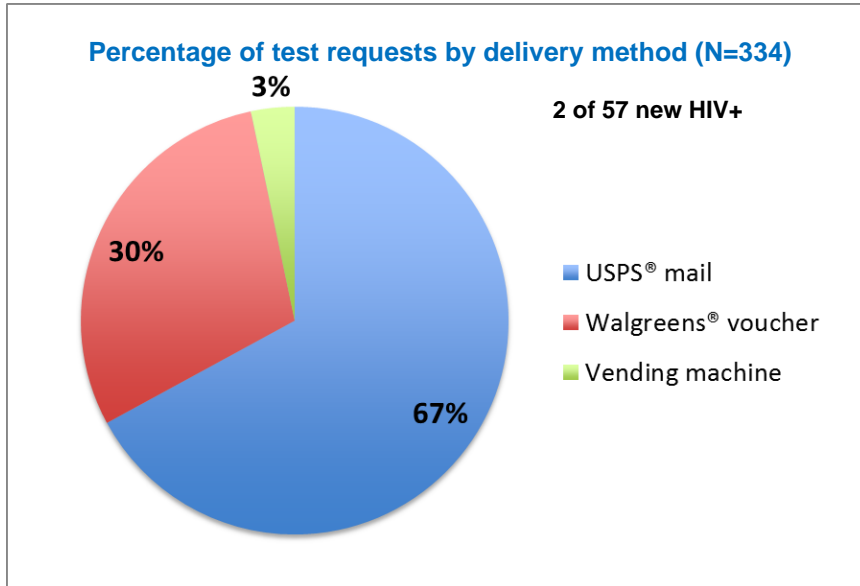
26

11,939 website visits in 6 weeks



Huang, AIDS Edu Prev 2016

27



Huang et al AIDS Edu Prev 2016

28

Social media promotion 2

Walgreens at the corner of happy's healthy

Prescription Refills Health Info & Services Contact Lenses Shop Products Photo

Store Locator Weekly Ad & Coupons Healthcare Clinic Balance Rewards Search by keyword or item #

Home > Shop > Personal Care > Home Tests & Monitoring > HIV Tests

OraQuick In-Home HIV Test 1.0ea
★★★★★ 4.9 (45)

\$43.99

Ships for FREE! Details
Arrives in 1-3 business days* Restrictions apply.
See shipping FAQ

Ship one time Ship every 30 days

1 Add to cart

Find a store

Add to shopping list

Online and store prices may vary

Rosengren et al Sexual Health 2016

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Social media promotion 2

Walgreens at the corner of happy's healthy

Prescription Refills Health Info & Services Contact Lenses Shop Products Photo

Store Locator Weekly Ad & Coupons Healthcare Clinic Balance Rewards Search by keyword or item #


Shopping Cart

Use Visa Checkout and get \$10 OFF your order of \$50 or more. One use per customer. Additional restrictions apply.

Continue shopping Proceed to checkout

Or Checkout with

Check out with PayPal VISA checkout

Product Info	Receiving Options	Price	Qty	Total
 OraQuick In-Home HIV Test 1.0 ea Weight: 1.05LB	<input checked="" type="radio"/> Ship one time Arrives in 1-3 business days* <input type="radio"/> Ship every 30 days with Auto Reorder & Save	\$43.99	1 Update Remove	\$43.99

Online and store prices may vary.

Promotion Codes & Coupons

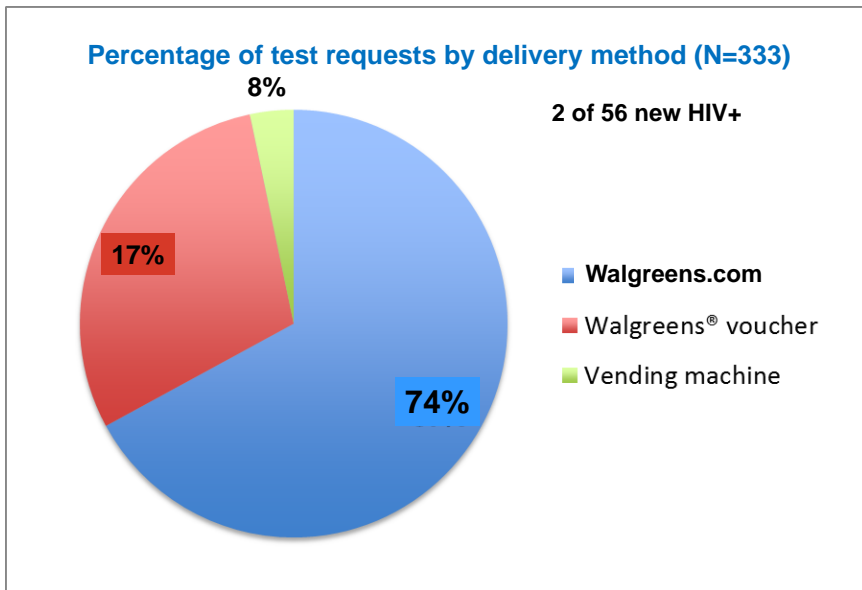
Enter Code Apply code

Gift cards are not eligible for promotional discounts

FREE shipping
Options available at checkout: Ship to you or Ship to Store
Learn more

Rosengren et al Sexual Health 2016

30



Rosengren, Sexual Health, 2016

31

Self-test kit dissemination-NYC

HIV Home Test Giveaway: Rapid Distribution among Men and Transgender People who have Sex with Men (MTSM), New York City 2015



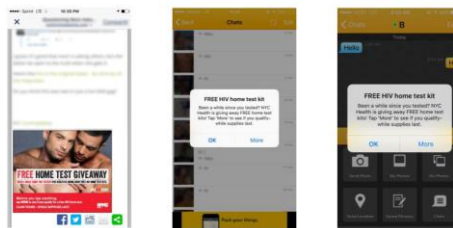
Edelstein, APHA, 2016

Self-test kit dissemination-NYC

Goal: Distribute 2,000 HIV in-home test kits to men and transgender individuals who have sex with men (MTSM)

- Tests sent at no cost, through the mail
- Conducted entirely online – recruitment, eligibility assessment, kit order

Recruitment: Dating apps and websites



*over 3 weeks

Edelstein, APHA, 2016

Self-test kit dissemination-NYC

- Eligibility assessed via online survey
 - Men and transgender individuals
 - Sex with a man in past 12 months
 - Residing in NYC (by ZIP)
 - Aged 18 and older
 - No previous HIV diagnosis
- Data collected also included
 - Race/ethnicity
 - Time since last HIV test



The Kit



Testing Insert

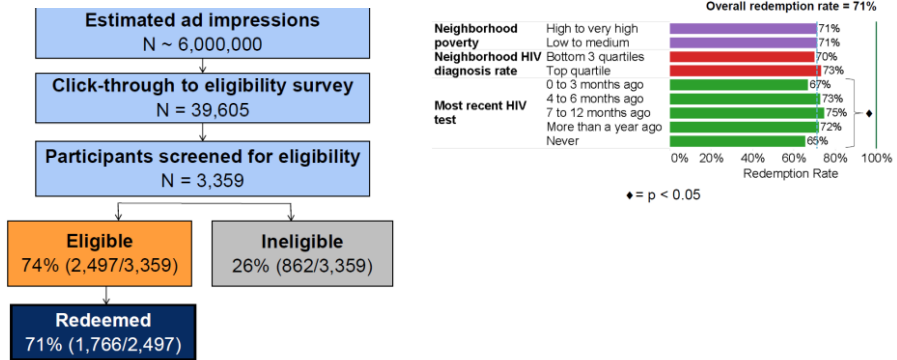


PrEP and PEP



Edelstein, APHA, 2016

Self-test kit dissemination- NYC



Edelstein, APHA, 2016

Self-test kit dissemination- NYC

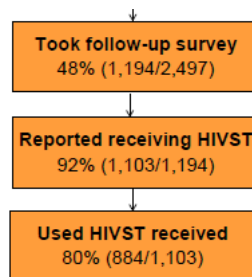


Table 3. Test Results Among HIVST Users, HIVST Giveaway, New York City, 2015-16

Characteristic	n/N	%
% with reactive results	7/868	0.8%
% with reactive results and reported no previous HIV-positive results	5/868	0.6%
% with confirmatory test	4/5	80%
% had HIV care appointment	4/4	100%
% starting taking antiretroviral medications	3/4	75%

Edelstein, CROI, 2017

Linkage to care

Among testers with positive or inconclusive results

- Kenya 72% of male partners sought confirmation [Gichangi, 2016]
 - 25% of those HIV-infected
- China 17% (N=29) sought confirmation [Ren XL, 2017]

Among positives

- Los Angeles 100% (N=7) [Marlin 2014, Huang; Rosengren 2016]
- Australia 100% (N=3) [Jamil, 2017]
- NYC 57% (N=7) [Edelstein, 2017]

Add HIV self-test as a reported element in HIV surveillance

Research Briefs

Will Men Who Have Sex With Men Use Short-Messaging Services to Send Photos of Completed HIV Self-Tests to Researchers?



Joseph Daniels, PhD^{*}
Lina Rosengren, MD, MS
Sean Young, PhD, MS
Jeffrey D. Klausner, MD, MPH

724 JANAC Vol. 27, No. 5, September/October 2016

Table 1. HIV Self-Testing Survey for MSM (N = 37) in Los Angeles County

Questions to Assess Preference and Comfort in Sending Photos of HIV Self-Test Outcome via SMS	n (%)
How would you MOST prefer to share your HIV self-test result with a researcher?	
By e-mail	14 (37.8)
Via text message	8 (21.6)
In person	6 (16.2)
By taking and sending a picture of your used self-test swab	5 (13.5)
In writing (e.g., checking a box on a postcard and mailing it)	2 (5.4)
By mailing in your used self-test swab	1 (2.7)
By phone	1 (2.7)
How comfortable would you feel taking a picture of your used HIV self-test swab and text messaging the picture to a researcher?	
Very comfortable	21 (56.8)
Somewhat comfortable	5 (13.5)
Neutral	4 (10.8)
Somewhat uncomfortable	2 (5.4)
Very uncomfortable	5 (13.5)

POLICY BRIEF

HIV TESTING SERVICES

WHO RECOMMENDS HIV SELF-TESTING

DECEMBER 2016





Reaching people with undiagnosed HIV

HIV self-testing (HIVST) is an empowering and innovative way to reach more people with HIV and help achieve the first of the United Nation's 90–90–90 targets – for 90% of all people with HIV to know their status by 2020. Expanded use of HIVST can contribute to these global targets by reaching first-time testers, people with undiagnosed HIV or those at ongoing risk who are in need of frequent retesting.

HIV self-testing is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts.

Source: WHO 2015.

HIVST has been shown to be an empowering, discreet and highly acceptable option for many users, including key populations, men, young people, health workers, pregnant women and their male partners, couples and general population groups.

HIVST represents another forward step in line with efforts to increase patient autonomy, decentralize services and create demand for HIV testing among those unreached by existing services.



UNITAID STAR Project Zimbabwe. © UNITAID/ETIC Grass

HIV self-testing strategy

The result of a single rapid diagnostic test (RDT) is not sufficient to make an HIV-positive diagnosis. HIVST requires self-testers with a reactive (positive) result to receive further testing from a trained provider using a validated national testing algorithm.

STD Self-Testing

- Self-collection for mail-in STD testing—urine
- Self-referral syphilis lab testing
- Commercial home-based collection and shipping
- True home-based collection and self-testing...not yet but coming soon!

Home-collection and mailed CT/NG testing August 2000

Community-Based Chlamydia and Gonorrhea Screening Through the United States Mail, San Francisco

PETER J. BLOOMFIELD, BA,* CHARLOTTE KENT, MPH,† DIANE CAMPBELL, BS,†
LARRY HANBROOK, BA,† AND JEFFREY D. KLAUSNER, MD, MPH†

Results: Participants picked up 209 test kits and returned 80 (38%); 3 (3.8%) of 76 were positive for gonorrhea and 1 (1.3%) of 76 was positive for chlamydia. The majority (95%) of participants were white gay men. The cost of specimen collection and transport was similar to that of other population-based screening programs.

Conclusion: Using the mail for home-based testing for gonorrhea and chlamydia was feasible and may be a useful addition to STD control efforts.

STD, 2002

Self-referral Syphilis lab testing 2005

Sexually Transmitted Diseases, February 2005, Vol. 32, No. 2, p.139-141
DOI: 10.1093/oxford-journals.000149733.07825.4d
Copyright © 2005, American Sexually Transmitted Diseases Association
All rights reserved.

Online Syphilis Testing—Confidential and Convenient

DEB K. LEVINE, MA,* KATHERINE C. SCOTT, MPH,† AND JEFFREY D. KLAUSNER, MD, MPH†

218 tests (13+)
6 new cases

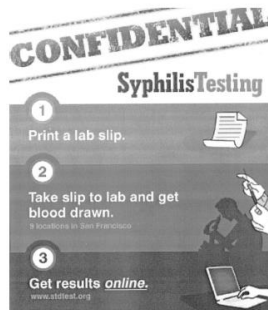
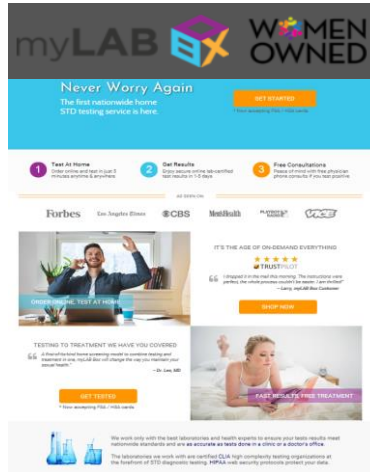


Fig. 2. Banner ad on gay.com

STD Home-collection: myLAB Box.com



myLAB Box has completed thousands of tests in all 50 states
over 160% increase in demand from 2016 to 2017

myLAB Box user information, USA

- Age range 16 – 82 years
- 60% male, 40% female
- Reasons for choosing **myLAB Box**: convenience, privacy, less stigma/shame than seeing health care provider, reasonable price
- Over 90% of ordered test kits complete specimen submission
- Higher-risk STI population: 8.2% CT and 1.3% NG-infected
- CT and NG-infected may be treated via telemedicine and obtain e-prescription for antibiotic



True point-of-care STD self test device



Summary

- HIV self-testing desirable, safe and effective
 - WHO recommended
- Need more evidence on outcomes, impact and cost-effectiveness
- STD home-specimen collection and self-referral options
- True STD home-based self-testing...coming soon

Thank you

- NIH Center for HIV Identification, Prevention and Treatment Services
- NIH Center for AIDS Research
- NIH Fogarty Center
- NIH NIAID
- NIH STI CTG STAR Network
- NIH NICHD

