HIV Testing: What’s New?
Kenneth H. Mayer, MD

CART Symposium, Chennai, India
April 28th, 2018
The Status Neutral Continuum

Adapted from https://www.nastad.org/domestic/hiv-prevention-health-equity
Timeline Following HIV Infection

- HIV RNA
- Acute HIV Infection
- 3rd Generation HIV Rapid Test
- 4th Generation HIV Rapid Test
- HIV-1 p24 Antigen starts appearing as early as 14 days after exposure
- HIV 1/2 Antibodies starts appearing 21 days after exposure
- Oral Fluid HIV Tests (90 days)
HIV Testing Algorithm

Lab-based 4th gen (Ab/Ag Combo)
Siemens ADVIA Centaur, Abbott ARCHITECT, Bio-Rad GS or BioPlex 2200

HIV-1/2 Ab Differentiation Assay
Bio-Rad Genius

Ab Detected
HIV-1 or HIV-2 infected

HIV-1 (-) or Indeterminate
HIV-2 Negative

HIV-1 NAT
Hologic APTIMA HIV-1 RNA

HIV-1 NAT (+)
Acute HIV-1 Infection

HIV-1 NAT (-)
Negative for HIV-1

Ab & Ag (-)
Negative for HIV-1 & HIV-2

HIV-1 NAT (+)
Acute HIV-1 Infection

HIV-1 NAT (-)
Negative for HIV-1

HIV-1 NAT (+)
Acute HIV-1 Infection

HIV-1 NAT (-)
Negative for HIV-1

HIV-1 NAT (+)
Acute HIV-1 Infection

HIV-1 NAT (-)
Negative for HIV-1

Never Testers Among MSM

- Internet survey of 1,170 MSM.
- Recruitment on social media and MSM networking sites.
- 13% reported never testing.

Nelson et al AIDS Pt Care STDS 2018
Strategies to Increase HIV Testing

• Individual
  – Incentives may have a role among some populations.
  – Home testing options.

• Social
  – Social and sexual network-based testing strategies.
  – Peer/social support (including family).
  – Social marketing.

• Structural
  – Increased access to healthcare services.
  – Non-clinical testing sites.
Home HIV-self Test (Oraquick)

- Approved in July 2012
- 20-40 minutes for result
- Comparable to older EIA (lab) tests (90 day window period)

After decades of controversy, the Food and Drug Administration approved a new H.I.V. test on July 3, 2012.
Home HIV testing: What is it?

• Remote self-collection of a specimen that allows for an HIV test to be conducted

• Kits are mailed to recipients in a plain, unmarked box

• For mail-in specimen kits, dried blood spot cards are generally used for finger prick whole blood collection
  • Return mail can be standard, not classified as biohazard.

• For home test kits, an oral fluid (mouth) swab. Orasure has the only CLIA-waived test
Home HIV Self-Testing (Oraquick)

• Advantages
  – Privacy
  – Control of testing
  – Availability (pharmacy/online)
  – Rapid result
  – Ease of use

• Disadvantages
  – Cost
  – Sensitivity (vs. blood tests)
  – Packaging (single use)
  – Linkage?
  – Lack of counseling?
Acceptable among YMSM

• Study of 425 YMSM randomized to receive home self-testing, home self-collection, or medical/CBO testing.
  – Self-testing and medical/CBO testing was higher than self-collection.
  – No difference by race/ethnicity (Black, Latino, White)

<table>
<thead>
<tr>
<th></th>
<th>Self-test n=142</th>
<th>Self-collection n=141</th>
<th>Medical/CBO n=142</th>
</tr>
</thead>
<tbody>
<tr>
<td>% completing test</td>
<td>66.2 (58.4, 74.0)</td>
<td>40.1 (32.1, 48.2)</td>
<td>56.0 (47.8, 64.2)</td>
</tr>
<tr>
<td>Time to completion (days)</td>
<td>14.0 (11.0, 17.0)</td>
<td>17.0 (15.0, 22.0)</td>
<td>17.0 (11.0, 26.0)</td>
</tr>
</tbody>
</table>
Dissemination of home HIV testing services: Healthmindr

- 4-month pilot assessment of app
  - 64/121 (53%) ordered home HIV tests
  - 2/3 of orders had not intended to test
- 77/121 (66%) ordered condoms
Home testing could address concerns

- Known barriers to HIV testing
  - Stigma
  - Access
  - Privacy/fear of disclosure

- Theoretically relevant: Diffusion of innovations
  - Best to provide laggards control: how, when, where
  - Perceived *relative advantage*
  - *Compatibility* for young populations accustomed to mobile solutions
  - *Trialability*: easy to try

Source: Rogers, E. Diffusion of Innovations.
Public Health Detailing to Increase Provider Screening

• Trained public health professional visits providers in high transmission areas of Baltimore.
  – Provided educational materials and resources to 85 clinics.

<table>
<thead>
<tr>
<th>Readiness to Screen</th>
<th>Primary Care Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>All providers</td>
<td>156 (100.0)</td>
</tr>
<tr>
<td>No interest in screening</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Some interest in screening</td>
<td>16 (10.3)</td>
</tr>
<tr>
<td>Moderate interest in screening</td>
<td>67 (42.9)</td>
</tr>
<tr>
<td>Starting to implement screening</td>
<td>33 (21.2)</td>
</tr>
<tr>
<td>Routinely screening</td>
<td>40 (25.6)</td>
</tr>
</tbody>
</table>

Safi et al Public Health Reports 2017
Impact of Rapid Testing Algorithm (RTA) on Linkage to Care

- 8,508 newly diagnosed people in NJ.
- RTA associated with faster linkage to care.

<table>
<thead>
<tr>
<th>Testing Location and Type</th>
<th>aHR - Linkage &lt;90days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical – Lab</td>
<td>1.0</td>
</tr>
<tr>
<td>Clinical – Rapid/WB</td>
<td>0.83 (0.76-0.91)</td>
</tr>
<tr>
<td>Clinical – RTA</td>
<td>1.41 (1.22-1.63)</td>
</tr>
<tr>
<td>Community – Lab</td>
<td>0.91 (0.81-1.02)</td>
</tr>
<tr>
<td>Community – Rapid/WB</td>
<td>0.82 (0.76-0.90)</td>
</tr>
<tr>
<td>Community – RTA</td>
<td>1.08 (0.97-1.21)</td>
</tr>
</tbody>
</table>

Mohammed et al STD 2018
Status Neutral Linkage Needs

• Common prevention and care linkage steps
  ➢ Navigation of complex healthcare system
  ➢ Motivational interviewing
  ➢ Linkage to a knowledgeable, non-stigmatizing provider/clinic
  ➢ Clinic availability
  ➢ Coverage for visits, labs, and medications.

Craw et al., 2010 BMC Health Services Research; Higa et al Current HIV/AIDS Reports 2012; Bradford et al AIDS Patient Care and STDs 2007; Konkle-Parker et al 2014; Naar-King et al AIDS Care 2009
## Linkage Barriers and Facilitators

- Qualitative study of program staff from 12 HIV linkage and retention programs.

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Facilitators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensity of client needs</td>
<td>Strong partnerships</td>
</tr>
<tr>
<td>Communication (clients &amp; partners)</td>
<td>Flexible model program</td>
</tr>
<tr>
<td>Staffing/Administrative</td>
<td>Staff characteristics</td>
</tr>
<tr>
<td>Harmonizing Partnerships</td>
<td></td>
</tr>
</tbody>
</table>

Maulsby et al AIDS Education and Prev 2017
SMILE Collaboration

• Strategic Multisite Initiative for the Identification, Linkage and Engagement (SMILE) in Care of Youth with Undiagnosed HIV Infection.
  
  – Focused on youth 12-24yrs
  – Outreach worker was provided as a clinical resource to support linkage.
  – Administrative database to track youth who were referred as a new case, linked within 42 days, and engaged in care at 16 weeks.

• Enrollment began in 2010.
SMILE Continuum Definitions

• Referred to care
• Linked to care: $\leq 42$ days after referral.
• Engaged in care: $\geq 1$ visit within 16 weeks of linkage.
• Retained in care: $\geq 1$ visit within 52 weeks of engagement.
• Viral suppression: HIV viral load below limit of detection during the study.

Factors associated with linkage and retention in care among adolescents

<table>
<thead>
<tr>
<th>Region</th>
<th>Linked to care N (%)</th>
<th>Odds ratio (95% CI)</th>
<th>Engaged in care N (%)</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwest</td>
<td>228 (77.8)</td>
<td>1.73 (1.27-2.36)</td>
<td>208 (91.2)</td>
<td>1.36 (0.81-2.30)</td>
</tr>
<tr>
<td>Northeast</td>
<td>185 (71.7)</td>
<td>1.25 (0.92-1.70)</td>
<td>161 (87.0)</td>
<td>0.88 (0.53-1.45)</td>
</tr>
<tr>
<td>South</td>
<td>578 (67.0)</td>
<td>Ref</td>
<td>511 (88.4)</td>
<td>Ref</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>60 (66.7)</td>
<td>0.99 (0.62-1.56)</td>
<td>55 (91.7)</td>
<td>1.44 (0.56-3.73)</td>
</tr>
<tr>
<td>West</td>
<td>121 (69.1)</td>
<td>1.10 (0.78-1.57)</td>
<td>108 (89.3)</td>
<td>1.09 (0.58-2.04)</td>
</tr>
</tbody>
</table>

Data sharing and outreach worker function:
- Model A: 259 (68.5) Ref 261 (97.0) Ref
- Model B: 95 (59.4) 0.67 (0.46-0.99)* 67 (70.5) 0.07 (0.03-0.17)*
- Model C: 808 (71.8) 1.17 (0.91-1.50) 715 (88.5) 0.24 (0.11-0.49)*

Clinic characteristics:
- Adolescent only: 413 (71.1) Ref 342 (82.8) Ref
- Shared: 499 (68.2) 0.83 (0.65-1.05) 466 (93.4) 2.93 (1.90-4.53)

**Model A** - Real time data sharing from local health departments and direct outreach worker/client contact

**Model B** – Real time data sharing without direct outreach worker client contact

**Model C** – Aggregate data sharing from local health department with direct outreach worker/client contact
Combination Strategies For Testing and Linkage

• New strategies to combine social, sexual, digital, and molecular networks.
• Enhance case finding for “hard to reach” populations.

McNulty et al AIDS 2018
The ZSFG RAPID Model

HIV+ Diagnosis
- Disclosure
- Referral
- Scheduling

1st Clinic Visit
- Registered
- Insured
- Housing/SU/MH
- Counseling
- Labs

1st PCP Visit
- Medical evaluation
- ART criteria met

ART start
- Pills taken

Viral load suppressed
- VL monitoring
- Adherence
- Retention

RAPID visit: ART start
- Disclosure, counseling
- Registration
- Insurance
- Housing/SU/MH
- Labs
- Counseling
- Medical eval

PCP Visits
- VL monitoring
- ART mgmt
- Adherence
- Retention

Pilcher 2017
RAPID Intervention Components

• Facilitation of same day appointments (PHAST* Team)
  – paged with any new confirmed HIV+ patients on SFGH campus
  – paged by testing sites in SF with any new HIV+ with no/public insurance (i.e., ZSFG eligible)

• Flexible scheduling for providers (on-call back-up)
• ART regimens pre-approved for use prior to genotyping or lab testing
• Available as 5 day starter packs
• Accelerated process for health insurance initiation (PHAST Team)
• Recommendation for 1\textsuperscript{st} dose to be taken observed in the clinic

*Positive Health Access to Services and Treatment

Slide courtesy of Pilcher
Engagement Timeline, ZSFG

Referral  1st Clinic Visit  1st PCP Visit  ART Prescribed  Viral load suppressed

CD4-guided (2006-9)

Universal (2010-3)

RAPID

37 132

1 56

0 30 60 90 120 150 180 210 240 270 300 330 360 390

Pilcher 2017
Linkage to PrEP

• Patients presenting for POC rapid testing – linked to prevention and care.

• 64/300 (21%) linked to PrEP and were more likely to be:
  – Women ($aOR \ 4.1$) or MSM ($aOR \ 10.2$) (vs. heterosexual men)
  – Interested in PrEP ($aOR \ 6.7$)
  – In a sero-different relationship ($aOR \ 14$)

Flash et al JAIDS 2018
Summary

• HIV testing is the entry into the prevention and care continuum.

• Home HIV self-testing has potential to increase testing among priority populations.

• Rapid HIV testing algorithms and rapid linkage navigation programs can reduce care linkage time.

• Additional data on linkage to PrEP and other prevention options needed.
HIV Testing Is the First Step of Either Continuum

- HIV-uninfected
  - Repeat HIV Testing
  - STI Testing and Tx
  - PrEP
  - PEP
  - Behavioral

- HIV Testing

- HIV-infected
  - Linkage to care
  - Immediate ART Retention
  - STI Testing and Tx
  - Behavioral

↓ Acquisition

- Structural
  - Health Equity
  - ↓ Stigma
  - Decriminalization

↓ Infectiousness

↓ HIV Incidence

Thank You

- Susan Buchbinder
- Al Liu
- Darpun Sachdev
- Oliver Bacon
- Chris Pilcher
- Hyman Scott
- Aaron Siegler
- Patrick Sullivan