Current and future HIV testing approaches and operational implications on testing uptake

Dr Rachel Baggaley

WHO MEETING WITH DIAGNOSTIC MANUFACTURERS AND STAKEHOLDERS
GLOBAL FORECASTS OF DIAGNOSTIC DEMAND FOR 2014-2018

WHO Geneva, Thursday 9 April and Friday 10 April 2015
Overview

- Where we are with HTC?
- Where are the gaps?
- New HTC approaches
- Concerns and issues

Toward the UNAIDS “90-90-90”
Right people? Right places?
Community and self-testing
Quality, prioritization
Nearly Half of All PLHIV Are Aware of Status

~16 million in 2013

Source: UNAIDS, Gap Report 2014
Estimated awareness of status among PLHIV varies significantly, but for 2/3s of countries it is within the 40%-60% range.

* By size of the epidemic
Sources: Courtesy of Frederic Seghers CHAI, UNAIDS Aidsinfo; DHS Statcompiler
Access to HIV Testing is Increasing

+33% growth in 4 years
21 million more tests
0.5 billion HIV tests to date

Source: WHO Global Reporting 2014, WHO Global Reporting 2014
Countries HTC Scale-up and Diagnosis of PLHIV of Over Time

Averaged evolution over time for the percent identification of PLHIV, Top 30 countries* by burden

- **Steep increase:** Ramping up the number of facilities and introduction of Provider-Initiated testing
- **Decelerated increase:** High hanging fruits are more difficult to reach via traditional strategies
- **Slow start:** Initial VCT efforts (Voluntary Testing)

On current trajectory, projection suggests ~25 years for top burden countries to identify 90% of PLHIV.

* By size of the epidemic
Source: Courtesy Frederic Seghers, CHAI Input data via UNAIDS Aidsinfo; DHS Statcompiler – projections via CHAI NMOT modeling
Evolution of HIV Diagnostics

1985
- 1st HIV Antibody test licensed

1988
- Rapid test (WHO eval)
- Numerous RTDs developed

1989
- 1st HIV Antibody test licensed

1999
- EIAs for Ag/Ab detection

2001
- Rapid test, oral fluid

2008
- Rapid HIV test for Ag/Ab detection

2010
- HIV / syphilis multiplex rapid test

2012
- Self-test approved by US FDA

2015
- Smartphone testing
Evolution of HTC Approaches

1985
Clinical diagnostic testing; Blood donors

1995
1999 Social marketing, e.g. New Start

1990 VCT sites, e.g. AIC Uganda

2000 Campaigns

2005
2013 Community-based HTC (WHO)

2007 PITC (WHO)

2015
HIV self-testing?
Trends in Reported Uptake of HIV Testing in Sub-Saharan Africa

Percentage of **women** ages 15-49 yrs ever tested for HIV & received results of most recent test

Percentage of **men** ages 15-49 yrs ever tested for HIV & received results of most recent test

Source: DHS data (Staveig, 2013; WHO 2014 progress report)
Malawi National HTC programme outputs 2008-14

People tested
• Negative
• First time positive
• Positive (%)

% Positives among people tested

Source: Ade Fakoya GFATM 2015
Overview

- Where we are with HTC?
- Where are the gaps?
- New HTC approaches
- Concerns and issues

Toward the UNAIDS “90-90-90”
Right people? Right places?

Community and self-testing

Quality, prioritization
Moving Testing Out of the Health Center into the Community

- **Home-based** (house to house)
  - General population
  - Index-case
- **Campaigns and campaigns plus**
  - HTC “plus” — malaria, safe water, Non-communicable diseases (IHD, DM, BP, BMI etc.)
- **Outreach** (mobile)
  - General populations
  - Key populations
- **Workplaces, schools**
HIV Self-Testing (HIVST)

- Huge potential
- Already happening in many settings, (formally & informally)
- ↑ countries allowing or considering allowing USA, Kenya, UK, France, South Africa, China...
- WHO March 2014 Supplement to ARV Guidelines & UNAIDS technical update
- WHO Evidence Map of HIVST (www.hivst.org)
Among Key Populations

- Generally acceptable
- Studies mostly among MSM in high-income settings
- Desire HIVST over-the-counter & via Internet
- Report they would link to care (80-100%)

Key issues for HIVST

- All +ve need confirming
- IFU critical
- Links to community groups for support and linkage + ? hotline
- Community messaging re "meaning" of a HIVST result

Source: Figueroa et al. forthcoming, WHO 2015
Catalyzing HIVST in southern Africa

Implementation-research partnership tackling market barriers by:

- Demonstrating approaches in multiple sites, models, & among populations
- Normalising HIVST in Southern Africa
- Providing evidence for scale-up
- Developing WHO Guidelines
- Influencing policy change
- Enabling the regulatory environment
- Encouraging market entry of low-cost HIVST products

Market size estimate for South Africa at 2.8 million annually

Countries

- Malawi
- South Africa
- Zambia
- Zimbabwe
Increase access to quality products:
- High quality products at affordable price
- Clients can safely access HIVST and post-test services with ease
- Systems in place to minimize harms and support post-test

Increase informed demand:
- Quality packaging and effective instructions for use
- Appropriate marketing strategies and branding defined
- Potential market size defined
- Costs and cost-effectiveness of HIVST defined

Impact goals:
- National testing algorithms include HIVST beyond project countries
- HIVST integrated into national frameworks in all project countries
- Oral fluid test adapted for HIVST included in approved list of diagnostic tests
- Improvements in health from sustainable high coverage HIVST

Reduce strategic barriers:
- Donors and policy makers supportive of HIVST
- Global HIV planning tools and commodity lists include HIVST
- Enabling national policies and algorithms
- Sufficient evidence for WHO HIVST guidelines and recommendations

Reduce structural barriers:
- Manufacturers invest in HIVST and seek product registration
- Competition for HIVST products increases and unit costs fall
- Manufacturers aware of HIVST market size
- Clear and transparent approval and device registration systems
- STAR Strategy overview
- Global HIV planning tools and commodity lists include HIVST
- National testing algorithms include HIVST beyond project countries
- Sufficient evidence for WHO HIVST guidelines and recommendations
- Improvements in health from sustainable high coverage HIVST
Overview

- Where we are with HTC?
- Where are the gaps?
- New HTC approaches

Toward the UNAIDS “90-90-90”
- Right people? Right places?
- Community and self-testing

- Concerns and issues

Quality, prioritization
Concerns and issues

• Quality of testing process – misdiagnosis
• Better targeting of community testing
• Overcoming barriers for community testing – lay testers
• Acute infection – esp. in PrEP
• HIVST – regulation, performance by uninitiated, ?linkage, adverse outcomes
#1. HTC Quality / Misclassification

- Reports of misclassification range from 2.6% to 10.3%\textsuperscript{1,2}
- Implications:
  - For public health
  - Undermines credibility of health system
  - Emotional & legal
  - False positive
- Unnecessary life long ART
  - False negative
- Ongoing transmission risk to partners & infants

Studies (N=44) Identified in a Literature Review, Reporting Factors Related to Misclassification

<table>
<thead>
<tr>
<th>Factor</th>
<th>#</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper practices around supplies</td>
<td>19</td>
<td>43%</td>
</tr>
<tr>
<td>Clerical / technical errors</td>
<td>14</td>
<td>32%</td>
</tr>
<tr>
<td>Incorrect / suboptimal testing strategy</td>
<td>13</td>
<td>30%</td>
</tr>
<tr>
<td>User error</td>
<td>11</td>
<td>25%</td>
</tr>
<tr>
<td>Weak positive</td>
<td>9</td>
<td>20%</td>
</tr>
<tr>
<td>Cross-reactivity</td>
<td>7</td>
<td>16%</td>
</tr>
</tbody>
</table>

#3. Legitimise Lay Provider HTC

WHO considering recommendation for lay provider rapid HIV testing, July 2015

Country policies, trained lay providers can perform HTC tasks

<table>
<thead>
<tr>
<th>Total Policies, 49 Countries</th>
<th>WHO African Region, 25 Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fingerstick HIV RDT</strong></td>
<td><strong>Pre- and Post-Test Counselling</strong></td>
</tr>
<tr>
<td>Yes</td>
<td>40%</td>
</tr>
<tr>
<td>No</td>
<td>33%</td>
</tr>
<tr>
<td>Not specified</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>27%</td>
</tr>
<tr>
<td></td>
<td>18%</td>
</tr>
<tr>
<td></td>
<td>58%</td>
</tr>
<tr>
<td></td>
<td>79%</td>
</tr>
<tr>
<td></td>
<td>42%</td>
</tr>
<tr>
<td></td>
<td>21%</td>
</tr>
</tbody>
</table>

Source: Flynn et al forthcoming
HIV “Test for Triage”

An Alternative Community-based HTC Approach

- Concerned complex testing algorithms may lead to errors
- Proposed policy for community-based sites
  - A **single rapid diagnostic test** in community-based HIV testing
  - **Not a definitive test result**
  - Emphasis on **HIV diagnosis** at health facility (start at A1)
- **Triage** – prioritize HTC where care most needed
- Community based tester to focus on **linkage** for re-test and clinical assessment

**Diagram:**

- **Perform HIV test for triage**
  - A0
    - A0 +
      - Link to HIV testing for diagnosis, care & treatment
    - A0 – report HIV-
      - Recommend repeat testing as needed