Progress towards the first 90:
Innovative approaches, including self-testing

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INTEREST Conference
Conflict of interest

Nothing to declare

18th May 2017

INTEREST Conference
Progress towards 1st 90

- Rapid scale up of services in Southern and East Africa
- Decentralised HTS via lay counsellor cadre
  - Home-based testing
- ~100 million HIV tests p.a.

Undiagnosed HIV, as % all PLHIV, globally

- 2005: 90% (10% undiagnosed, 55% diagnosed)
- 2015: 45% (55% undiagnosed, 45% diagnosed)
Testing gaps by global region

West and Central Africa well below global average

Source: UNAIDS, 2016
Confidentiality impedes decentralisation of HTS

Survey in health workers in 5 countries

Treat, train and retain: 2007

- Need for a moment of privacy when learning results
  - Testing at own facility out of question
- Thereafter, easier to turn to someone you know than to tackle the health system alone
  - HIV treatment at own facility preferred by many
UNITAID Application $46 million

2013

UNITAID and the Global Fund expert panel approves the first HIV self-testing product

2017

A short technical update on self-testing for HIV

HIV self-testing

Cost of Oral HIVST kit $40 ➔ $3.40
May reach $2
Lots of new products

Malawi, Zim & Zam HIVST kits in GFA17

2016

UNITAID

$46 million

2013

$40 ➔ $3.40

May reach $2

Lots of new products
HIV self-testing should be offered as an additional approach to HIV testing services (strong recommendation, moderate quality evidence)
Outline

Data from Malawi 2012-15

• (Accuracy)
• Social harms
• Linkage

UNITAID-PSI-STAR HIV self-testing grant
HIVST in Malawi: 2012-15

Huge potential and unmet demand

Community can take ownership
• Acceptable for neighbours to provide kits
• High levels of motivation within community
  • First-time testers
    – young people & men
  • HIV-ve women & other repeat testers
  • Transforms couples-testing
• Add-on interventions can
  • Increase demand for
    – ART
    – HIV prevention
    – Provide TB screening
Combined HIVST+ linkage intervention
Blantyre, Malawi
MacPherson JAMA 2014

Original Investigation
Effect of Optional Home Initiation of HIV Care Following HIV Self-testing on Antiretroviral Therapy Initiation Among Adults in Malawi
A Randomized Clinical Trial

Peter MacPherson, PhD; David G. Laloo, MD; Emily L. Webb, PhD; Hendriamorothy Maheswaran, MSc; Augustine T. Choko, MSc; Simon D. Makombe, DipClin Med; Anthony E. Butterworth, PhD; Joop J.van Oosterhout, PhD; Nicola Desmond, PhD; Deus Thirdwa, MSc; Stephen Bertel Squire, MD; Richard J. Hayes, DSc; Elizabeth L. Corbett, PhD

Percentage of all adult residents who initiated ART

- Home: 1.4%
- Facility: 0.8%
- Facility: 0.7%
- No HIVST: 0.7%

RR: 2.94 (2.10-4.12)

Combination of HIVST+ linkage intervention

Optional home initiation after HIVST
Facility initiation after HIVST
No HIVST
Social harms

- An intended or unintended cause of physical, economic, emotional, or psychosocial injury or hurt from
  - one person to another,
  - a person to themselves,
  - or an institution to a person

- May be the result of the threat of or actual force or power
Key Findings

- Acceptability of “force” in context of gender inequality
- HIVST fosters openness between couples

Key Lessons taken forward

- Coercion: harm or benefit?
- Short-term harms translating to long-term benefits
- Ethics around
  - individual autonomy vs public good
  - relational responsibility
What does it cost?

• Potential to be cost-saving, especially in countries with poorly decentralised services
  • Costs to client can be close to $0.00
  • Willingness to pay is very low in Malawi

• Easier to achieve cost-effectiveness if still far from reaching first 90
  • But do need linkage
  • Linkage into prevention becomes a key driver of cost-effectiveness

• Easier to achieve cost-effectiveness with Universal Test-and-Treat

• Potential for very low distribution costs (while maintaining linkage and 5Cs..)
  • Partner-delivered
  • Social and sexual networks
  • MoH distribution
  • Community-led campaigns

• Paradigm shift towards ensuring rational use
  • Desirable commodity
Implementing HIVST in Blantyre, Malawi was cost-effective
• US$ 230/QALY gained
• WHO 2010 ART guidelines

HTC comparable to facility-based HTC
• US$8.90 for HIVST
• US$8.78 for facility HTC

Implementing HIVST will increase healthcare spending
• But will improve health

Willingness to pay
1 X GDP
3 X GDP

Incremental Costs (2014 US Dollars)
HIVST and ART guidelines: cost-frontier for Blantyre, Malawi

Which strategy is optimal with increasing willingness to pay for gains in health (QALYS)?

Cost-effectiveness acceptability frontier (CEAF) evaluating 4 strategies involving:
• Facility HTC v Facility + HIVST
• WHO ART Guidelines
  • 2010 vs 2015 initiation
Catalysing HIVST: UNITAID STAR high-level goals

1) Develop global normative HIVST guidelines
   • Informed by project evaluation
   • Released by WHO

2) National guidelines and algorithms to accommodate HIVST in all countries by end of project

3) ≥1 HIV kit packaged for HIVST added to approved diagnostics list for donors

4) Price reductions for ≥1 quality assured HIVST product
   • to ≤ USD$2.75 from USD$40.00/ kit
STAR data to date

379,945 HIVST kits distributed March 2016 – May 2017

% to clients in key target groups

- Men < 25yrs
- 1st time testers

- Malawi
- Zambia
- Zimbabwe
1. How feasible and accurate is HIVST in rural Malawi?

2. Can peer-led services provide HIVST for sex workers safely and affordably?

3. Health & social impacts in rural Malawi?
   • Cluster-randomised trial in 4-Districts

4. Key preferences for HIV services?

5. Costs and benefits of different models?

6. Policy & regulatory barriers to HIVST?

7. Priority new low cost models from Sept 17
   • Community-led distribution
   • Facility-based with Ministry
   • Randomised trials: linkage to HIV prevention

5 to 10 million tests by 2020

General Population
Target: 648,588

Female Sex Workers
Target: 10,002
11 facility catchment areas in rural Malawi
Change in HIV testing coverage by gender: repeat household survey
11 facility catchment areas in rural Malawi
Change in HIV testing coverage by age group: repeat household survey

**Ever tested for HIV**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Baseline</th>
<th>Midline</th>
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<tbody>
<tr>
<td>16-19 yrs</td>
<td>86%</td>
<td>90%</td>
</tr>
<tr>
<td>20-25 yrs</td>
<td>96%</td>
<td>91%</td>
</tr>
<tr>
<td>26-49 yrs</td>
<td>95%</td>
<td></td>
</tr>
<tr>
<td>Ages 50+</td>
<td>76%</td>
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**Tested in past 12 months**

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<th>Midline</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-19 yrs</td>
<td>92%</td>
<td>75%</td>
</tr>
<tr>
<td>20-25 yrs</td>
<td>91%</td>
<td>77%</td>
</tr>
<tr>
<td>26-49 yrs</td>
<td>84%</td>
<td>63%</td>
</tr>
<tr>
<td>Ages 50+</td>
<td>73%</td>
<td>52%</td>
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Female Sex Workers (FSW) peer-led model

- **Objective:** Investigate appropriate models for delivering HIVST kits to FSWs

**Progress**
- **Rapid ethnographic assessments** (Participant observations and semi structured interviews with FSWs) and
- **participatory workshop with stakeholders**

**Results**
- Peer-delivery HIVST valued for convenience, confidentiality, privacy, and ease-of-use
- Preferences for distribution through peers
  - Trusted to keep result confidential
  - Already provides social support; could help to detect social harms
  - Allows flexible pick-up location
- Some concerns around lack of counselling and linkage to care if positive
Social harms reporting to support female-controlled HIV prevention technologies

- Establish prototype grading and reporting systems for HIVST
- Relate those to other female-controlled methods: event grading, event reporting, response system
  - Female condoms
  - Microbicides
  - PrEP
- Stakeholder workshops to develop SHRS in consultation with DfID and WHO
Multi-arm multi-stage (MAMS) cluster randomised trial design (Phase 2)

Methods development
Unit of randomisation: ANC day (cluster)
One interim analysis (end of first stage) drop for
  • Futility
  • Safety
Cost and acceptability to Gov
  • Financial incentives

Trial arm
1. Standard of care
2. Self-test (ST) kits only
3. ST + Low amount incentive ($3)
4. ST + High amount incentive ($10)
5. ST + Low amount through lottery
6. ST + phone call reminder

1st stage 2nd stage Phase III
?
?
?
?
?
?

Total number of antenatal clinic days per arm ST: self-test

Choko unpublished
Conclusions

HIVST is an exciting and promising new development

- Everyone you want to get tested wants to self-test
- Built-in “moment of privacy” allows for “standard” decentralisation approaches
- Men, adolescents, key pops
- Complementary coverage including first time-testers
- Can be a “disruptive” technology in context of low coverage/no task-shifting

Public health --- needs linkage!

- PHIA studies reassuring in STAR countries
- Demonstrated effect on ART demand (MacPherson)
- Effect on VMMC (Choko)
- Tools to capture linkage from HIVST at scale need improvement

Affordability & cost-effectiveness

- Rational use and minimising distribution and linkage costs
- Effective linkage to prevention an increasingly important issue for community-based HTS models
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Ayles