HIV SELF TESTING IN SA: TRANSLATING POLICY INTO PRACTICE

Dr T Chidarikire

NDOH: HIV PREVENTION STRATEGIES

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Current Situation

**South Africa (2015)**

- 7 million people living with HIV
- 19.2% adult HIV prevalence
- 380,000 new HIV infections
- 180,000 AIDS-related deaths
- 48% adults on antiretroviral treatment

National HIV Care and Treatment Cascade

HIV Cascade - Total Population
(Dec 2016 - South Africa)

- 100% PLHIV
- 74% PLHIV who know their status
- 52% PLHIV on ART
- 32% Viral loads done
- 26% Virally Suppressed

Department: Health
REPUBLIC OF SOUTH AFRICA
Reaching the first 90

- Focused and targeted HTS
- Appropriate interventions for maximum impact
- Targeted testing modalities: HTS
  - HIV ST
  - Facility based (CICT; strategic use of PICT)
  - Community based (Stand alone, mobile/outreach, work-place, higher institutions incl TVETs, home based, index tracking)
- Increased linkage to care
Interventions

• HTS: HIV ST
• MMC
• PreP
• PEP
• ARVs: Test and Treat
• Condoms
  – Male
  – Female
Policy

• HTS Policy revised in 2016 – embraces full range of services incl ST (self screening)

• Task sharing/shifting: Lay counselors trained to conduct HTS using RDT – 2010 (more efficient use of resources)

• Quality HTS and Delivery of Correct Results – Validation of national algorithms
Policy guidance

- SA HTS Policy recommends HIVST as expansion to testing to reach hard to reach populations such as AGYW
- HIVST should be seen as screening test and not diagnostic test
- Confirmation of every positive test with national algorithms
- Guidelines for implementation are still in draft form in collaboration with the SA Clinician Society
HIV ST Benefits

• Potential impact on 1st ‘90’ by increasing access and acceptability for under-tested & at-risk populations that need frequent or routine testing

• Can reach untested and test-averse populations.

• Potential approach to scale-up HTS and accelerate case detection

• Contribute to closing testing gap in South Africa

• Particularly for young women and girls, their partners, men in general, female sex workers, MSM
Target profile

- High quality manufacturing standards

- Must be appropriate for an untrained, non-professional layperson

- Acceptable analytical performance in laboratory settings.

- High clinical sensitivity/specificity with untrained users

- Pictorial instructions for use with any text-based instruction translated into local languages
Target profile

- Fewer test steps with simple sample transfer
- Simple to interpret test results
- Fast time to result
- Test results to remain stable for a longer period
- Product to include referrals for assistance with results and linkage to care
HIVST delivery models

Targeted delivery models dependant on the target population:

- PHC facilities, Hospitals and pharmacies
- Workplace programmes (mines, farms, construction, mostly to reach men)
- Special services (ANC, STI clinics, FP, VMMC, PrEP)
- AGYW, TVETS, in and out of school
- Other outreach incl mobiles and campaigns

(for both directly assisted and unassisted HIVST)
National Guidance for HIVST in SA

SA HIV Self-Testing Policy Guideline consideration - DRAFT
Regulatory challenges

- 2015: SA Pharmacy Council approved selling of HIV self testing kits by pharmacies: Recommends QA
- 2016: Published a notice regarding minimum standards for selling of the kits
- On-going demonstration projects to inform implementation: cover feasibility, acceptability, useability, targeting, distribution, waste disposal etc
- NDOH working with Wits RHI, WHO and the SA Clinician Society to finalise the implementation guidelines
- Working with NICD for quality recommendations in laboratories
- Rollout in Public Sector will be informed by WHO Pre-qualification
- Different types of HIV Self test kits are already available in the market (private sector) and need to be regulated and guided.
Regulation challenges
Demo projects

1. Who should have **access**?
   
   i. All populations or priority groups?
   
   ii. Adolescents and young people?
   
   iii. Age of consent: 12

2. **How & where** will it be implemented & distributed? Distribution models especially for young people, waste management

3. **Cost?** Will it be **free** or **subsidized** to users? Critical

4. **PQ** by WHO
Demo Projects

Project underway in Malawi, Zambia and Zimbabwe – South Africa to participate following Phase-I

The project will be critical to identifying the most ethical, acceptable, effective and sustainable HIVST approaches for South Africa
Demo Projects

Wits RHI HSTAR Programme

HIV Self-Testing RDT Evaluation

Non Clinical studies

LEVEL 1 Usability Assessment

LEVEL 2 Trained User Assessment

LEVEL 3: Intended Use Assessment

LEVEL 4 Expected Use Assessment

LEVEL 2

LEVEL 1

HIV Self-Testing Assessments & Research
Demo projects Findings
HST and young people

- Evaluating community-based “assisted” HIVST among young people in Cape Town
- Report high uptake among first time testers, high acceptability & preference for HIVST compared to standard HTS

Source: Bekker et al AIDS 2016
Demo Projects Findings

- Ndlovu Health (Limpopo): High usability, concordance, Sens and Spec in rural population
- HSTAR (Gauteng): High usability in Oral Fluid and Finger stick products in Inner City Johannesburg
- iTEACH (Gauteng, Mpumalanga, KZN)
  - High concordance, but low LTC in Truck Drivers
- UCT: Western Cape: High acceptability in MSM and demonstrated utility of online platforms for sale and dist
- ANOVA (NW): High Acceptability in MSM
- WRHI STAR Programme: Usability and assessment studies
Conclusion

• Facilitate finalisation of minimum standards to regulate currently available HIVS test kits
• Finalisation of the implementation Guidelines on HIVST
• Finalisation of the demo projects to provide critical data to guide implementation
• **Awaiting WHO PQ**
• Target implementation in specific geographic areas, populations and settings
Conclusion

- Thank you to everyone who was involved!
  - WHO
  - NICD
  - WITS RHI
  - NDOH