Selection and Evaluation of a Third Rapid HIV Assay as a Tie Breaker to Enhance Early HIV Diagnosis and Linkage to Care in the Kingdom of Swaziland

Authors: *Rogers Kisame[1], Sindisiwe Susan Dlamini[2]*

Affiliations: *University Research Co., LLC (URC)[1] ; MoH, Swaziland Health Laboratory Services (SHLS)[2], Mbabane, Swaziland.*

Dec 03, 2014

ASLM2014 CONFERENCE
30 NOVEMBER – 4 DECEMBER 2014INNOVATION AND INTEGRATION OF LABORATORY AND CLINICAL SYSTEMS"

BACKGROUND

- Swaziland continues to have the highest overall HIV prevalence rate in the world (31% among adults). Prevalence is higher in women (38%) compared to men (23%).
- A successful public health response to HIV, not only requires robust HIV testing program, but also requires successful linkages to HIV care and treatment.
- Since 2006, a 2 rapid test HIV serial testing algorithm was adopted (Determine®HIV-1/2 and Uni-GoldTM HIV-1/2) and centralized ELISA, as a 3rd test offered at NRL.

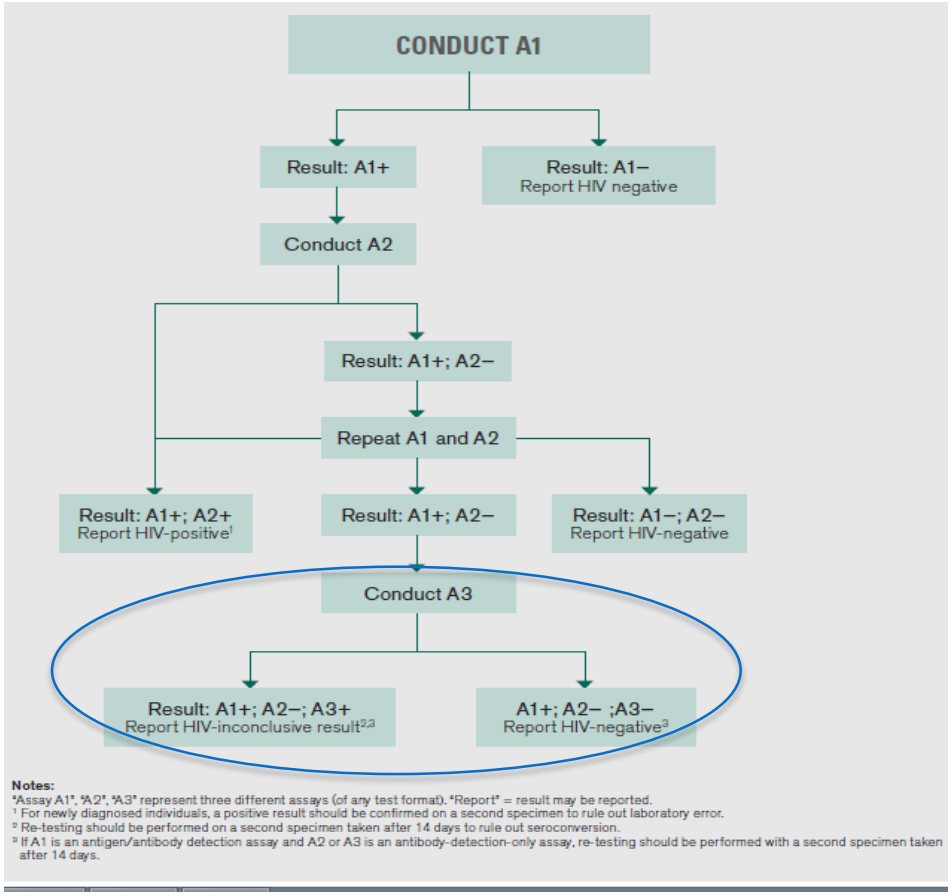
ALgorithm Programmatic barriers at laboratory and community level:

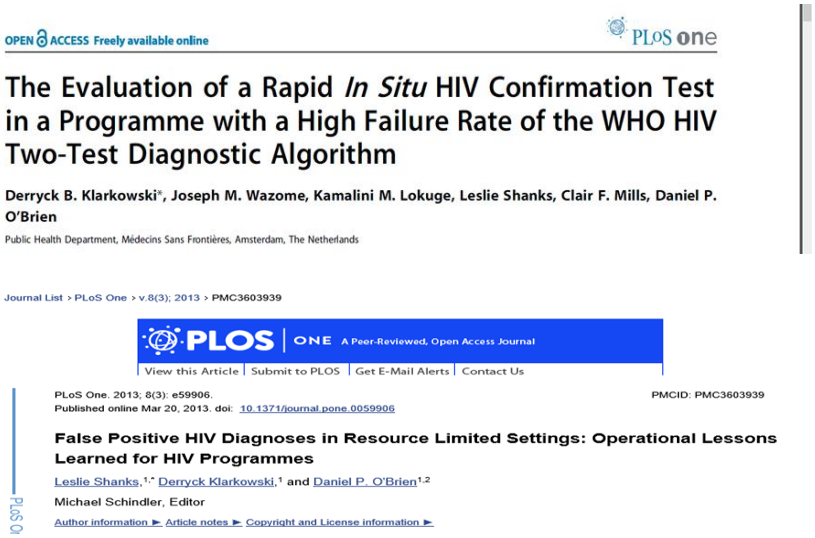
ELIZA equipment down time → Reagent stock outs → Necessities for batching samples → specimen and result delivery delays → **Limits HTC uptake and delays linkage to care.**

Swaziland HIV Incidence Measurement Survey (SHIMS), 2012

‘Looking beyond the laboratory optimize early detection and linkage to care’

HIV Testing strategy for Diagnosis in High Prevalence Settings




OPEN ACCESS Freely available online PLoS one

The Evaluation of a Rapid *In Situ* HIV Confirmation Test in a Programme with a High Failure Rate of the WHO HIV Two-Test Diagnostic Algorithm

Derryck B. Klarkowski*, Joseph M. Wazome, Kamalini M. Lokuge, Leslie Shanks, Clair F. Mills, Daniel P. O'Brien

Public Health Department, Médecins Sans Frontières, Amsterdam, The Netherlands

Journal List › PLoS One › v.8(3); 2013 › PMC3603939

PLOS | ONE A Peer-Reviewed, Open Access Journal

View this Article | Submit to PLOS | Get E-Mail Alerts | Contact Us

PLoS One. 2013; 8(3): e59906. PMCID: PMC3603939
Published online Mar 20, 2013. doi: 10.1371/journal.pone.0059906

False Positive HIV Diagnoses in Resource Limited Settings: Operational Lessons Learned for HIV Programmes

Leslie Shanks,[1,*] Derryck Klarkowski,[1] and Daniel P. O'Brien[1,2]

Michael Schindler, Editor

Author information ► Article notes ► Copyright and License information ►

A1: Determine A2: Unigold A3: ELISA (NRL)

Service delivery approaches to HIV testing and counselling (HTC): a strategic HTC policy framework. WHO, 2012

Goal and objectives

- **Goal:**
  - Introduce a third rapid HIV test as a tie breaker to boost early diagnosis and linkage to care in the country.

- **Objectives:**
  - To select 4 HIV rapid test kits (Phase 1).
  - Evaluate the performance a selected rapid test kit against a gold standard (Phase 2).
  - Review and recommend a 3rd rapid HIV test tie breaker algorithm for Swaziland (Phase 2).

Method

5 months

Phase 1 (July to Aug 2014): Candidate kit identification

Preliminary kits selection

- Cost per test (≤8US dollars per test)
- WHO pre-qualification and USAID approval
- ISO 13485 CERTIFICATION
- Ability to perform testing on serum, plasma, or whole blood (venous/capillary)
- Specificity (≥ 99.9 i.e. the specificity of 2nd HIV rapid assay in the serial algorithm for Swaziland)

Determine comparative advantage

- Evaluate selected WHO-prequalified and USAID approved test against a pre determined criteria/checklist

Phase 2 (Oct to Dec 2014)

Determine:

- Sensitivity
- Specificity
- PPV
- NPV

*CLSI guidelines

Review HIV algorithm

Selection Criteria 'Comparative advantage'

Criteria	Grading /Score
Ease of use	6 score =Satisfactory
Number of reagents needed [1 for only 1 reagent and 0 for more than 1]	
Storage conditions [1 for 8 to 30°C required and 0 for 2 to 8°C required]	
Total number of assay steps [1 for less than 4 steps and 0 for more than 4 steps]	
Total performance time [1 for 15 min and 0 for more than 15 min]	
Technical skill needed by operator [1 for no lab experience and 0 for Lab experience]. Note: Sample size =20	
Shelf life [2 for ≥ 18 months and 1 for < 12 months]	
Packaging; Supply chain-allow for easy distribution of singe tests to several sites, considering that tie breaker demand may relatively be low	2 score =Satisfactory
Overall packaging [1 for < 25 test per manufacturer package and 0 for > 25 test per manufacturer package]	
1, for test with individual buffer incorporated per test, and 0, for buffer shared by multiple tests within package.	
Availability of approved distributer in the SADC region [1 for yes and 0, for no]	1 score =Satisfactory
Post marketing evaluation; 1 for Good reputation and 0 for poor reputation (based on published evidence)	1 score =Satisfactory
ISO certification. 1 For certifies manufactures and 0 for non-certified manufacturers	1 score =Satisfactory
Overall Result	
Key	11 score =satisfactory
	10 scores =Area of Concern
	<10 scores =unsatisfactory

Results : phase 1 preliminary kit selection

Candidate kit identification criteria

- Cost per test (≤8US dollars per test)
- WHO pre-qualification and USAID approval
- ISO 13485 CERTIFICATION
- Ability to perform testing on serum, plasma, or whole blood (venous/capillary)
- Specificity (≥ 99.9 i.e. the specificity of 2nd HIV rapid assay in the serial algorithm for Swaziland)

Identified kits included:

4 WHO-prequalified and USAID approved kits:

- DPP® HIV 1 / 2 (Chembio Diagnostic Systems, Inc);
- HIV 1/ 2 STAT-PAK® Assay (Chembio Diagnostic Systems, Inc)
- Clearview® COMPLETE HIV1/2 (Alelle)
- SD Bioline HIV 1/2 3.0 (Standard Diagnostics)

Results : 'Comparative advantage'

Criteria	Scores/ Results			
	DPP® HIV 1 / 2	HIV 1/ 2 STAT-PAK®	Clearview® COMPLETE HIV1/2	SD Bioline HIV 1/2 3.0
Ease of use	4=Unsatisfactory * Number of reagents needed	6=Satisfactory	6=Satisfactory	6=Satisfactory
Packaging	1=Unsatisfactory * buffer shared by multiple tests within package	1=Unsatisfactory * buffer shared by multiple tests within package	2=Satisfactory	1=Unsatisfactory * buffer shared by multiple tests within package
Availability in the region;	1=Satisfactory	1=Satisfactory	1=Satisfactory	
Post marketing evaluation;	1=Satisfactory	1=Satisfactory	1=Satisfactory	0=Unsatisfactory * product recall in 2012 (WHO, 2012)
ISO certification.	1=Satisfactory	1=Satisfactory	1=Satisfactory	1=Satisfactory
Overall Result	8=Unsatisfactory	10=Unsatisfactory	11=Satisfactory	8=Unsatisfactory

Discussion and conclusion

- For Swaziland, results indicated comparative and excellent operational results for Clearview® COMPLETE HIV1/2 assay.

- These findings provide a basis for harmonizing national HIV rapid testing strategies and have future implication on maximizing HTC uptake and patient linkage to care and treatment.

Way forward

- Conduct a broader laboratory based performance evaluation of selected assay against a gold standard test (ELISA).
  - Sensitivity, Specificity, positive predictive value, Negative Predictive Value

- Review and recommend an 3rd tie breaker HIV testing algorithm (serial).

Acknowledgment

- MoH
- Management -Swaziland Health Laboratory Services
- SNAP

The work is made possible with the technical and financial support of the CDC/URC HIV/AIDS and TB related Laboratory support and Technical assistance project.