Early Adoption of a 3-RDT-based HIV Testing Algorithm - Lessons from Eswatini

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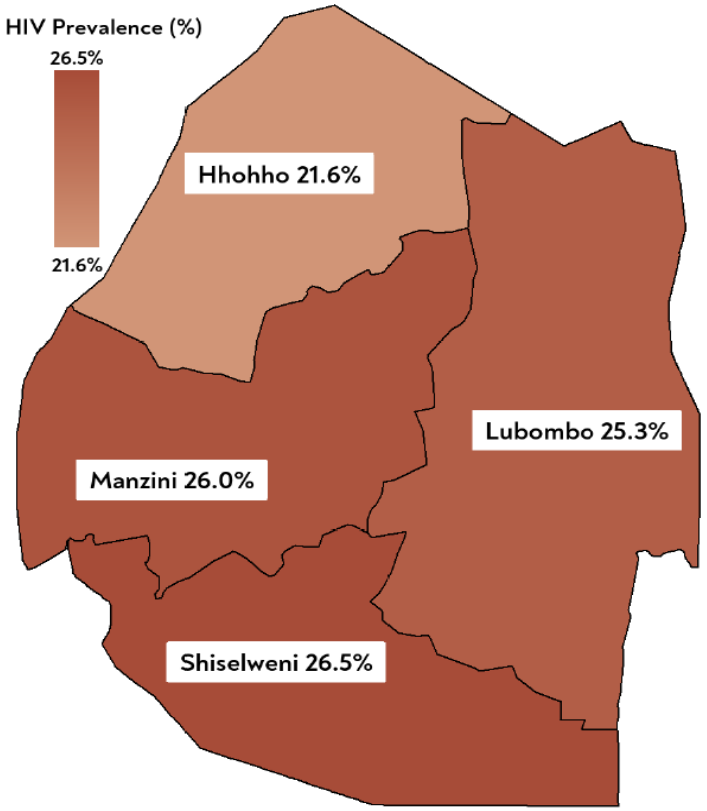
Presentation Outline

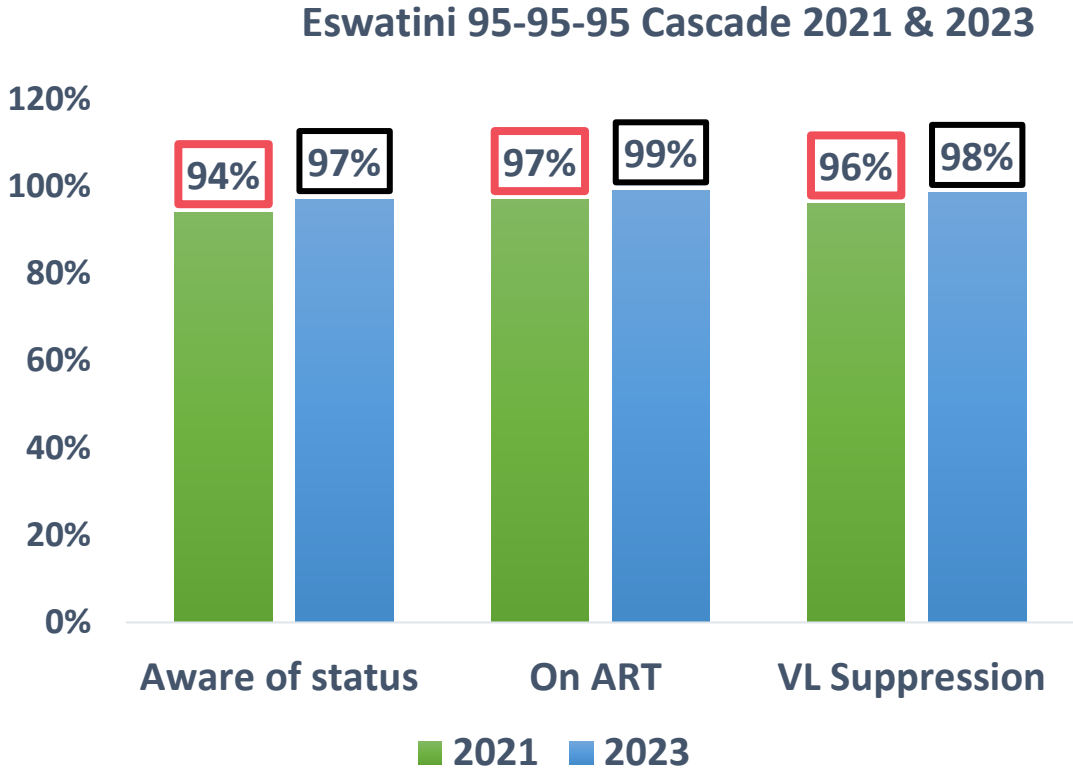
- Country HIV Epidemiology
- dHTS CMM results, 2023-2024
- Steps taken to adopt the 3-RDT algorithm
- Challenges and solutions
- Lessons learned
- Next steps

Country HIV Epidemiology



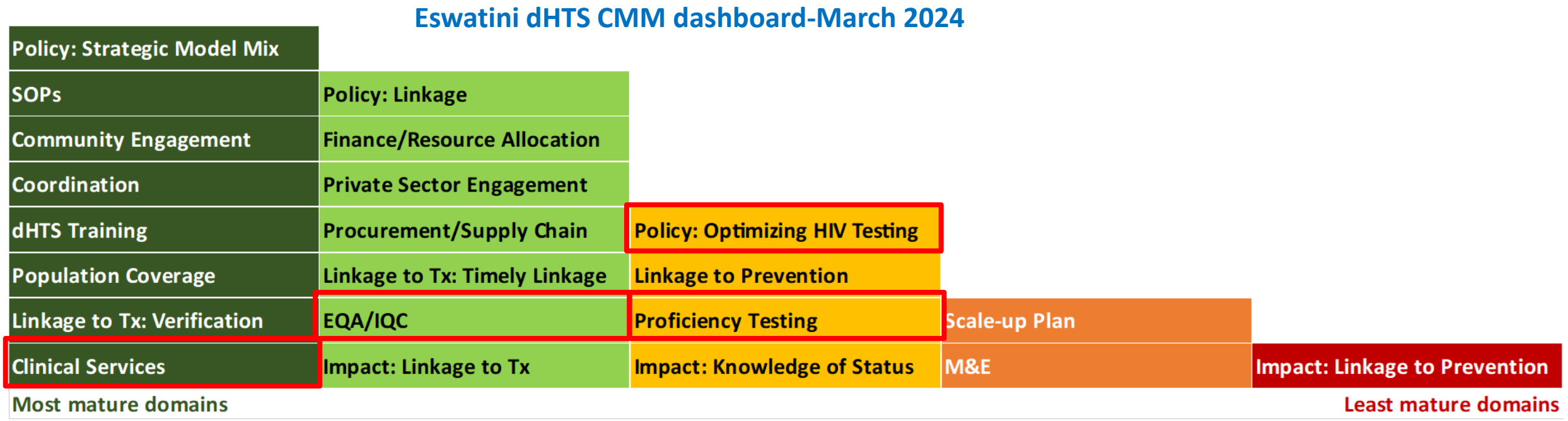
- Eswatini HIV prevalence is **24.8%**
- HIV prevalence in women is almost **TWO times** higher compared to males **(30.4% vs 18.7%)**
- HIV incidence is **0.62% (1.11% in women vs 0.17% in men)**

In 2023 Eswatini had an estimated **221,183 PLHIV** with **213,416 active on ART**.



Source: 2021 SHIMS 3 and 2023 Eswatini HIV Report

dHTS CMM results, highlighting Quality Domains



- Adoption of the 3-test Algorithm is meant to address the **Policy** domain on **Optimizing HIV Testing**
- Adoption of the 3-RDT algorithm, with increased focus on **Proficiency Testing** will help improve overall **Quality of Testing** - Correct results

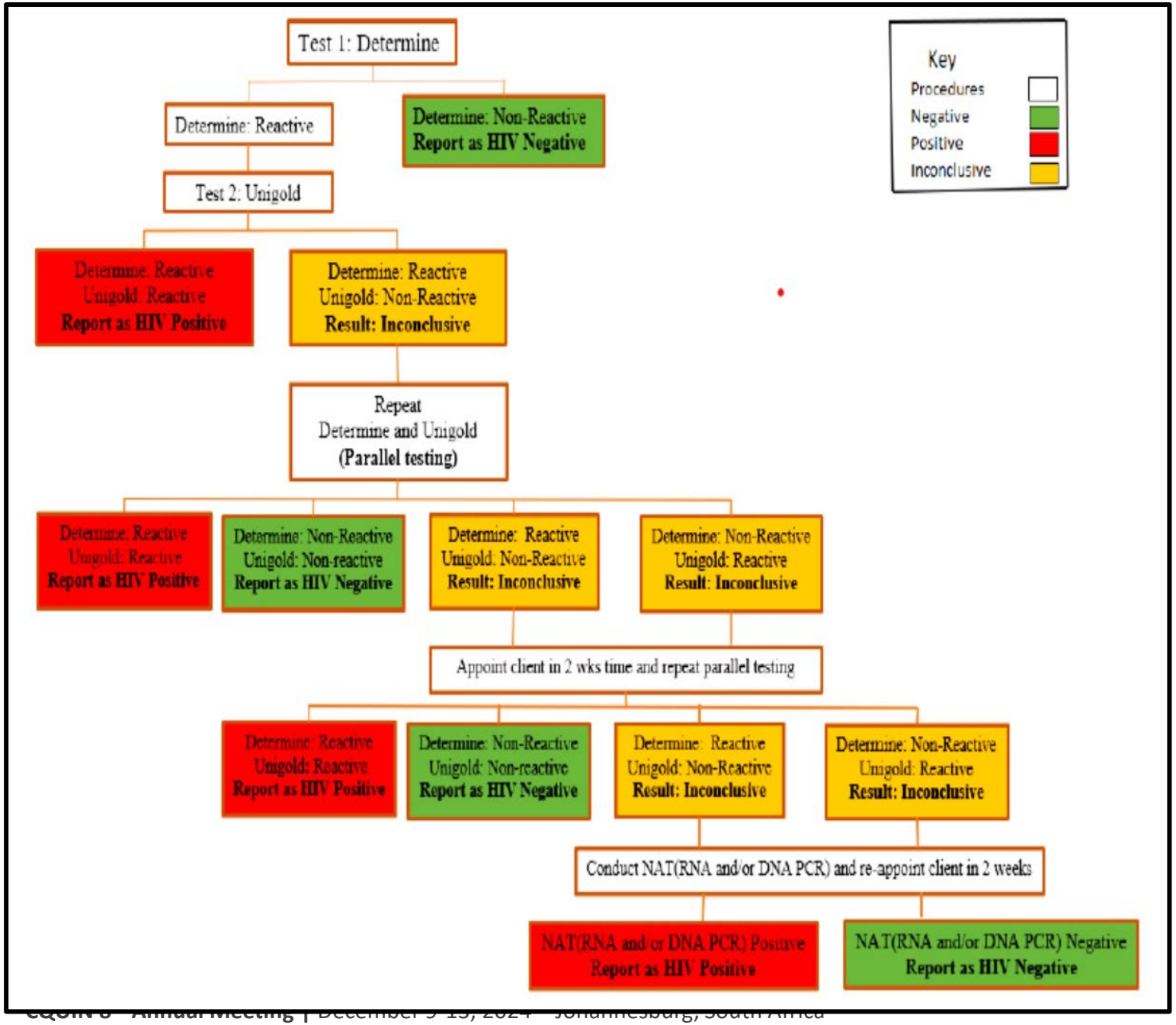
Eswatini dHTS CMM Results – 2023 vs 2024

Domains	2023	2024
Policy: Strategic Model Mix		
Policy: Optimizing HIV		
Policy: Linkage		
Finance/Resource Allocation		
SOPs		
Scale-up Plan		
Community Engagement		
Private Sector Engagement		
Coordination		
dHTS Training		
M&E		
Procurement/Supply Chain		
Population Coverage		
Linkage to Tx: Timely Linkage		
Linkage to Tx: Verification		
Linkage to Prevention		
EQA/IQC		
Proficiency Testing		
Clinical Services		
Impact: Knowledge of Status		
Impact: Linkage to Tx		
Impact: Linkage to		

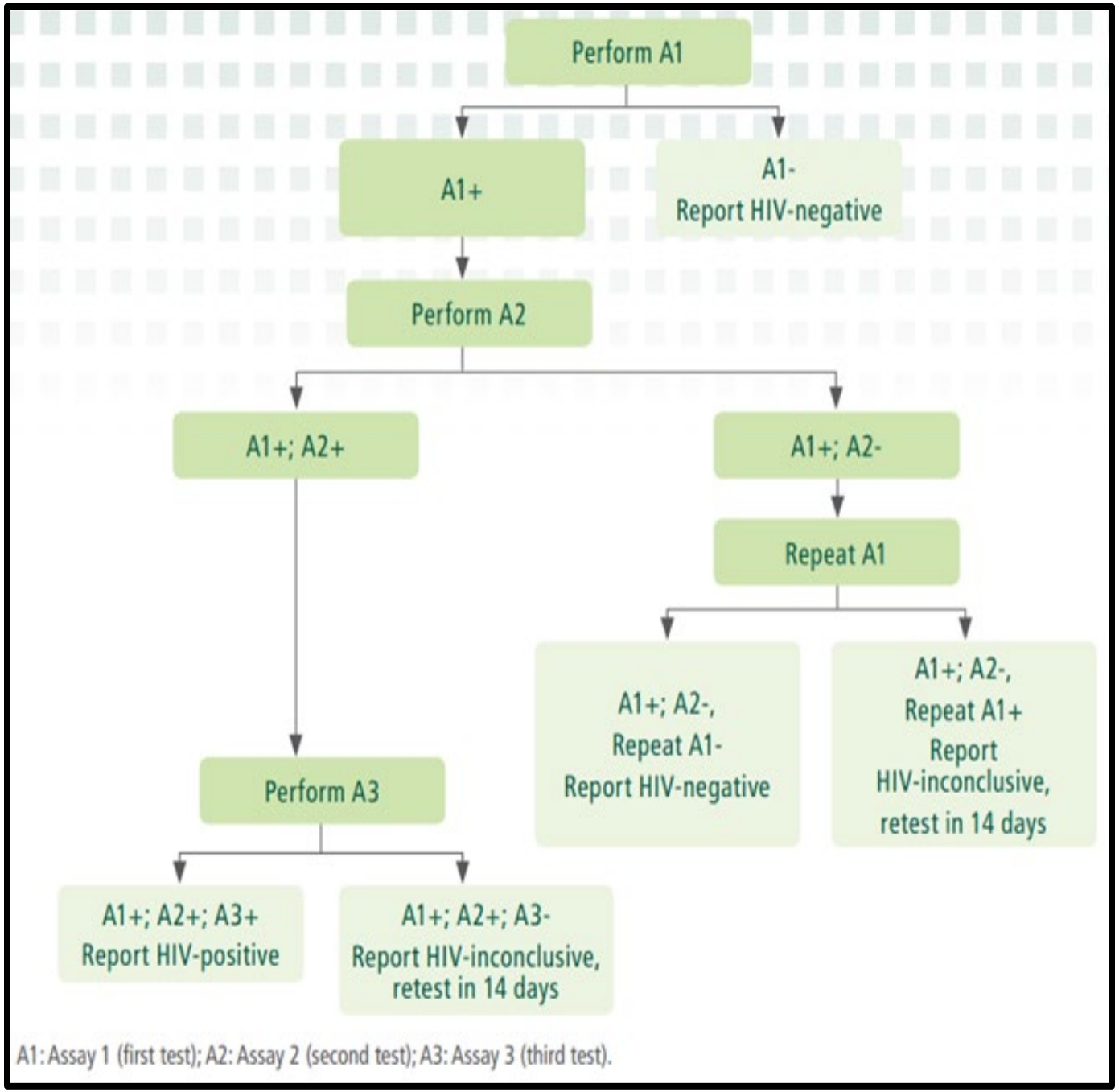
Observations

- **Optimizing HIV testing:** The country's testing algorithm did not use the three-serial validated rapid diagnostic tests to confirm HIV positive status, however the country was validating the tests
- **Scale-up Plan:** This plan was developed and approved by MOH, however there have been delays in implementation due to frequent stockout of testing commodities.
- **M&E:** The country is still working on defining and tracking linkage to HIV combination prevention
- Proficiency Testing: The PT system is developed and implemented, however there are no systems to track and monitor those who have passed or failed the PT assessment

Previous HIV Testing Algorithm



- **Screening Kit (A1)-** Determine
- **Confirmatory Kit (A2)-** Unigold
- **Tie-Breaker**: No tie Breaker: ***Determine and Unigold are used (Parallel testing) for discrepant results (A1+, A2-)***



Process of adopting the 3-Test Algorithm

- In 2019, WHO recommended the 3-test strategy to minimize the risk of misdiagnosis by ensuring a Positive Predictive Value (PPV) of 99% and above
- In 2021 Eswatini MoH commissioned a verification study to determine the best possible combination of tests to inform the design of the 3-test algorithm
- The verification study was led by MoH through the Eswatini Health Laboratory Services (EHLS) and Eswatini National AIDS Program (ENAP)
- WHO was the key TA provider, with additional support from local implementing partners

Stakeholder engagement during the algorithm validation meeting

Process of adopting the 3-Test Algorithm- (2)

- The HTS unit included the adoption of the 3-test strategy in in ENAP's April 2024 - March 2025 annual work plan.
- The HTS core team and treatment and care team, planned for the implementation of the 3-test process
- Engaged a wider stakeholder that includes recipient of care, private sector, community and facility partners for buy in
- Advocated and quantified for A3 procurement to be included in global fund grant
- Drafted and submitted the verification process to local IRB verification
- WHO supported the verification process, data analyses, report writing and development of the implementation plan.
- With technical support from WHO the successfully constructed the country's 3-test HIV Testing algorithm

Eswatini's HIV Verification Study

OBJECTIVES

Goal: To assess the level of shared false reactivity of individual candidate HIV products including dual HIV/syphilis rapid diagnostic tests to design optimal 3-test algorithms for the final diagnosis of HIV infection

Specific objectives:

1. To describe the process of selection of quality-assured HIV products for the verification study and the establishment of the verification specimen panel
2. To assess the level of shared false reactivity among individual HIV tests
3. To construct HIV testing algorithms based on the results of the verification study
4. To compare the cost of the different candidate HIV test products and the constructed HIV testing algorithms

PROCESS

- 165 samples were collected for the study
- Samples were first characterized using Enzyme Immunoassay (EIA) and a Rapid Diagnostic Test (RDT) to exclude positive and discordant samples
- Negative samples (159) were tested using the 10 shortlisted WHO-prequalified HIV candidate products which included dual HIV/Syphilis RDTs to be used in ANC settings

RESULTS

Of the 10 candidate products, 3 showed false positive reactivity across 6 samples and none of the false positive reactivity was shared amongst the products

Selecting the 3-test HIV Algorithm

The proposed algorithm was selected based on the following criteria:

- A1 with ***highest sensitivity*** above 99% .
- A2/A3 with ***highest specificity*** above 99% .
- Selected products that are **not** from the same manufacturer.

In addition, the following factors were taken into consideration:

- Current use in the country which would simplify the transition process
- Availability on the market
- Cost
- Use of products in neighboring countries

Final 3-test HIV testing algorithm

Algorithm	Assay 1	Assay 2	Assay 3	Intended Use
1	Alere™ Determine HIV ½ **Sensitivity: 100% Specificity: 98.9%** **Cost per test: US$ 0.80**	Uni-Gold™ HIV **Sensitivity: 99.8% Specificity: 99.9%** **Cost per test: US$ 0.77**	ONE STEP Anti-HIV (1&2) Test **Sensitivity: 100% Specificity: 100%** **Cost per test: US$ 0.57**	**General population**
2	First Response® HIV 1-2-0 Card Test **Sensitivity: 100% Specificity: 100%** **Cost per test: US$ 0.75**			**General population (backup for Assay 1)**
3		INSTI HIV-1/HIV-2 Antibody Test **Sensitivity: 100% Specificity: 99.7%** **Cost per test: US$ 1.72**		**General population (backup for Test 2 or 3)**
4	First Response® HIV1+2/Syphilis Combo Card Test **Sensitivity HIV: 100% Specificity HIV: 99.5%** **Sensitivity Syphilis: 99% Specificity Syphilis: 100%** **Cost per test: US$ 1.15**	Uni-Gold™ HIV **Sensitivity: 99.8% Specificity: 99.9%** **Cost per test: US$ 0.77**	ONE STEP Anti-HIV (1&2) Test **Sensitivity: 100% Specificity: 100%** **Cost per test: US$ 0.57**	**ANC settings**
5	SD BIOLINE HIV/Syphilis Duo **Sensitivity HIV: 100% Specificity HIV: 99.5%** **Sensitivity Syphilis: 87% Specificity: 99.5%** **Cost per test: US$ 1.30**			**ANC settings (backup for Test 1)***

Challenges and Lessons Learned during the Verification Study and Implementation

Challenges

- Fewer samples were analyzed 165/210 due to sample rejection
- Data collection was compromised due to expiry of the candidate products that were selected for the study
- Procurement delays for some of the candidate products

Lessons Learned

- The verification process was MOH led providing more ownership, sustainability, and an opportunity for domestic financing during the roll-out process
- Collaboration within MOH programs and implementing partners made the verification process easier
- The use of local samples ensured acceptability of the results

Next Steps

- Give feedback and sensitize to the Senior Management Team (SMT) on the recommended kits for the updated algorithm
- Engage a wider stakeholder body to discuss the implementation arrangements

Road map

- Advocate for funding for the updated algorithm
- Amend the HIV consolidated guidelines to include the new algorithm (develop SOPs, Job aids)
- Procurement of the test kits in the new algorithm
- Conduct one national Training of Trainers (TOT)
- Conduct onsite trainings and activate sites to start implementing the new algorithm
- Site level implementation proposed to start October 2025

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Thank You!