Assessment of a Revised Protocol for Selection of HIV Rapid Tests for the National HCT Programme in South Africa

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Background I

- It is estimated that 6.2 million persons are infected with HIV(a prevalence estimated to be 12.2 % in South Africa)
- Approximately a third of these (2.2 million persons) are on ART.
- There is the need to extend coverage of testing to ensure that ALL HIV infected individuals know their status
- HIV rapid testing is the current method to ensure widespread coverage through facilities/mobile clinics and home-based testing
- HIV Rapid test device performance thus needs to be accurate to ensure that the correct results are provided

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Background II

- Noted that at facility level there is reported lower sensitivity of HIV rapid tests
- Reasons for this lower sensitivity not always explored
- Important from a programme perspective to select HIV rapid test kits that will have a high degree of accuracy assessed through evaluations and follow-up through post-marketing surveillance

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Background III

- Large number of HIV test devices commercially available but quality of tests/performance not known/variable
- Selection based on evaluations from agencies such as WHO/USAID-CDC or FDA/CE-marked useful for a national programme but fallible e.g. SD Bioline
- Some form of in-country verification required.
- Following the international withdrawal of SD Bioline, WHO invited to review programme in South Africa for HIV rapid test kit selection
- The result of the review led the NICD to develop a more robust process for both HIV rapid test kit evaluation and post-marketing surveillance

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Background IV

AIMS

- To review and implement robust evaluation and post-marketing surveillance protocols in the selection of HIV rapid tests to be used in South Africa

OBJECTIVES

- Review current processes that require revision
- Revise documentation
- Revise laboratory procedures
- Apply revised processes to the national tender for selection of test devices and post-marketing surveillance

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Methods I

- Developed an overarching view of what a robust evaluation of HIV rapid test kits would comprise
- Consulted with experts in the field (WHO/CDC) participated in training (WHO/Post-marketing surveillance at PEI)
- Reviewed/revised all related documentation in order to meet the process requirements
- Revised laboratory methods and procedures to meet process requirements
- Applied the revised processes to the national HIV rapid kit tender of 2013-2014
- Applied revised processes to HIV post-marketing surveillance post award of the tender

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Results I

Major changes:

- Limited the number of HIV test devices to be evaluated to those HIV rapid testing devices with a history of assessment e.g. WHO prequalification, USAID-CDC evaluations or other international approval: FDA/CE marking
- Inclusion of Health Technology Assessment (HTA) Unit of the NHLS to perform administrative screening of submitted document from potential suppliers of RTD and other criteria: type and generation of HIV RTD; duration in market, batches/lots produced in last three years and proof of certification.
- Introduced additional laboratory steps to discriminate between different test device performance: inclusion of challenging specimens such as sero-converter panels, specimens from recently infected individuals, mixed titres panels, low titre/S/CO samples, whole blood samples, detection of HIV-2.
- End-point dilution series for post-marketing surveillance to serve as a baseline for selected kits
- Revised scoring sheet to reflect defined strict criteria

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Results II

- Applied post-marketing surveillance testing to 33 batches to date
- Internal Quality Programme (IQC) programme to serve as post-marketing tool (see poster number 122) to assess site performance
- Due to stringent testing processes (pre- administrative/ laboratory pre-screen) the time spent on laboratory evaluation of the kits reduced considerably: 6 weeks for the 2013 tender vs. 4 months for the 2011 tender.
- The number of serum test panel members in the revised process increased from 514 to 750 samples.
- Analysis of results in phases e.g. initial agreement followed by Se/ Spe:
- In the current tender calculation and scoring of results was introduced for the challenging/mixed titre/low S/Co/recently infected/Se/Sp samples: 80% agreement. The final outcome of the evaluation based on the score obtained from each set of panels and overall score.

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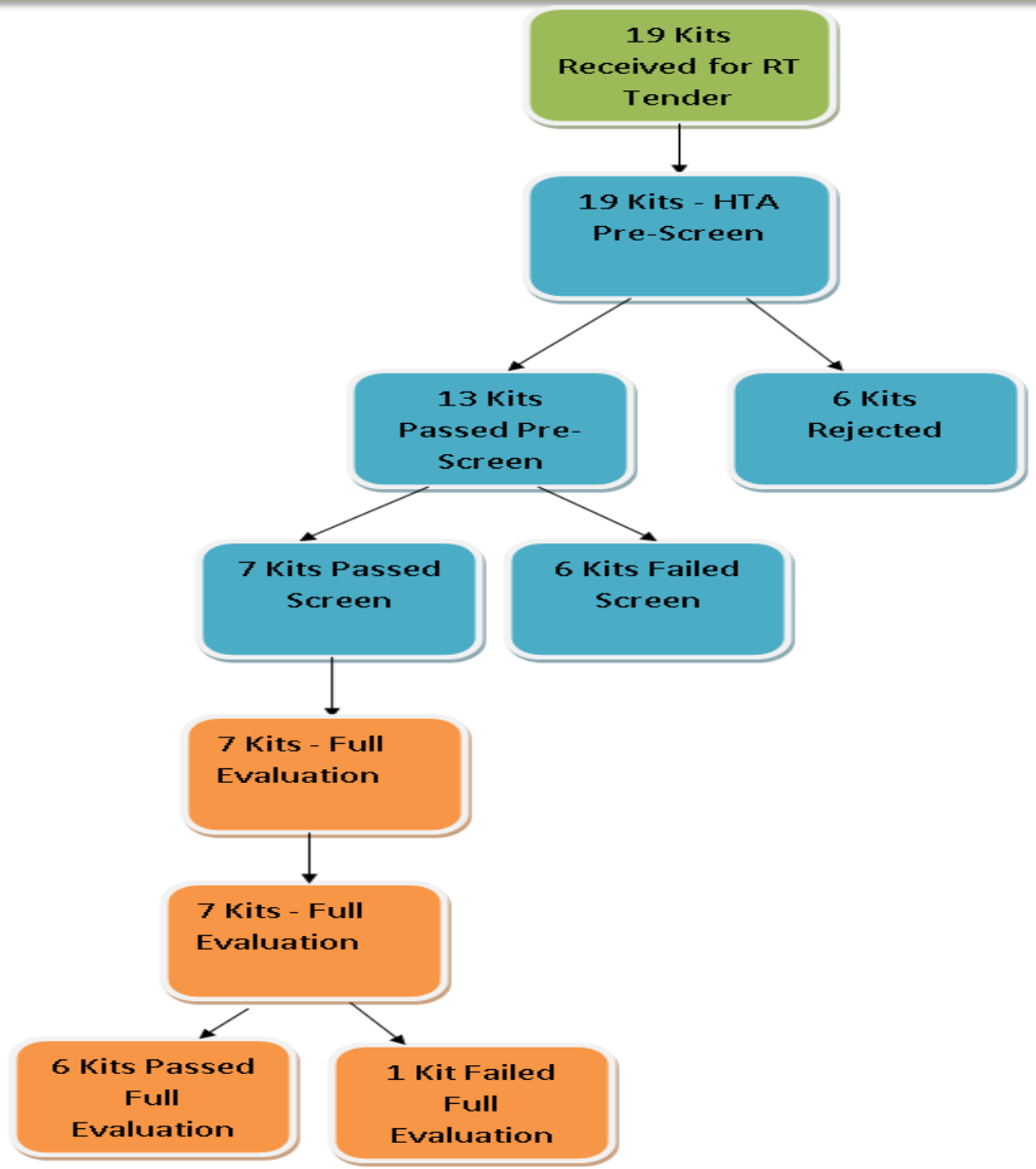
Results III



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Discussion I

- Methods more in line with major organisations that perform such evaluations e.g. WHO and CDC
- Methods to provide a more rigorous process for HIV rapid test selection was successful: achieved by additional pre-screening at administrative and laboratory testing levels
- The additional requirements add to the cost: pre-screening programme (HTA), laboratory materials (seroconversion panels, additional testing and identification of materials for use); Estimated cost of evaluation per kit ZAR15,000.
- Provides assurance that processes are robust and that selection of devices will perform with high degree of accuracy and that baseline for post-marketing surveillance is established.

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