External Validation of Rapid STI Tests

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Plan of Presentation

- Objectives of external validations
- Planning an external validation
- Implementing the validation
- Lessons learnt
Background

• Numerous diagnostic tests being sold and used in the developing world without evidence of effectiveness

• Lack of quality standards for:
  — diagnostic evaluations
  — regulatory approval

• Lack of mechanism for translation of research evidence into policy and practice

• Challenge of introducing novel tests into frail or non-functional health systems
WHO/TDR DRD Strategy
Validating STI Rapid Tests: Syphilis

• Lab-based evaluation conducted in 8 countries

• Field trials conducted in 6 countries

• Mathematical models developed for:
  – Estimating potential impact
  – Estimating cost-effectiveness of different strategies for introduction
  – Assessing required tests performance

• 6 rapid syphilis tests with acceptable performance included in WHO Procurement

• Use of Rapid Syphilis Test Guide developed --- advocacy and to ensure appropriate use of new tests

• Use to be recommended in WHO STI management guidelines
Objectives of External Validations

- To validate test performance characteristics in populations of intended use
- To validate operational characteristics of test

Accuracy and operational characteristics data to be used for:

- policy decisions
- regulatory approval
- procurement
Planning an External Validation

- Protocol development
  - consult regulatory agencies/control programmes/policy makers/end users
  - draft master protocol
  - post Request for Applications for sites
  - invite potential PIs to protocol development workshop
  - submit final protocol for ethical approval
Planning an External Validation

• Site selection
  – post RFA specifying requirements
    - Access to patients
    - Capacity to perform diagnostic evaluations in a timely manner
    - Proficient at performing reference standard tests (subscription to EQA)
    - Mechanism and time required for IRB approval
    - Good standard of care
  – Review applications and shortlist
  – Site assessment visits
External Validation: Site Preparation

- Translation of SOPs
- Training in GCP and GCLP for study team using study as example
- EQA for reference standard test, esp for quantitative assays
- Data management
- Procurement of supplies
  - Liaise with MOH to prevent delay in customs
  - Monitor temperature spikes
External Validation: Implementation

- Study initiation
- Study monitoring and trouble shooting
- Collect data for mathematical models
- Collect data for test format improvement
- Ongoing monitoring of stability of reagents
Lessons Learnt

• Delays in IRB approval

• Training
  – on safety issues in use of tests
  – for action on test results

• Lack of laboratory infrastructure for QA/QC
  – monitor stability of tests after import and in field settings
  – monitor quality of testing using proficiency panels

• Long delays in test adoption
  – Lack of mechanism for translation of research findings into policy and practice – need for policy platform
  – Lack of funding
  – Lack of functioning health infrastructure