COULD GOOD POINT-OF-CARE TESTING REVOLUTIONISE ISSUES IN THE REGION?

TIM TUCKER
M.B.Ch.B – Ph.D. – F.C.Path(SA)Viro

PETER MANYIKE
B.Pharm – Ph.D.
Conflict of interest statement

- No interest in any product mentioned
- Board member – National Health Laboratory Service
National clinic and laboratory network

NDoH Healthcare Facilities

Legend
- NDoH Health Facilities
- Provinces

256 NHLS labs
National clinic and laboratory network
New POCTs - What are we trying to achieve?

What are Inputs, Outputs, Outcomes and Impact?

The Logic Model Approach

- **INPUTS**
  - Resources dedicated to or consumed by the project
  - Usually a NOUN (e.g., staff, facilities, money, time)

- **ACTIVITIES**
  - What the project does with inputs to fulfill its mission
  - Usually a GERUND (e.g., assessing, enabling, reviewing)

- **OUTPUTS**
  - The volume of work accomplished by the project
  - Usually a QUANTITY (e.g., the number of projects, the number of case studies)

- **OUTCOMES**
  - Benefits or changes for participants during or after project activities
  - Usually a CHANGE (e.g., increased skills)

- **IMPACT**
  - The long term consequences of the intervention
  - **A fundamental CHANGE intended or unintended in a system or society**

Your Planned Work

Your Intended Results
What are we trying to achieve?

- A fundamental change intended or unintended in a system or society

Hogben test
Typical development of POCTs

- A fundamental CHANGE intended or unintended in a system or society
Where do POCTs fit?
Where do POCTs fit?
Where do POCTs fit?
COMPLEX RELATIONSHIP TO NATIONAL MODEL
POCT quality falls within a system

• **POCT’s are a lab test**
  • In the hands of non-lab people

• **Same QA principles**
  • Continuous quality improvement
POCTs need to have patient impact

- **Accuracy**
  - Sensitivity
  - Specificity

- **Improve the patient experience**
  - Take less time off
  - No need to come back again for result
  - Home-based
POCT and the 90’s – molecular tests

• Antibody POCT
  • Relatively simple and robust

• Molecular POCT - Greatest systemic complexity
  • Specimen issues
  • Specialized human capital
  • Infrastructure

• Significant opportunity

The accuracy of HIV rapid testing in integrated bio-behavioral surveys of men who have sex with men across 5 Provinces in South Africa

The image shows a graph with three red squares indicating 90% in each category: diagnosed, on treatment, and virally suppressed.
Do they work in the field?

Field Evaluation of Performance of Alere and Cepheid Qualitative HIV Assays for Pediatric Point-of-Care Testing in an Academic Hospital in Soweto, South Africa

Tanya Y. Murray, a Gayle G. Sherman, a,b,c Firdose Nakwa, b William B. MacLeod, d,e Nosisa Sipambo, b Sithembiso Velaphi, b Sergio Carmona, f,g

Peripheral clinic versus centralized laboratory-based Xpert MTB/RIF performance: Experience gained from a pragmatic, stepped-wedge trial in Botswana

Tefera Agizew 1,*, Rosanna Boyd 1,2, Ndwapi Ndwapik 3, Andrew Auld 4, Joyce Basotli 1, Sambayawo Nyirenda 1, Zegabriel Tedla 1, Anikie Mathoma 1, Unami Mathebula 1, Chawangwa Lesedi 1, Sherri Pals 4, Anand Date 4, Heather Alexander 4, Thomas Kuebrich 1, Alyssa Finlay 1,2
POCT vs. near-to-care test

- Where to place?
- Examples
  - GeneXpert and Alere
- Implications for the system
  - Patient implications
  - Critical health system difference
  - Infrastructure
  - HR implications
Operational requirements:

- Uninterrupted power supply
- Ambient temperature no higher than 30°C
- Biosafety equivalent to smear microscopy
- Adequate storage for test kits (or cartridges) at temperatures no higher than 28°C
POCT falls within a system

- Should we presume that POCT/NTC will have impact?

At full placement
Predicted Time to diagnosis

- Currently 46% of cases are diagnosed by visit 2 and a further 40% by visit 3
- Xpert scenario prediction at full coverage: 83% by visit 2 and 89% by visit 3
- By full placement: 87% diagnoses to be made by GeneXpert

W. Stevens

Boehme study, 2011. Time to detection: 1 day for Xpert/smear, 20 days for LPA, 106 days for DST
Special purpose rapid tests
Special purpose rapid tests

- **Incidence testing**
  - Differentiates between
    - Recent infection
    - Established infection
  - Possible population-level impact
  - Annual Antenatal Clinic survey
    - Incidence and prevalence in same test

- **Home-based tests**
  - Significant empowerment
  - Partner testing
  - QA issues
  - What does positive mean

Asante™ HIV-1 Rapid Recency® Assay for Identification of Recent HIV-1 Infections

Figure 1. Point-of-Care Recency Test (Asante HIV-1 Rapid Recency Assay) Illustration
POCT and connectivity – the importance of data
YES!

- Define need – impact
- Monitor
- Robust policy base
- QA
- Overload existing staff
Concluding thoughts

• Already a game changer
• New age – molecular POCT
• Works within a system
  • Cannot presume impact
• Importance of data linkage
• Cost implications
• Need to find ways of expanding in region
MANY THANKS