Deploying Within Programs: Addressing implementation questions

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Introduction

- HIV, TB, Hepatitis, HPV are leading causes of morbidity and mortality
- SARS CoV–2 has infected >480m pax
- HIV VL and EID testing is well established in Kenya
Existing HIV testing technologies have been repurposed before

- Instruments repurposed for SARS-CoV-2 in 2020
- Hepatitis, HPV tests can be run on same platforms
- Opportunity for TB Testing
  - Diversify testing base for TB
    - increased flexibility & resilience
  - Create workflow efficiencies and cost savings
    - enhance delivery

SARS-CoV-2 Test Kits
Snapshot of TB Testing in Kenya Today: Busia County

- Specimens collected at health facilities
- Transported to county hospital labs
- Samples Tested
- Results returned to health centers
- Patients managed

• High volume HIV testing in county lab
# Critical considerations

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<thead>
<tr>
<th>Implementation Considerations:</th>
<th>Questions to answer:</th>
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<td>Would TB testing in the country lab change time to patient management?</td>
<td>What is the turn around time from patient sampling to result return to the health center today?</td>
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<td>Do differentiated INH and RIF results matter for patient management?</td>
<td>Is mono–INH and/or mono–RIF resistance significant in the population?</td>
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<td>Would this be cost-neutral? Cost-saving?</td>
<td>What is the real-world cost of the two TB testing scenarios?</td>
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<td>Is it possible to integrate TB testing into the virology lab testing workflow? What do we not know?</td>
<td>Impact on HIV testing TAT? Contamination issues?</td>
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**UTILIZE Study—Using Multi-disease Testing to Enable Capacity Optimization Everywhere**

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<tr>
<th>Objective</th>
<th>Description</th>
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| **Workflow**| • Determine the best workflow to optimize efficiencies for MTB and HIV testing on the cobas® 6800/8800 Systems  
               • Understand staffing requirements and volume potential to integrate MTB testing into the existing 8800 HIV testing workflow |
| **Costing** | • Calculate the cost per test in real-world settings for the cobas® MTB and cobas® MTB RIF/INH assays executed in the KEMRI laboratory and the Xpert MTB/RIF assay executed in county hospital laboratories |
| **Epidemiology** | • Collect data on the rates of RIF mono-resistant, INH mono-resistant, and MDR MTB in the Busia population. |
UTILIZE Study rationale

- Optimize resources to address healthcare needs via expanding diagnostic testing capabilities
- Using high volume systems that test for many pathogens increases the resilience of our labs
  - Meet current demand
  - Complement other testing capabilities
  - Flexibility to quickly respond to emerging health threats
- More data is needed in the context of real world implementation
UTILIZE Study Population

- Will recruit patients eligible for testing based on established screening protocols (history and cough monitors).
- The current prevalence in the population is 2.5% – 5%
- Monthly volume = 600 samples
- 2000 raw sputums will be tested for MTB on the Xpert system (either at hub or from clinics).
- A minimum of 100 positives required at the cobas® MTB

Enrollment starts in April 2022.