Early Implementers of Xpert MTB/RIF: Experiences from TB REACH

Jacob Creswell
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Overview

• Xpert MTB/RIF in TB REACH projects
• Case detection strategies
• Progress to date
• Innovations
• Challenges
• 75 Projects in 36 countries
• Xpert MTB/RIF as part of the case finding strategies
  – 30 Projects in Wave 2
  – 3 Projects in Wave 1
• Centralized procurement to fast-track the process, better coordinate shipments, communicate with manufacturer and assist projects
  – GDFs order management system (OMS) tracked shipment
• TB REACH-GDF procured 152 Xpert machines and 256,520 cartridges ~6.4 Million USD
  – Procurement process has been quick generally with a few exceptions
• TB REACH-GDF also procuring for other projects
  – CIDA funded equipment for selected Expand TB countries, other countries and WHO
Algorithms

• TB REACH is an initiative that is geared towards increasing TB case detection (not MDR)
  – No projects use Xpert on TB cases (MDR suspects)
  – Can use Xpert machines for testing MDR suspects if the cartridges come from other funders

• A wide variety of approaches are used:
  – All SS- (some using LED Mx)
  – SS- with suggestive CXR
  – HIV+
  – All suspects with abnormal/suggestive CXR
  – Patients with a history of TB
  – SS- and HIV+
  – Direct to Xpert
Location

- Mobile labs on a vehicle
- One day clinics (using generators)
- Hospital reference labs
- National Reference Labs
- NTP clinics (with and without renovation)
- Border area clinics
- Private laboratories
TB REACH Reporting Forms

- Quarterly data web-based data submission
- Electronic database
- Data by Xpert machine
- Test data as well as algorithm specific data (results for SS, HIV and CXR)
Overall Progress

Data as of March 31, 2012 where possible
Includes data from 18 projects

• Total tests conducted = 7894 (13-1463)
• Total MTB/Rif- cases detected = 1179
• 124 Rif Resistant results (pending DST)
• 8% error rate (quite high in some projects)
• 16 MTB+ but Rif Indeterminate cases
Overall Progress

• Overall 15% yield using Xpert MTB/RIF (Range 5-36)
• Projects using CXR generally have better yields
• Type of case finding intervention will influence positivity rates
• Error rates must be addressed and improved
• Most projects will have begun by March and more data will be forthcoming
Challenges and Issues

• Errors:
  – Unknown codes for many errors
  – Some errors due to poor quality of electricity
  – Need to document lower errors with 4th generation cartridges

• NTP reporting issues – how to report (ss-? Bac+?)

• Feedback about the initial training being too basic

• Some confusion over the GLI validation panels and results

• Short shelf life complicates the shipping and implementation logistics

• Few customs and/or shipment problems

• Unknown test to most private providers

• In some projects demand for Xpert grew as smear was seen as no longer useful
## Analysis

<table>
<thead>
<tr>
<th></th>
<th>Karachi</th>
<th>Dhaka</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>invalid</td>
<td>1.2%</td>
<td>2.8%</td>
<td>Track location, shifts, personnel and error numbers</td>
</tr>
<tr>
<td>error5007</td>
<td>0.3%</td>
<td>0.5%</td>
<td>For Dhaka, the invalid rate is 2.8%. A bit higher than the regular one allowed 2%. More sample control required before processing.</td>
</tr>
<tr>
<td>error2008</td>
<td>0%</td>
<td>3.9%</td>
<td>Invalid mostly linked to PCR inhibitors: blood, pus, food particles.</td>
</tr>
<tr>
<td>error5011</td>
<td>0.2%</td>
<td>0%</td>
<td>Get in touch with TB REACH, WHO, Cepheid</td>
</tr>
<tr>
<td>error5006.</td>
<td>0.2%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>error2127</td>
<td>0.1%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

### INVALID
- Mostly linked to PCR inhibitors: blood, pus, food particles.
  - For Dhaka, the invalid rate is 2.8%, a bit higher than the regular one allowed 2%. More sample control required before processing.

### Error 2008
- Linked to sputum Viscosity
  - Rate is about 3.9%, too high!!
  - Need to wait 5-10 more min and process sample once liquid.

### Error 5007
- 0.5% = lower than the usual rate, no major issue,
  - Usually linked to Volume lower than 2 ml, or bubbles

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**QUALITY OF SAMPLES MATTERS**

**QUALITY OF SAMPLE PREP MATTERS**

**SHOULD TRIGGER AN ALARM EARLIER**

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*Transforming the Fight*  
*TOWARDS ELIMINATION OF TUBERCULOSIS*
Innovations

- Local innovations is bringing test to POC even in areas without electricity
- PPM project linking private laboratories to NTP reporting centers
- TB REACH is developing a mobile phone based tool that will allow direct reporting of results and link with patient management systems to improve care
- FIND has developed solar panels for running the machines and a number of projects use car batteries
- UPS supplied by manufacturer are not very useful (20 mins) and better ones can be procured locally
- Some projects have been able to use large numbers of tests and help non-TB REACH projects in expiry management
GeneXpert with Solar power, Luweero HC IV, Uganda

1. Roof-top Solar Panel (120 Watt x 4; serial connection)

2. Solar power Charge controller 12/24vols, 20AMP

3. Bat. Pack cased

4. Inverter 1100Watt; Input- Batteries. Output: Connected to Gx via Extension box (with (use)

Two serially Connected 12V & 200Ah batteries
MODULE 1 : Un stabilisateur permet de réguler les variations d'intensité du courant électrique, et principalement d'éviter de transférer un courant trop intense qui abîmerait le Genexpert. Coût : 45 USD

MODULE 2 : Un chargeur-convertisseur couplé à une batterie de voiture permet de réaliser au minimum 8 tests sur le Genexpert en cas de coupure prolongée. Coût : 450 - 1500 USD en fonction de la qualité du Chargeur-convertisseur.

MODULE 3 : Un onduleur permet de pallier aux petites variations du courant électrique, notamment en cas de coupure de moins de 15 minutes ou le temps d'activer le module 2. Coût : 75 USD
CENAT
Cambodia
One day chest camps
Summary

- TB REACH/GDF centralized procurement desired by programmes and helps the process.
- Innovations are bringing the test to the point of care.
- 15% overall yield - can increase using screening tools - CXR.
- Implementation is slower than envisioned by projects in most cases but will grow exponentially.
- Clear case detection strategies and diagnostic algorithms are needed. Screening helps in judicious use of the test cartridges and active case finding approaches increase the number of people that can benefit from this technology.
- Good quality reliable electricity, management of expiry of cartridges and reducing errors are the key challenges.
Thank You!