Innovation from the field

GenXchange

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Medical Microbiologist
Assistant to the NTP, DRC
Global context

Cumulative number of GeneXpert instrument modules and Xpert MTB/RIF cartridges procured under concessional pricing
South-Kivu Province (DRC) context

6 million hab. Existing network of 100 microscopy centres

**Primary indication of Xpert tests**
- Context of under detection of TB
- TB REACH project -> Smear negative TB suspects tested with Xpert
- +-20,000 Xpert tests performed to date

**Implementation of 10 Xpert machines**
- Major cities of the province
- No internet access in 9/10 Xpert sites
- No Laboratory Informatic Systems
- Samples referred from > 50 microscopy laboratories

No prior local experience using molecular biology technologies

Very limited local experience of MDR-TB management

No on-site support from manufacturer for installation of machines, training or maintenance
Xpert network implemented

3 Xpers in Bukavu (1 million hab)

7 Xpers in cities 20 – 200,000 hab
  - 1 only accessible by plane
  - 2 only accessible by boat

All requiring 3 – 5 days travel for on-site supervision

Security & logistical issues

1 Xpert moved after year 1 from major mining city (Kamituga) because of impossible adequate supervision
RESEARCH ARTICLE

Results from early programmatic implementation of Xpert MTB/RIF testing in nine countries

Jacob Creswell1*, Andrew J Codlin2, Emmanuel Andre3, Mark A Micek4, Ahmed Bedru5, E Jane Carter7, Rajendra-Prasad Yadav8, Andrei Mosneaga9, Bishwa Rai10, Sayera Banu11, Miranda Brouwer12, Lucie Blok13, Suwanand Sahu1 and Lucica Ditu1

Table 4 Result data from first 12 months of Xpert MTB/RIF implementation in nine countries

<table>
<thead>
<tr>
<th>Xpert site</th>
<th>Tests</th>
<th>MTB Positive</th>
<th>Rifampicin</th>
<th>Failed Tests</th>
<th>Type of failed test</th>
<th>MTB w/o failed tests</th>
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<td></td>
<td>N</td>
<td>%</td>
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</table>

*Reference 26. Data for South Africa is presented as a comparison after 25 months of implementation.

The overall module failure rate in the projects was 42%
Feasibility of Decentralised Deployment of Xpert MTB/RIF Test at Lower Level of Health System in India

Neeraj Raizada1, K. S. Sachdeva2, Achuthan Sreenivas3, Bhavin Vadera1, R. S. Gupta2, Malik Parmar3, Shubhangi Kulsange1, Ameet Babre1, Rahul Thakur1, Christen Gray4, Ranjani Ramachandran3, Umesh Alavadi1, Mayank Ghedia3, Balasangameshwara Vollepoore1, Puneet Dewan3, Catharina Boehme4, C. N. Paramasivan1

1 Foundation for Innovative New Diagnostics, New Delhi, India, 2 Central TB Division, Government of India, New Delhi, India, 3 World Health Organization, India Country Office, New Delhi, India, 4 Foundation for Innovative New Diagnostics, Geneva, Switzerland

Significant variation was observed in failure rates both across instruments and over time; furthermore, substantial variation was observed in failure rate in two cartridges lots.

Of the total 108 modules in the study, 34 required replacements on account of various performance related issues; 10 had an overt malfunction and 24 showed degraded performance in test validity rates indicating impending malfunction.
Development of a surveillance system

- Patients (>20,000)
- Referring health centers (50 - 100)
- Health staff
- Xpert centers (10)
- Central unit
  - Early identification of Rif resistant cases
  - Maintenance
  - Stock monitoring

Early identification of Rif resistant cases
Stock monitoring
Short video (2 min)

GenXchange presentation.mp4
Monitoring of activity

Xpert tests performed per week

![Graph showing Xpert tests performed per week from 1st Oct to 1st Jan. The number of tests ranges from 0 to 200, with peaks in late November and early December.]

Genexpert sms database South Kivu

Extraction Febr. 2014
Monitoring of various pre-analytical indicators

Time between microscopic analysis and Xpert

Number of samples

0 100 200 300 400 500

Time (days)

Extraction Febr. 2014
Monitoring of error rates per laboratory

Proportion of Genexpert errors by laboratory

Genexpert sms database South Kivu

Extraction Febr. 2014
Monitoring of error rates per module

Proportion of errors made by module

Extraction Febr. 2014
Analysis of error rates per site & per module

Proportion of error by module in labs with error-prone modules

- Genexpert sms database South Kivu

Extraction Febr. 2014
Actions performed after observation of abnormal error rates

Centres with general high rate failure
- Additional staff training (conservation of samples, ...)
- Calibration (failed) -> replacement

Centres with isolated module dysfunction
- Calibration (failed) -> Replacement
- Time for replacement : +- 2 months

Actions implemented in March 2014
- Ex : Module 632792 was replaced on 17/3 by new module (625842)
- Direct impact not measured yet (insufficient number of tests performed with new modules)
Q1 2014 (Jan – March 2014) : 1.706 tests performed

VALID RESULT AVAILABLE (n = 1392 ; 81,6%)
- MTB POSITIVE (n = 139 ; 10%)
  - RIF Resistance detected (n = 13 ; 10%)
  - RIF INDETERMINATE (n = 19 ; 13,7%)
  - No data available (n = 5 ; 3,6%)
- RIF resistance not detected (n = 101 ; 72,7%)
  - 1253 NEGATIVE (90%)

NO VALID RESULT AVAILABLE (n= 314 ; 18,4%)
- 229 ERROR
- 79 INVALID
- 6 NO RESULT
Conclusion

Module failure is the major cause of errors in our setting

Cost linked failing modules/cartridges is high
- Direct cost (including transport and importation)
- Additional manpower and cost of on-site travels

Solutions
- Improved quality of modules
- Strict quality controls by manufacturer
- Early detection of abnormal error rates
- Rapid replacement / calibration after identification of problem

Direct issues for DRC
- Handover from « project » to NTP of existing Xpert network showing evident signs of fragility
- Ongoing pressure/support from partners for buying additional Xpert machines without prior consolidation of monitoring system
Thank you!

**IT developer**
Benjamin Nyange

**NTP/DRC**
Dr Georges Bakaswa
Dr Dieudonné Kalumuna
Jean-Paul Chirambiza
Rosette Nyota
Eric Mulume Musafiri

**UCLouvain**
Prof Michel Delmée

**IRD**
Ali Habib
Dr Aamir Khan

**LSHTM**
Dr Olivier le Polain de Waroux

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