Xpert MTB/RIF

Site selection

Workshop for Early Implementers
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Positioning in tiered health system

- Surveillance
- Reference methods
- Network supervision

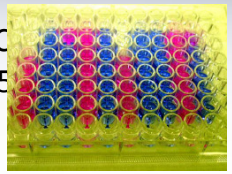
Resolution testing (screening-test negative drug resistance)

- Screening
- Passive case finding
- Detect and treat

- Clinical screening
- Primary care

Reference Labs

LC
15



In house DST (MODS, NRA, CRI)
Special settings and conditions

Regional Labs

/ DST DST
d /16d/ 30d

LPA Rif / INH 2d

District Level

SubDistrict Level

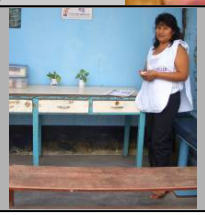
ZN 2-3d

Integrated NAAT +40% /2h

Microscopy Level

LED FM +10%

Community Level



Positioning and site selection criteria for Xpert MTB/RIF – facility type

Ideally **district or sub-district** level, NOT central/reference lab level

WHY?

1. Reference laboratory facilities require well trained personnel , are expensive to establish and maintain, and have high level requirements for biosafety containment.

2. Need to minimise routine diagnostic testing at central level where possible to enable:
   1. **DST for drugs other than rifampicin**
   2. **Culture for monitoring response MDR-TB patient response to therapy**

3. Xpert MTB/RIF provides an opportunity to move TB diagnostic technology equivalent to culture on solid media lower down the health system.

Positioning and site selection criteria for Xpert MTB/RIF – Which facility?

There are a range of possibilities for facilities where Xpert MTB/RIF could be installed including:

1. AFB microscopy centre
2. HIV testing / treatment centre
3. Health care clinic
4. District hospital laboratory

Choosing which facility type needs to consider local epidemiology, referral mechanisms, workload capacity, and patient access

Positioning and site selection criteria for Xpert MTB/RIF -epidemiology

Site selection needs to be guided by a sound knowledge of the country-specific epidemiology

1. What is the magnitude of the **drug resistance** or **HIV associated TB** problem?
2. Have implementation plans for Xpert been decided within the context of national plans for appropriate management of TB, MDR-TB and HIV associated TB?
3. What are the country-specific screening algorithms?
4. Have adequate resources been allocated for testing?
5. Are reference laboratory services established for referral of rifampicin resistant strains for further testing.

Patient monitoring during treatment

- ✓ **Molecular tests, including Xpert MTB/RIF, are not suitable for patient monitoring as these tests also detect DNA from non-viable bacilli.**

- ✓ **Patients whose diagnosis of TB is confirmed by Xpert MTB/RIF and who have rifampicin susceptible TB disease should be monitored during treatment with sputum smear microscopy.**

- ✓ **Patients with TB and rifampicin resistance confirmed by Xpert MTB/RIF and placed on MDR-TB treatment should be monitored by sputum smear and culture as per current WHO guidelines.**

Positioning and site selection criteria for Xpert MTB/RIF – Workload capacity

1. What is currently being performed at the proposed implementation site?
   - What is existing workload at each site, what methods are used?
   - Xpert MTB/RIF implementation will not eliminate the need for AFB microscopy to monitor patient response to therapy
   - Have the operational challenges of implementation be addressed?
2. What is the anticipated **workload** of the facility (considering a 4 module GeneXpert system testing capacity of 15-20/day)?
3. How will samples be submitted to the facility? i.e.is transportation of sputum specimens or suspect referral feasible?

Positioning and site selection criteria for Xpert MTB/RIF – access barriers

1. What are barriers to access services in the selected site – geographical, economic?
2. What are the health seeking behaviours in the population where Xpert will be positioned– education needs?
3. If the Xpert MTB/RIF will be positioned to improve TB case detection have strategies to promote the availability of diagnostic services been identified
4. What is the interaction with private sector?
5. Is there sufficient capacity for appropriate **treatment** of all identified patients including those with rifampicin resistance

Operational considerations impacting site selection

Adoption of Xpert MTB/RIF must consider:

- ✓ The **need for conventional smear, culture, DST**
- ✓ Requirement for **stable electricity supply**
- ✓ Has range of ambient **operating temperatures** max. 30C°
- ✓ **Storage space for cartridges** (at 2-28C°), shelf life 18 months
- ✓ **Testing capacity** of 4 module system per working day is 15-20 tests (depending on working hours, each test approx. 2 hours.)
- ✓ **Annual calibration needs**
- ✓ Xpert MTB/RIF testing require bio-safety conditions similar to the conventional sputum smear microscopy sample processing or testing

Positioning and site selection criteria for Xpert MTB/RIF

Summary:

1. Ideally **district or sub-district** level, not central/reference lab level
2. Magnitude of the **drug resistance** or **HIV associated TB** problem
3. Current or estimated **workload** of the facility (taking into consideration 4 module system testing capacity, 15-20/day)
4. Personnel who can be trained, perform testing and keep equipment in good order
5. Facility where transportation of sputum specimens or suspect referral is feasible
6. Sufficient capacity for appropriate **treatment** of all identified patients including those with rifampicin resistance