**Excerpts from an Example of a Situational Analysis Report**

Background

Country X, in conjunction with its donors and implementing partners, introduced the Xpert MTB/RIF test as a replacement test for smear microscopy five years ago. Currently there are 29 GeneXpert instruments in the country. 23 GeneXpert instruments are supported by the NTP and six are supported by partner organizations. One of the partner instruments is used for research only. There are no non- laboratory testing sites. The GeneXpert instruments are distributed in the macro areas as follows:

**A (Easy accessible): 9 instruments (6 NTP, 3 Partner B) B (Moderate accessible): 8 instruments (8 NTP)**

**C (Difficult accessible): 12 instruments (8 NTP, 3 Partner A, 1 Partner B)**

The NTP manager delegated the responsibility of conducting a situational analysis to the GeneXpert Focal Person. The GeneXpert Focal Person organized a team and selected the testing sites (7 testing sites were selected; 2 in macro area A, 2 in macro area B and 3 in macro area C). The situational analysis was conducted and the situational analysis checklist was completed.

Country X GeneXpert Quality Assurance Situational Analysis Report

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| **Country name:** | *Country X* |
| **Assessor name:** | *John Smith* |
| **Assessor contact details:** | *NTP, Main Street, Country X* |
| **Date of assessment:** | *23 January to 14 March 2015* |

#### Part A: National and Regional Quality Assurance Structures

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|  | **Yes** | **No** | **Partial** | **Comments** | **Recommendation** |
| **1. Governance** | | | | |  |
| b. Is there a TB laboratory or Xpert MTB/RIF National Technical Working Group? |  |  |  |  |  |
| c. Does a Technical Working Group exist to assist the NTP in identifying and reviewing TB testing strategies and algorithms? |  |  |  |  |  |
| d. Is there GeneXpert Focal Person or equivalent to oversee the implementation of the Xpert MTB/RIF test? |  |  |  |  |  |
| i. If Yes, are they responsible for QA oversight? |  |  |  | *The Focal Person hasn’t been given the responsibility, but it is inferred in their job description, which mentions some (but not all) activities* | *The GeneXpert Focal Person be formally acknowledged as the person responsible for Xpert MTB/RIF quality assurance implementation.* |
| e. Is there a National Quality Assurance Unit within MOH/NTP to oversee quality assurance of diagnostic testing? |  |  |  | *The unit is responsible for distributing and reporting PT results. It is not involved in other quality assurance activities* e.g. *training. These are responsibilities of the NTRL* | *MOH/ NTP designate additional Xpert MTB/RIF quality assurance responsibilities (in addition to PT) to the National Quality Assurance Unit* |
| i. If Yes, is the Quality Assurance Unit responsible for Xpert MTB/RIF test PT? |  |  |  |  |  |
| f. Is there a regional Quality Assurance officer responsible for the oversight of EQA/PT? |  |  |  |  |  |

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|  | **Yes** | **No** | **Partial** | **Comments** | **Recommendation** |
| **2. Strategic planning, policies and resources** | | | | |  |

Are the following national guidelines & policies in place:

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| a. National Health Strategic Plan |  |  |  |  |  |
| b. National TB Strategic Plan |  |  |  |  |  |
| c. National TB Laboratory Strategic Plan |  |  |  |  |  |
| d. Xpert MTB/RIF Implementation Plan |  |  |  |  |  |
| f. Are QA activities for Xpert MTB/RIF test referenced in the available guidelines? |  |  |  |  |  |
| g. If Yes, do they include specific QA measures including   * Use of standardized documents, records and forms at all testing sites? |  |  |  | *The Implementation plan does not directly address quality assurance, but a number of the activities (training and on-site supervision are mentioned in plan* | *Revisions to the Xpert MTB/RIF Implementation Plan be made to include all quality assurance activities (*e.g. *standardized documentation, equipment maintenance and PT).* | |
| * Maintenance, servicing and verification of GeneXpert instruments? |  |  |  |  |  | |
| * Training and competency assessments? |  |  |  |  |  | |
| * Participation in proficiency testing program? |  |  |  |  |  | |
| * Conducting supervisory visits at testing sites? |  |  |  |  |  | |
| * Monitoring & evaluation? |  |  |  |  |  | |

1. This example of a situational analysis is not fully inclusive as an assessment. The situational analysis checklist must be used to provide a comprehensive overview of Xpert MTB/ RIF quality assurance activities.

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|  | **Yes** | **No** | **Partial** | **Comments** | **Recommendation** |
| **3. Quality procedures and documentation** | | | | | |
| a. Is the use of standardized documents, records and forms described in the national laboratory policy, or other national policies? |  |  |  |  |  |

b. Are the following standardized documents, records and forms available?

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| i. TB diagnostic algorithm |  |  |  |  |  |
| ii. Sample request form |  |  |  |  |  |
| iii. Xpert MTB/RIF test reporting form |  |  |  | *There is no standard format for reporting Xpert MTB/ RIF test results* | *Revisions be made to Xpert MTB/ RIF reporting forms to include standardized reporting codes.* |

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| iv. PT results form & failure follow-up form |  |  |  | *The result form is sent from the supplier of the PT panels; but, the testing sites don’t have a form for following up failures* | *A standardized PT follow-up form be developed for circulation to all testing sites performing Xpert MTB/RIF PT.* | | |
| d. Is there a mechanism to review, update and disseminate standardized documentation from the central-level to testing sites? |  |  |  | *Documentation is circulated randomly by the Focal Person during supervision visits* | | *A system (documentation log) is adopted to ensure that all testing sites receive standardized documentation.* |
| **4. Training, competency assessment and certification** | | | | | | |

a. Is a national, approved standardized training available for:

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| i. GeneXpert users? |  |  |  |  |  |
| ii. GeneXpert advanced users? |  |  |  | *Only one training has been given to date by Partner B- the training needs revision* | *The standardized training curriculum be circulated to all implementing partners. The importance of using standardized training be emphasised at the next partners meeting.* |
| iii. Clinicians and healthcare workers? |  |  |  | *None* |  |
| b. Is there an Xpert MTB/RIF standardized training for ‘training of trainers’ (TOT)? |  |  |  | *Some, but not all partners* |  |
| c. Is there a current national level database of all Xpert MTB/RIF testing personnel? |  |  |  | *None* |  |

e. Are there criteria for assessing competency for:

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| --- | --- | --- | --- | --- | --- |
| i. GeneXpert users? |  |  |  |  |  |
| ii. GeneXpert advanced users? |  |  |  |  |  |
| f. Are competency assessments for users and advanced users conducted annually and bi-annually respectively? |  |  |  | *None* |  |

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|  | **Yes** | | **No** | | **Partial** | | **Comments** | | **Recommendation** |
| **7. Equipment and supplies** | | | | | | | | | |
| **7.1. Equipment service and maintenance** | | | | | | | | | |
| a. Are policies (e.g. in the Xpert MTB/RIF Implementation Plan) in place requiring testing sites to maintain and service GeneXpert instruments? |  | |  | |  | |  | |  |
| c. Is there a mechanism in place to monitor GeneXpert instrument repairs at testing sites? |  | |  | |  | | *Repairs are reported to the Focal Person, but there is no log of repairs* | | *The GeneXpert Focal Person document s which instruments are being repaired and at which testing sites.* |
| **7.2 Quality supplies** | | | | | | | | | | |
| d. Is there a policy in place for quality verification of new Xpert MTB/RIF test lots coming into your country? |  |  | |  | |  | |  | | |

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|  | **Yes** | | **No** | | **Partial** | | **Comments** | | **Recommendation** |
| **8. External quality assessment (EQA)** | | | | | | | | | |
| **8.1. On-site supervisory visits** | | | | | | | | | |
| a. Are there national policies requiring on-site supervisory visits to all testing sites? |  | |  | |  | |  | |  |
| b. How frequently are supervisory visits conducted? |  | |  | |  | | *One a year* | |  |
| c. Is there documented evidence of regular on-site supervisory visits to testing sites? |  | |  | |  | | *Testing sites far from the capital are infrequently visited* | | *GeneXpert Focal Person to establish a timetable for site visits. Circulate to sites, MOH & partners.* |
| d. Who conducts the supervisory visits? |  | |  | |  | | *GeneXpert Focal Person, advanced users* | |  |
| e. How many supervisors are trained to conduct supervisory visits? |  | |  | |  | | *4* | |  |
| f. Are all testing sites covered by current supervisory activities? |  | |  | |  | | *No, there are no supervisors to cover Region B* | |  |
| g. Are approved standardized checklists available for conducting Xpert MTB/ RIF test supervisory visits? |  | |  | |  | | *Not all checklists are standardized* | |  |
| **8.2. Proficiency testing (PT)** | | | | | | | | | | |
| b. How many sites are currently participating in a PT programme for Xpert MTB/RIF? |  |  | |  | | *25* | |  | | |
| f. Are mechanisms in place to follow- up with testing sites that produce incorrect PT results? |  |  | |  | | *No supervisors in Region B. Testing sites far from the capital are hard to reach.* | | *Collaborate with implementing partner in the region to schedule training.* | | |
| g. If the NTP is considering producing its own Xpert MTB/RIF PT panels? |  |  | |  | | *Due to capacity, the PT panel supplier is unable to enrol all the testing sites. There is no expertise for developing the panels in country.* | | *MOH/NTP consider either developing PT panels in-country, or using an additional service provider to supply the testing sites that are currently not receiving PT.* | | |

h. If Yes, does the NTRL or a regional TB culture laboratory have sufficient:

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| i. Funding to produce PT panels? |  |  |  |  |  |
| ii. Trained competent staff to produce PT panels? |  |  |  |  |  |
| iii. Laboratory infrastructure to produce PT panels? |  |  |  | *There is limited space at NTRL, but it is possible, with minor modifications, to use the existing media preparation area* |  |
| iv. Capacity to distribute panels and PT results? |  |  |  |  |  |
| v. Currently produce PT panels for other tests e.g. smear microscopy? |  |  |  |  |  |

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| **9a. Monitoring and evaluation** | | | | | | |
| a. Is there a national policy in place requiring the collection of performance indicators? |  |  |  |  |  | |
| b. Does the NTP collect, analyse and use the following performance indicators for decision making: |  |  |  | *NTP does collect, analyse and use all performance indicators for decision- making* | | *MOH/NTP put data collection forms in place to collect all performance indicators. In addition, MOH/NTP delegate responsibility of analysing and reviewing of the performance indicator data.* |