360°
Drug-Susceptibility Testing Quality Assurance Assessment Dashboard

360° DST QAAD
A practical tool based on the latest WHO recommendations
The World Health Organization (WHO) End TB Strategy calls for the early diagnosis and prompt treatment of all persons of all ages with any form of drug-susceptible or drug-resistant tuberculosis (DR-TB). This requires ensuring access to the rapid diagnostics recommended by WHO and universal access to drug-susceptibility testing (DST) for all patients with signs and symptoms of tuberculosis (TB). WHO defines universal access to DST as rapid DST for rifampicin (RIF) as a minimum, and further DST for fluoroquinolones at least for all TB patients with RIF resistance.

TB drug resistance is a major global public health problem, and one third of deaths attributed to antimicrobial resistance (AMR) are caused by DR-TB which is threatening the progress made in TB care and prevention. Drug resistance in the *Mycobacterium tuberculosis* complex is caused by selection of naturally occurring mutants. People acquire DR-TB either when TB treatment is suboptimal, due to inadequate policies and failures of health systems and care provision, poor quality of TB drugs, poor prescription practices, patient non-adherence, or a combination of the above, or via the direct transmission of DR-TB from one person to another, which is responsible for the majority of cases of multidrug-resistant TB (MDR-TB) in high-burden settings. In 2020, approximately 130 000 people worldwide either developed TB that was resistant to RIF, the most effective first-line drug, or TB that was resistant to RIF and isoniazid, defined as MDR-TB.

The 360° DST Quality Assurance Assessment Dashboard (QAAD) is a digital tool designed to provide a thorough and standardized assessment of all the procedures involved in producing the results required for the efficient and effective treatment of DR-TB comprising both phenotypic and genotypic methods.
For infectious diseases caused by pathogens that develop drug resistance, such as TB, it is vital that DST is included as part of the treatment to ensure that patients receive the most accurate, effective and efficient treatment regimen. Thus, high-quality and timely laboratory results are essential for rapid and successful treatment outcomes. Culture-based phenotypic DST (pDST) methods are currently the gold standard for the detection of drug resistance, but these methods are time-consuming and require sophisticated laboratory infrastructure, qualified staff, and need strict quality control and quality assurance (QA) measures in place.

To obtain DST results of sufficient quality, each test must be carried out to a high standard and the laboratory setting in which the tests are performed must be adequate for the task. QA monitoring for DST testing is usually accomplished by annual external quality assurance (EQA panel testing); however, this type of QA procedure, using a limited number of samples at a single annual time-point, only provides a snapshot of testing quality. The annual EQA panel tests should, ideally, be tested alongside the laboratory’s routine samples and should only be tested once, but EQA panel tests are often processed with more care than other samples; that is, with a level of care that may not reflect everyday practice. For example, the test samples may be processed by the most experienced laboratory workers, and the tests may be repeated to reduce the possibility of errors or uncertainty. The 360° DST QAAD tool should allow laboratories to quickly and easily assess the quality of their testing procedures on a comprehensive, regular and unbiased basis to ensure quality DST results.

Use of the 360° DST QAAD tool should ensure the quality of both phenotypic and genotypic DST and verify the diagnostic processes used in laboratories. The tool is designed to identify shortcomings or errors in laboratories’ quality management systems and to provide suggestions for improvements. The tool comprises questions on eight of the key areas of the DST process to evaluate how each laboratory is implementing the steps in these areas and to identify any weak points present in the laboratory’s systems. Using the answers to these questions, the tool is able to provide a comprehensive analysis and plan for the steps to be taken by the laboratory to update and/or correct procedures to improve performance, if this is found to be necessary.

In its present form, the tool is designed to assess the laboratory procedures required for the majority of tests used for DST in the countries in the WHO European Region which have high rates of DR-TB and low levels of resources. The tool is currently being adapted to work with the latest WHO guidelines on TB detection.1 It includes questions on all the key procedural steps outlined

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Use of this tool in combination with other relevant tools designed to optimize diagnostic services, including diagnostic network optimization tools, will enable a comprehensive improvement of diagnostic service outcomes.
This tool has been specifically developed based on the needs and capacities of laboratories within the WHO European Region and will be continuously updated based on the latest WHO global guidelines and recommendations.

in the relevant standard operating procedures (SOPs) and all recent WHO technical guidance documents. In addition, every procedural sheet includes a chapter that enables the main quality documents and actions to be checked. The assessment questions are based on ISO 15189 requirements and provide quality improvements that work towards ISO 15189 accreditation. Some sections of the tool are only relevant for specific levels of the TB laboratory network; that is, some questions are designed for laboratories working at the national, regional or district level and some sections are for laboratories at the testing site level.

It is also possible to assess each section of the tool separately (for example, contamination control may be assessed separately in situations in which there are frequent contamination problems). The User Manual includes chapters for all sections and these chapters contain links to the most recent relevant documents; for example, WHO guidelines, training tools, SOPs etc. After the initial assessment, laboratory staff can use all these materials to create, for example, SOPs that the tool indicated were missing, training curricula and plans, competency assessments, and procedure implementation instructions.

Baseline assessment

For each laboratory using the tool, the QA assessment plan should include a baseline assessment outlining the main areas for improvement. We recommend that the baseline assessment is performed by an independent assessor with no conflict of interest with the QA capacity of the laboratory being assessed. To ensure this, the body commissioning the 360° DST QAAD assessment should be responsible for ensuring the independence of the assessor. WHO Regional Office for Europe, through the European Laboratory Initiative will train a group of assessors for this purpose. Regular follow-up assessments based on the output of the initial baseline assessment should be carried out by the laboratory’s quality control manager following training in how to use the assessment tool. WHO and its technical partners will be able to help laboratories plan and implement any remedial actions highlighted by the tool.

Key areas of the tool

The key areas covered by the tool are outlined below. Each section of the 360° DST QAAD questionnaire covers one of these key areas and contains detailed questions to elicit the information required for a full QA assessment of each laboratory.
1. Diagnostic algorithms, good laboratory practice and general quality indicators

Diagnostic algorithms are essential for making the correct clinical decisions and ensuring timely and successful treatments. They also help to avoid over testing and the financial costs associated with this. The questions in this section are designed to elucidate if the diagnostic algorithms used by the laboratory are working well (e.g. timely and optimal use of diagnostics) and whether they reflect the latest WHO recommendations including access to Molecular WHO-recommended Rapid Diagnostic (mWRD) tests for TB. This section also includes questions on good laboratory practice and the general indicators of laboratory performance that are specified by WHO. During the assessment, the assessor should have access to all available data on these indicators as they give a good overall picture of the laboratory workflow, organization and effectiveness. Data on these indicators should be available for at least 3–6 months.

2. Key quality assurance activities

QA is a management method defined as “all those planned and systematic actions needed to provide adequate confidence that a product, service or result will satisfy given requirements for quality and be fit for use”. A QA programme is Quality assurance: A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled. QA monitoring covers the entire testing process from the preanalytical to the analytical and the postanalytical phases, including sample collection and transport, the personnel involved, the procedures, the processes, equipment, environment and reagents. This section includes questions on the set of key indicators for the Quality Assurance/Continuous Quality Improvement system that should be monitored at the supervisory or national level. Countries should review the quality indicators proposed in line with their country guidelines and priorities.

The development of the indicators, as well as the data collection and analysis, will require a strong collaborative effort led by the national programme manager for that country, and the development should also include personnel from laboratory services and other stakeholders involved in the programme. A full monitoring and evaluation (M&E) framework as part of the QA programme includes data collection tools, and countries should review their existing tools to ascertain which data are being collected and which tools need to be revised to enable collection of the additional data required. It is possible that countries may need to acquire additional data collection tools. The frequency of data collection should be decided on taking into consideration the feasibility and resources required for data collection and for providing feedback, and the planned schedule of meetings when the data will be reviewed. Data should be collected at a frequency that ensures that any non-conformities or lack of progress towards targets can be acted upon in a timely manner, and that the necessary operational changes can be applied.

This section gives an overview of GeneXpert testing and the quality indicators of the test. The current version of the tool only checks Xpert tests. In the future, other low complexity NAATs (e.g. Truenat MTB/MTB RIF-Dx) and moderate complexity NAATs (Abbott RealTime MTB/MTB RIF/INH; BDMax™ MDR/TB, Bruker-Hain FluoroType MTB/MTBDR, cobas® MTB/MTB RIF/INH) will be added to the Initial diagnostic tests section. TB-LAMP and LF-LAM tests will also be added to the tool.

4. Follow-on diagnostic tests including line probe assays and low complexity automated NAATs to detect INH resistance and resistance to second-line anti-TB drugs (i.e. Xpert MTB/XDR)

This section gives an overview of line probe assay (LPA) testing and the quality indicators of the test. Based on the latest guidelines, key QA questions have been added to cover low complexity automated NAATs to detect INH resistance and resistance to second-line anti-TB drugs (i.e. Xpert MTB/XDR) as follow-on tests.

5. Specimen collection, TB culture testing

This section gives an overview of specimen collection and TB culture testing (liquid and solid) and the quality indicators of the test.

6. Phenotypic DST and drug concentrations

This section gives an overview of laboratory response to the treatment regimens in the country. Recently, critical concentrations for anti-TB drugs in pDST have been reviewed and new guidelines and technical manuals have been published. This means that laboratories have had to review their pDST procedures, update their preparations of drug stock solutions and reflect this in their pDST SOPs.

7. Phenotypic DST, procedure

This section gives an overview of pDST performance and DST media preparation and the quality indicators of the test.

8. Contamination control

This section helps to reveal problems with contamination control in the laboratory. It includes questions on bacterial contamination in BSL-3 facilities, cross-contamination and contamination in molecular laboratories.