Inclusion of TB diagnostics on the WHO Essential Diagnostics List

ON 16 MAY 2018, the World Health Organization (WHO) published its first Model List of Essential In Vitro Diagnostics (EDL),1 a catalogue of the tests needed to diagnose the most common medical conditions as well as selected global priority diseases, including tuberculosis (TB), the leading single infectious cause of mortality worldwide.2

The EDL focuses on diagnostics that ‘satisfy the priority health care needs of the population and which are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy, and comparative cost-effectiveness, similar to the definition of an essential medicine.’1 It contains 113 products used in human specimens such as blood, urine and sputum: 58 tests are listed for detection and diagnosis of a wide range of common conditions, providing an essential package for screening and management of patients. The remaining 55 tests are designed for the detection, diagnosis and monitoring of selected priority diseases such as TB, the human immunodeficiency virus, malaria, hepatitis B and C, and human papillomavirus and syphilis.

The EDL was developed following extensive consultation within the WHO and externally. The draft list was then reviewed by the recently established WHO Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD).3 Specifically, the general laboratory diagnostics were compiled based on existing WHO guidelines and technical manuals and priority medical devices lists.

The technologies specific to the diagnosis of TB are referred to in the EDL, with links to the respective guidelines. These commercial IVDs include molecular line probe assays (LPAs) for the detection of resistance to first- and second-line anti-tuberculosis medicines (Hain Lifesciences, Germany; Nipro Corporation, Japan), Xpert® MTB/RIF and Xpert® MTB/RIF Ultra for the detection of TB and rifampicin resistance (Cepheid, Sunnyvale, CA, USA), interferon-gamma release assays (IGRAs) (Qiagen, Valencia, CA, USA; Oxford Immunotec, Oxford, UK) and the tuberculin skin test (TST) for the diagnosis of latent tuberculosis infection, the lateral flow lipooligosaccharide assay (LF-LAM) to assist in the diagnosis of TB in seriously ill human immunodeficiency virus positive individuals (Alèrè, Waltham, MA, USA), loop-mediated isothermal amplification (TB-LAMP) for the diagnosis of pulmonary TB (Eiken Chemical Co, Tokyo, Japan), the automated liquid culture and drug susceptibility testing MGIT system (BD, Franklin Lakes, CA, USA) and light emitting diode (LED) fluorescence microscopy.

For the development of guidelines on TB diagnostics, the WHO uses the international GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to assess the quality of evidence and to develop and report recommendations.4 TB diagnostics currently recommended by the WHO comprise relatively unique and complex technologies, developed almost exclusively by single-source manufacturers. These technologies are applicable to specific patient populations and require dedicated levels of laboratory infrastructure, biosafety and technical training. In vitro results should be used to guide appropriate treatment, especially for drug-resistant TB. The latest WHO policies for TB diagnosis, treatment and care have therefore been consolidated into a concise compendium.5

The WHO End TB Strategy calls for universal access to testing and treatment for TB, including drug-resistant forms of the disease.6 The EDL serves as a guiding reference for countries to update or develop their own lists of essential diagnostics based on their local context and disease epidemiology. Ensuring that WHO-recommended TB diagnostics are included in national EDLs is an important first step on the path to reaching universal coverage. Moreover, ensuring that the required laboratory infrastructure, high-quality laboratory supplies and training of laboratory workers to accurately conduct TB testing are included in adequately budgeted plans for national laboratory services is imperative for scale-up and to truly benefit patients.

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References