WHO Technical Report Series

1017

First WHO Model List of Essential In Vitro Diagnostics

World Health Organization

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Contents

Abbreviations and acronyms

CLIA	chemiluminescence immunoassay
ECL	electrochemiluminescence
EDL	Model List of Essential In Vitro Diagnostics
EIA	enzyme immunoassay
G6PD	glucose-6-phosphate dehydrogenase
GLASS	Global Antimicrobial Resistance Surveillance System
HBV	hepatitis B virus
HCV	hepatitis C virus
IVD	in vitro diagnostic
MSF	Médecins Sans Frontières
RDT	rapid diagnostic test
SAGE	Strategic Advisory Group of Experts
TB	tuberculosis
USCDC	Centers for Disease Control and Prevention (USA)
USFDA	Food and Drug Administration (USA)

1. Introduction

The three strategic priorities of WHO stated in its Thirteenth General Programme of Work 2019–2023 are to advance universal health coverage, address health emergencies and promote healthier populations (*1*). The WHO Model List of Essential Medicines contains the medications considered to be the most effective and safe to meet the most important needs in a health system, thus advancing these strategic priorities. Access to good-quality, affordable in vitro diagnostics (IVDs) that allow health providers to make timely diagnoses and offer the most appropriate treatment is also essential for reaching these goals. The WHO Model List of Essential Medicines published in 2017 (*2*) included a recommendation by the Expert Committee on the Selection of Essential Medicines that WHO prepare a list of essential in vitro diagnostics, which will make an important contribution to universal health coverage.

Like the Model List of Essential Medicines, the Model List of Essential In Vitro Diagnostics ("essential diagnostics list", EDL) is intended to provide evidence-based guidance to countries for creating their own lists of essential in vitro diagnostic tests. National essential medicines lists have been successful in facilitating access to treatment, particularly in low-resourced countries, by prioritizing the most important medicines all countries should make available to their populations. It is expected that national EDLs will provide the same benefits for in vitro diagnostic tests. It should be noted that EDLs may be included in national lists of essential / priority medical devices that are used for public procurement, reimbursement or for universal health coverage (*3*).

The EDL comprises a group of IVDs that are recommended by WHO for use at various levels of a tiered national health care system (*4*). The List is not intended to be prescriptive with respect to the IVDs nor the levels at which they can or should be used. Countries should make their own decisions about which IVDs to select and where they are to be used on the basis of the national or regional burden of the disease, unmet needs, available resources and priorities.

The EDL will provide guidance and serve as a reference to ministries of health, programme managers, users such as laboratory managers, procurement officers and reimbursement systems in Member States, who are establishing or updating national lists of essential IVDs for universal health coverage. It will also inform United Nations agencies and nongovernmental organizations that support the selection, procurement, supply, donations or provision of IVDs. Finally, it will inform and guide the private sector for medical technology on IVD priorities and the IVDs needed to address global health issues.

While the EDL provides a list of tests required at various levels of the health care system, the EDL cannot be useful without an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory

infrastructure and regulatory and quality-assurance systems (*5*). Its impact also requires adoption and adaptation of the EDL by Member States, establishment of national and regional EDLs and the selection and supply mechanisms necessary to ensure access to the IVDs.

This report presents the first EDL and describes the process by which it was established and proposed next steps.

7, 2019