World Health Organization

EXECUTIVE BOARD
152nd session
Agenda item 5

EB152(6)
1 February 2023

Strengthening diagnostics capacity[1]

The Executive Board, having considered the report by the Director-General,[2]

Decided to recommend to the Seventy-sixth World Health Assembly the adoption of the following resolution:

The Seventy-sixth World Health Assembly,

Having considered the report by the Director-General,

Recognizing the Declaration of Alma-Ata (1978), which identified primary health care as "essential health care based on practical, scientifically sound and socially acceptable methods and technology […] at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination", and the Declaration of Astana (2018) on building sustainable primary health care in accordance with the call of the 2030 Agenda for Sustainable Development to achieve universal health coverage and the health-related Sustainable Development Goals, and that diagnostics are important to ensure quality, comprehensive and integrated primary health care and health services everywhere and for everyone;

Recognizing that diagnostic services are vital for the prevention, diagnosis, case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities;

Noting that the WHO Constitution upholds the enjoyment of the highest attainable standard of health as one of the fundamental rights of every human being, without distinction of race, religion, political belief, economic or social condition, and recognizing that the achievement of any state in the promotion and protection of health is of value to all, and that governments have a responsibility for the health of their peoples that can be fulfilled only by the provision of adequate health and social measures;

Recognizing that access to diagnostics in many countries may be reduced for households living in remote and rural areas, hard-to-reach and pastoral communities, low-income households and people in vulnerable situations, as well as those at higher risk of disease, and that equitable access to diagnostics, in particular diagnostic imaging in developing countries, is particularly deficient and that targeted efforts are needed to lift these barriers;

[1] For the purpose of this resolution, the term "diagnostics" includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types.

[2] Document EB152/5.

Recognizing that increasing access to diagnostics from current levels could reduce annual premature deaths, including for people living in developing countries;

Noting that equitable access to safe, effective and quality assured diagnostics requires a comprehensive health-systems approach that addresses all stages of the value chain;

Recalling the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also recalling the Doha Declaration on the TRIPS Agreement and Public Health, which affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and which recognizes that intellectual property protection is important for the development of new medicines while also recognizing the concerns about its effects on prices;[1]

Recalling resolution WHA67.20 (2014) on regulatory system strengthening for medical products, requesting the Director-General to prioritize support for "strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics";[2]

Recalling resolution WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage;[3]

Noting regional resolutions and initiatives on the regulation, assessment and/or management of medical devices, including in vitro diagnostics, and on strengthening public health laboratories;[4]

Noting the publication of the First WHO Model List of Essential In Vitro Diagnostics,[5] followed by a second[6] and a third edition,[7] the guidance on selection of essential in vitro

[1] Resolution WHA74.6. Strengthening local production of medicines and other health technologies to improve access. In: Seventy-fourth World Health Assembly, Geneva, 24 May–1 June 2021. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf, accessed 1 February 2023).

[2] Resolution WHA67.20. Regulatory system strengthening for medical products. In: Sixty-seventh World Health Assembly, Geneva, 19–24 May 2014. Geneva: World Health Organization; 2014 (https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf, accessed 17 October 2022).

[3] Resolution WHA67.23. Health intervention and technology assessment in support of universal health coverage. In: Sixth-seventh World Health Assembly, Geneva, 19–24 May 2014. Geneva: World Health Organization; 2014 (https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf, accessed 5 January 2022).

[4] Strengthening Public Health Laboratories in the WHO African Region: A Critical Need for Disease Control. Geneva: World Health Organization; 2008 (https://www.afro.who.int/sites/default/files/sessions/resolutions/AFR-RC58-6.pdf, accessed 4 January 2023).

[5] First WHO Model List of Essential In Vitro Diagnostics. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1017; https://apps.who.int/iris/bitstream/handle/10665/311567/9789241210263-eng.pdf?ua=1, accessed 4 January 2023).

[6] The selection and use of essential in vitro diagnostics. Geneva: World Health Organization; 2020 (WHO technical report series, No. 1022; https://www.who.int/publications/i/item/9789241210317, accessed 4 January 2023).

[7] The selection and use of essential in vitro diagnostics. Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1031; https://www.who.int/publications/i/item/9789240019102, accessed 31 January 2023).

diagnostics at country level[1] and the guidance for procurement of in vitro diagnostics and related laboratory items and equipment;[2]

Recalling resolution WHA60.29 (2007) on health technologies, which covers issues arising from the deployment and use of health technologies and the need to establish priorities in the selection and management of health technologies, in particular medical devices;[3]

Recognizing the development of the Universal Health Coverage Compendium[4] and the WHO lists of priority medical devices,[5] including those required for reproductive, maternal and newborn health,[6] cancer management,[7] coronavirus disease (COVID-19),[8] and cardiovascular diseases and diabetes,[9] and for covering the broad range of medical devices used for diagnostic purposes;

Recognizing that some of the barriers to improving equitable access to medicines are similar to those for diagnostics and that the regulation, selection, process, training for proper use, maintenance and – where appropriate – infrastructure support are different and in some instances even more complex, but nevertheless recognizing that synergies can be used wherever possible when addressing the barriers to access to medicines and diagnostics;

Recognizing the need to establish priorities in the management of diagnostics, considering procurement,[10] the supply chain, maintenance, safe use and decommissioning, to improve health outcomes through optimal use of the resources that are often capital intensive;

Recognizing the critical role of rapid and accurate diagnostics to combat antimicrobial resistance by guiding the correct management of infections, and the appropriate use of new and existing antimicrobials through improved antimicrobial stewardship and surveillance;

---

[1] Selection of essential in vitro diagnostics at country level. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240030923, accessed 31 October 2022).

[2] Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241512558, accessed 4 January 2023).

[3] Resolution WHA60.29. Health technologies. In: Sixtieth World Health Assembly, Geneva, 14–23 May 2007. Geneva: Word Health Organization; 2007 (https://apps.who.int/iris/bitstream/handle/10665/22609/A60_R29-en.pdf?sequence=1&isAllowed=y, accessed 4 January 2023).

[4] UHC Compendium: Health interventions for universal health coverage [website]. Geneva: World Health Organization; (n.d.) (https://www.who.int/universal-health-coverage/compendium, accessed 30 October 2022).

[5] Prioritizing medical devices [website]. Geneva: World Health Organization; (n.d.) (https://www.who.int/activities/prioritizing-medical-devices, accessed 31 January 2023).

[6] Interagency List of Priority Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn and Child Health. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/bitstream/handle/10665/205490/9789241565028_eng.pdf, accessed 31 January 2023).

[7] WHO list of priority medical devices for cancer management. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241565462, accessed 30 October 2022).

[8] Priority medical devices for the COVID-19 response and associated technical specifications. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2, accessed 30 October 2022).

[9] WHO list of priority medical devices for management of cardiovascular diseases and diabetes. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240027978, accessed 30 October 2022).

[10] Considering alternative procurement mechanisms, including pooled procurement, bundled procurement – including reagents and accessories – public-private partnerships (PPP), leasing, etcetera.

Recognizing the lack of equitable access to basic diagnostics in many parts of the world for priority pathogens, which have been identified by WHO as having the greatest outbreak potential;

Recognizing that appropriate diagnostics are needed to inform prediction, prevention, detection, monitoring and control of outbreaks and pandemic diseases; and noting that diagnostics capacity at national and subnational levels is essential;

Noting the emphasis of the Access to COVID-19 Tools Accelerator[1] (ACT-A) "to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines";

Noting the learnings derived from the Access to COVID-19 Tools Accelerator[1] (ACT-A), including its diagnostics pillar, regarding the strengths and weaknesses of ACT-A;

Noting that during the COVID-19 pandemic response, despite the sharing of the genome sequence of the novel coronavirus that paved the way for the rapid development of diagnostic tests, the lack of access for developing countries in particular to diagnostic tests created inequities in the public health response;

Noting that the benefit of diagnostics can be maximized by a suitable health system (including laboratories), which enables the selection/regulation and use of them in a proper way, with a skilled and licensed workforce operating in safe and operational facilities with the appropriate infrastructure and adequate financing;

Recalling resolution WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which underscores that timely, fair and equitable access to health products is a global priority and that the availability, accessibility, acceptability and affordability of health products are fundamental to tackling global public health emergencies;[2]

Recognizing the increasing burden of noncommunicable diseases[3] and the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2030,[4] which includes addressing the lack of diagnostics for noncommunicable diseases through multistakeholder collaborations to develop new technologies that are affordable, safe, effective and quality controlled, and improving laboratory and diagnostic capacity and human resources;[5]

[1] The Access to COVID-19 Tools (ACT) Accelerator [website]. Geneva: World Health Organization; (n.d.) (https://www.who.int/initiatives/act-accelerator, accessed 1 February 2023).

[2] Resolution WHA 74.7. Strengthening WHO preparedness for and response to health emergencies. In: Seventy-fourth World Health Assembly, Geneva, 24 May–1 June 2021. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R7-en.pdf, accessed 22 December 2022).

[3] Including those that affect eye, ear and oral health.

[4] Implementation roadmap 2023–2030 for the Global action plan for the prevention and control of NCDs 2013–2030 [website]. Geneva: World Health Organization; (n.d.) (https://www.who.int/teams/noncommunicable-diseases/governance/roadmap, accessed 31 January 2023).

[5] Global Action Plan for the Prevention and Control of NCDs 2013–2020. Geneva: World Health Organization; 2013 (https://apps.who.int/iris/handle/10665/94384, accessed 9 November 2022).

Recognizing the need to ensure the integrated and coordinated provision of high-quality, affordable, accessible, age and gender sensitive and evidence-based diagnostic interventions, for all individuals without discrimination, with a view to achieving universal health coverage;

Noting the importance of point-of-care tests at the primary health care level as well as at the community level, including self-testing, to increase access to and the affordability and use of diagnostics;

Noting the opportunities for improved diagnostics including, but not limited to, the research and development of simple, affordable tests for diseases currently lacking good quality tests, digitalization, telediagnosis and clinical decision support and improved information management,[1] point-of-care testing and genomic sequencing;

Noting resolution WHA72.8 (2019) on improving the transparency of markets for medicines, vaccines and other health products;[2]

Noting the challenges associated with the cost of diagnostic tests in developing countries that affect access;

Recalling resolution WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, which recalls "resolution WHA61.21 (2008), decision WHA71(9) (2018) and document A71/12 (2018), insofar as they address the role of technology transfer and local production of medicines and other health technologies in improving access;"[3]

Noting that although high-burden infectious diseases persist globally, considerable efforts over the last decade by Member States, WHO, donors and other stakeholders have expanded laboratory diagnostic services and access to in vitro diagnostics for several high-burden infectious diseases,[4]

1. URGES Member States, taking into account their national context and circumstances:

(1) to consider the establishment of national diagnostics strategies, as part of their national health plans, that include regulation, assessment and management of diagnostics and development of integrated networks to tackle all diseases and medical challenges, avoiding current silos often observed;

[1] Recommendations on digital interventions for health system strengthening – Executive summary. Geneva: World Health Organization; 2019 (document WHO/RHR/19.8).

[2] Measuring medicine prices, availability, affordability and price components, 2nd edition. Geneva: World Health Organization; 2008 (https://apps.who.int/iris/bitstream/handle/10665/70013/WHO_PSM_PAR_2008.3_eng.pdf?sequence=1&isAllowed=y, accessed 25 November 2022).

[3] Resolution WHA74.6. Strengthening local production of medicines and other health technologies to improve access. In: Seventy-fourth World Health Assembly, Geneva, 24 May–1 June 2021. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/WHA74-REC1/A74_REC1-en.pdf#page=27, accessed 9 February 2022).

[4] Global technical strategy for malaria 2016–2030, 2021 update. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240031357, accessed 1 February 2023).

(2) to consider health technology assessment systems for the systematic evaluation of the effectiveness and cost-effectiveness of diagnostics to support decision-making for the selection of diagnostics for interventions for universal health coverage;

(3) to consider the development of national essential diagnostics lists, adapting the WHO Model List of Essential In Vitro Diagnostics and the WHO lists of priority medical devices to local context, and plans to fund gaps in access to essential diagnostics, and to update them regularly;

(4) to extend the scope of packages of essential diagnostic services, and to make essential diagnostics available, accessible and affordable at the primary health care level;

(5) to invest in developing skilled workforce at all levels of their respective health systems, with the training needed to support advances in diagnostics and the management of these technologies;

(6) to commit to the safe use of diagnostic imaging procedures by applying standards based on the International Basic Safety Standards, where appropriate, and by considering the protection of patients, staff and the public;[1]

(7) to commit resources to invest in research and product development and to promote local production capacity for diagnostics, particularly in developing countries;

(8) to consider including provisions that facilitate access in funding agreements for research and development in diagnostics;

(9) to take policy measures for equitable and timely access for all to diagnostics technologies and products, in particular for the benefit of developing countries, including joint development and transfer of diagnostics technologies, on voluntary and mutually agreed terms;

(10) to take into account the rights and obligations contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, including those affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, in order to promote access to diagnostics and other health technologies for all;

(11) to consider, as appropriate, legislative, administrative or policy measures to prevent anti-competitive practices that hinder access to diagnostics;

(12) to leverage international and/or regional collaboration for harmonizing and promoting twinning practices and reliance mechanisms for the regulation, manufacturing and supply of all types of diagnostics;

(13) to establish routine data collection systems for monitoring key data on the market shaping and effective use of diagnostics, and to use these data for evidence-based policy-making;

[1] Document EB131/11. Radiation protection and safety of radiation sources: International Basic Safety Standards. Report by the Secretariat. In: 131st session of the Executive Board, Geneva, 28–29 May 2012. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/EB131/B131_11-en.pdf, accessed 4 January 2023).

(14) to invest in diagnostic services, including the selection and use of essential in vitro diagnostics;

(15) to strengthen international collaboration and assistance, including during epidemics and pandemics, aligned with the International Health Regulations (2005);

2. REQUESTS the Director-General:

(1) to collect data on affordability, availability and access to essential diagnostics;

(2) to support Member States, upon their request and as appropriate, with technical advice for procurement that will enable access to good quality, affordable diagnostics for all Member States;[1]

(3) to provide cross-references between the WHO Model List of Essential In Vitro Diagnostics and the diagnostic devices already included in the WHO priority medical devices lists, in order to facilitate the identification of relevant diagnostics for comprehensive diagnostic services, in particular through the open electronic platforms eEDL[2] and MeDevIS;[3]

(4) to update the WHO Model List of Essential In Vitro Diagnostics and the WHO lists of priority medical devices, to include innovative diagnostics, following a review of the latest evidence and/or health technology assessments;

(5) to support Member States upon their request to develop policies for health technology management of diagnostics, including national maintenance systems and disposal;

(6) to continue to support Member States upon their request in promoting quality and sustainable local production of diagnostics, including, as appropriate, by facilitating research and development and technology transfer on voluntary and mutually agreed terms, and by coordinating with relevant international intergovernmental organizations and agencies to promote local production in a strategic and collaborative approach;[4]

(7) to support Member States upon their request to strengthen national and regional regulatory systems for diagnostics;

(8) to support the development and updating of Member States' national diagnostics lists, considering the WHO lists, including cost-effectiveness and state-of-the-art diagnostics products and technologies;

---

[1] And, where applicable, regional economic integration organizations.

[2] Model List of Essential In Vitro Diagnostics [electronic platform]. Geneva: World Health Organization; (n.d.) (https://edl.who-healthtechnologies.org/, accessed 31 January 2023).

[3] Priority Medical Devices Information System [electronic platform]. Geneva: World Health Organization; (n.d.) (https://medevis.who-healthtechnologies.org/, accessed 31 January 2023).

[4] Resolution WHA74.6. Strengthening local production of medicines and other health technologies to improve access. In: Seventy-fourth World Health Assembly, Geneva, 24 May–1 June 2021. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf, accessed 5 January 2022).

(9) to categorize a subset of the WHO Model List of Essential In Vitro Diagnostics as tailored to emergency situations, including the Interagency Emergency Health Kits;[1]

(10) to publish publicly available information on diagnostic products and technologies[2] from the WHO Model List of Essential In Vitro Diagnostics and the WHO lists of priority medical devices, through the open electronic platforms eEDL and MeDevIS;

(11) to develop or strengthen national, regional and global laboratory networks and diagnostics initiatives and to support Member States in developing and implementing quality management systems for ensuring safe, affordable, accessible diagnostic services and quality assured diagnostics;

(12) to develop and/or update WHO definitions of diagnostics, through a group of experts and public consultations, and to publish revised definitions before the 156th session of the Executive Board;

(13) to take a horizontal health programme approach for all diagnostics (both in vitro and non-in vitro) across diseases and to avoid siloed guidance, policy and funding streams;

(14) to support Member States in creating optimized, integrated diagnostic networks and services that best serve country programmes to tackle all diagnostic systems needs, removing the oftentimes siloed programmatic and diagnostic services;

(15) to prioritize and review rapidly clinical evidence for new diagnostic interventions, services or products for consideration in guidelines, across diseases and with an effort to integrate recommendations in a disease-agnostic way, where possible;

(16) to report on progress in the implementation of this resolution to the Seventy-eighth World Health Assembly in 2025.

Sixth meeting, 1 February 2023
EB152/SR/6

= = =

[1] Interagency Emergency Health Kit 2017. Geneva: World Health Organization; 2017 (https://www.who.int/emergencies/emergency-health-kits/interagency-emergency-health-kit-2017, accessed 31 January 2023).

[2] Decision WHA75(25). Standardization of medical devices nomenclature. In: Seventy-fifth World Health Assembly, Geneva, 22–28 May 2022. Geneva: World Health Organization; 2022 (https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(25)-en.pdf, accessed 31 January 2023).