World Health Organization

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Agenda item 5

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Strengthening diagnostics[1] capacity

Draft decision proposed by Indonesia and Member States of the African Region

The Executive Board, having considered the report on reorienting health systems to primary health care as a resilient foundation for universal health coverage,[2]

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

The Seventy-sixth World Health Assembly,

(PP1) Recognizing the Alma-Ata Declaration of 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 2030 Agenda for Sustainable Development's call to achieve universal health coverage and health-related Sustainable Development Goals, and that diagnostics are important to ensure quality, comprehensive, and integrated primary health care and health services for everyone and everywhere;

(PP2) 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;

(PP3) Noting that the WHO Constitution upholds the enjoyment of the highest attainable standard of health as a fundamental right 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 governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures;

(PP4) Recognizing that access to diagnostics in many countries may be reduced for households living in remote and rural areas, hard to reach and pastoralist communities, low-income households, and people in vulnerable situations, as well as those at higher risk of disease,

[1] For the purpose of this resolution, "diagnostics" include medical devices used for: diagnostic, screening, monitoring, prediction, staging or surveillance of diseases or health condition, both "in vitro" and "non in vitro" types.

[2] Document EB152/5.

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;

(PP5) 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;

(PP6) Recalling also the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and recalling the 2001 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 recognizes that intellectual property protection is important for the development of new medicines and also recognizes the concerns about its effects on prices (ref: res on local production);

(PP7) 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 products that are the least developed, such as regulation of medical devices, including diagnostics";[1]

(PP8) Recalling resolution WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage;[2]

(PP9) Noting regional resolutions and initiatives on: regulation, assessment, or management of medical devices including in vitro diagnostics and on strengthening public health laboratories;[3]

(PP10) Noting the publication of the First WHO Model List of Essential In Vitro Diagnostics[4] (2019); followed by the second edition[5] (2020), third edition[6] (2021), the guidance

[1] Regulatory system strengthening for medical products, resolution WHA67.20 https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf (accessed 17 October 2022).

[2] Health intervention and technology assessment in support of universal health coverage, resolution WHA67.23 https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf (accessed 5 January 2022).

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

[4] First WHO Model List of Essential In Vitro Diagnostics. Geneva: World Health Organization; 2019 (WHO Technical Report Series, no. 1017). Licence: CC BY-NC-SA 3.0 IGO. https://apps.who.int/iris/bitstream/handle/10665/311567/9789241210263-eng.pdf?ua=1 (accessed 4 January 2023).

[5] The selection and use of essential in vitro diagnostics. (WHO technical report series, no. 1022). 2020. Available at https://www.who.int/publications/i/item/9789241210317 (accessed 4 January 2023).

[6] The selection and use of essential in vitro diagnostics. (WHO Technical Report Series, no 1031). https://www.who.int/publications/i/item/9789240019102 (accessed 31 January 2023).

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

(PP11) Recalling resolution WHA60.29 (2007) on health technologies covering issues arising from the deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices;[3]

(PP12) Recognizing the development of the WHO Universal Health Coverage Compendium[4] and the WHO Lists of Priority Medical Devices[5] including those required for reproductive, maternal, newborn health,[6] cancer management,[7] COVID-19,[8] and cardiovascular diseases and diabetes,[9] and for covering the broad range of medical devices used for diagnostic purposes;

(PP13) 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 some even more complex, nevertheless recognizing that synergies can be used wherever possible when addressing barriers to access to medicines and diagnostics;

(PP14) Recognizing the need to establish priorities in the management of diagnostics considering procurement,[10] supply chain, maintenance, safe use and decommissioning, to improve health outcomes through optimal use of the resources that are often capital intensive;

(PP15) 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;

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[1] Selection of essential in vitro diagnostics at country level. Geneva, WHO; 2021. Available at 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. Available at https://www.who.int/publications/i/item/9789240030923 (accessed 4 January 2023).

[3] Health technologies, resolution WHA60.29 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. Geneva: World Health Organization; 2021. https://www.who.int/universal-health-coverage/compendium (accessed 30 October 2022).

[5] WHO Priority Medical Devices Lists 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 childcare (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 (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 (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 (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, accessories-, private public partnerships (PPP), leasing, etc.

(PP16) 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;

(PP17) 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;

(PP18) 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";

(PP19) Noting the learnings derived from the Access to COVID-19 Tools Accelerator,[2] including its diagnostics pillar, regarding the strengths and weaknesses of ACT-A;

(PP20) Noting that during 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 public health response;

(PP21) Noting that the benefit of diagnostics can be maximized by the suitable health system (including laboratories), which enables selection/regulation and use of them in a proper way, with the skilled and licensed workforce operating in safe and operational facilities with the appropriate infrastructure, and adequate financing;

(PP22) Recalling resolution WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, underscoring 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;[3]

(PP23) Recognizing the increasing burden of noncommunicable diseases[4] and WHO's Global Action Plan for the Prevention and Control on Noncommunicable Diseases 2013–2030[5] that 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;[6]

(PP24) Recognizing the need to ensure the integrated and coordinated provision of high-quality, affordable, accessible, age and gender sensitive, and evidence-based diagnostic

[1] *Ibid.*

[2] *Ibid.*

[3] Strengthening WHO preparedness for and response to health emergencies, resolution WHA 74.7 (2021) Available at https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R7-en.pdf (accessed 22 December 2022).

[4] Including eye, ear and oral health.

[5] Implementation roadmap 2023–2030 for the Global action plan for the prevention and control of NCDs 2013–2030 https://www.who.int/teams/noncommunicable-diseases/governance/roadmap (accessed 31 January 2023).

[6] Global Action Plan for the Prevention and Control of NCDs 2013-2020. Geneva: World Health Organization; 2013. Available at https://apps.who.int/iris/handle/10665/94384 (accessed 9 November 2022) (Reference to 80% of basic technologies).

interventions, for all individuals without discrimination with a view to achieving universal health coverage;

(PP25) 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, affordability and use of diagnostics;

(PP26) 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;

(PP27) 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;

(PP28) Recalling resolution WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, which "recalls resolutions 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]

(PP29) 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]

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

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

[1] WHO guideline: recommendations on digital interventions for health system strengthening. Executive summary. Geneva: World Health Organization; 2019. (WHO/RHR/19.8). Licence: CC BY-NC-SA 3.0 IGO.

[2] WHO and Health Action International. Measuring medicine prices, availability, affordability and price components, 2nd ed. 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] Strengthening local production of medicines and other health technologies to improve access. Resolution 74.6. Geneva: World Health Organization; 2021. Available at https://apps.who.int/gb/ebwha/pdf_files/WHA74-REC1/A74_REC1-en.pdf#page=27 (accessed 9 February 2022).

[4] https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_R20-en.pdf ; https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/full-final-who-ghss-hiv-vh-sti_1-june2022.pdf?sfvrsn=7c074b36_13 (accessed 31 January 2023); Global technical strategy for malaria 2016-2030, 2021 update (who.int).

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

(3) to consider development of a national essential diagnostics list, 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 regularly update them;

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

(5) to invest in developing skilled workforce at all levels of the health system, 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, considering the protection of patients, staff and the public;[1]

(7) to commit resources to invest in research and product development and promote local production capacity for diagnostics,[2] 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 in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 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 practice and reliance mechanism for the regulation/ manufacturing/supply of all types of diagnostics;

[1] International Basic Safety Standards: Report by the Secretariat. EB131/11. 2012. Available at https://apps.who.int/gb/ebwha/pdf_files/EB131/B131_11-en.pdf (accessed 4 January 2023).

[2] For the purpose of this resolution, “Diagnostics” as those medical devices used for: diagnostic, screening, monitoring, prediction, staging or surveillance of diseases or health condition including, both “in vitro” and “non in vitro”.

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

(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);

(OP)2. REQUESTS the Director-General:

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

(2) to support, upon request of Member States and as appropriate, 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 List, in order to facilitate the identification of relevant diagnostics for comprehensive diagnostic services, in particular through the WHO electronic platforms: e-EDL[2] and MeDevis;[3]

(4) to update the WHO Model List of Essential in vitro diagnostics and WHO Lists of Priority Medical Devices, including innovative diagnostics, following review of latest evidence 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 in promoting 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;

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

[2] WHO Model List of Essential In Vitro Diagnostics, electronic platform. (https://edl.who-healthtechnologies.org/) (accessed 31 January 2023).

[3] WHO Priority Medical Devices information system (https://medevis.who-healthtechnologies.org/) (accessed 31 January 2023).

[4] Strengthening local production of medicines and other health technologies to improve access, resolution WHA74.6 https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf (accessed 5 January 2022)

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

(9) to categorize a subset of the WHO Essential Diagnostics List, 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 WHO open platforms e-EDL 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 towards ensuring safe, affordable, accessible diagnostic services and quality assured diagnostics;

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

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

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[1] https://www.who.int/emergencies/emergency-health-kits/interagency-emergency-health-kit-2017 (accessed 31 January 2023).

[2] Decision WHA75(25) (2022), https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(25)-en.pdf (accessed 31 January 2023).