

WHO model list of essential in vitro diagnostics: strengthening diagnostics capacity to transform health care for all



In May, 2023, governments at the 76th World Health Assembly adopted a historic resolution on strengthening diagnostics capacity,¹ urging Member States to establish national diagnostics strategies. These strategies include the creation of national lists of essential diagnostics and the inclusion of both in-vivo (eg, radiology) and in-vitro diagnostics (IVDs) in the broader scope of health planning to deliver health care for all.¹ Almost half of the world's population has little or no access to diagnostics.² Several diagnostic capacity gaps have been described across different components of health systems, but the absence of an essential set of IVDs is particularly detrimental.² IVD testing has been neglected in public health for decades. Poor political commitment and poorer global health interest has led to ineffective strategies and insufficient investments in IVDs, despite them having key roles in addressing global health priorities, such as universal health coverage (UHC), antimicrobial resistance, communicable and non-communicable diseases, and global health security, including pandemic preparedness and responses.³ Furthermore, IVDs are instrumental in delivering quality health care across the life course and disease continuum.^{3,4}

In 2018, WHO released its first essential diagnostics list (EDL), which was followed by three updates in 2019, 2021, and 2023.⁵ The EDL is strategic, normative guidance organised across levels of care, and aims to ensure effective access and availability of IVDs that are relevant to public health and UHC, accelerating progress towards the UN's health-driven Sustainable Development Goals.⁶

According to estimates from the 2018 *Lancet* Series on pathology and laboratory medicine in low-income and middle-income countries⁷ (LMICs) and the 2021 *Lancet* Commission on diagnostics,² investment in diagnostics—including IVDs—could avert 1.1 million premature deaths per year in LMICs by narrowing diagnostic gaps in just six tracer health conditions, thereby making essential IVDs an impact-oriented, cost-effective investment for health systems. Such an effect can only

be achieved through a holistic approach to health system strengthening, with a firm commitment to equity and health care for all. IVD testing strategies should be developed as part of broader national health planning and aligned with priority disease areas. WHO's EDL aims to help countries plan the introduction of IVDs within their national health strategies. Context-appropriate implementation planning of national EDLs on the basis of WHO's EDL is key to informing budget allocation and developing benefit packages, therefore ensuring IVD availability at different levels of health systems to deliver UHC.⁶ National EDLs should be linked to national health guidelines to ensure policy cohesion and action. Strategies for IVDs should be funded and should include robust frameworks for assessing current IVD accessibility and affordability, and monitoring progress to track their effects and enable adjustments as needed. An integrated, tier-based IVD testing network can improve resource procurement, allocation, and distribution while also increasing the efficiency of health-care investments. Primary health care approaches should be prioritised in national EDLs, with a focus on community-oriented care.⁸ A driver for IVD testing transformation is the establishment of financially assured and accessible benefit packages that explicitly incorporate IVDs.² Quality improvement should be pursued through auditing and accreditation given its notable effect on health determination. Capacity-building efforts should be aligned with the workforce strategy, taking into account current gaps and opportunities to improve efficiency in specific areas through organisational solutions, increasing human resources,⁹ and digitalisation of more complex interventions for remote consultations.

A summary of key actions to support the strengthening of IVD testing services as part of a health systems approach is shown in the panel. We believe that case studies in pilot countries are needed to pursue local actions, understand the extent to which policy implementation can provide population health benefits, and identify enablers, challenges, barriers, and issues in translating evidence into action. Global health-oriented sustainable innovations

Panel: Key implementation areas and actions to support strengthening of in-vitro diagnostic (IVD) testing services and diagnostics capacity

Primary health care for universal health coverage and equity

- Focusing on primary health care and pursuing community-oriented goals⁸ to provide access for patients, especially in underserved, rural, and remote areas.
- Developing financially assured and accessible benefit packages that explicitly include diagnostics to avoid catastrophic health-care expenditure.
- An integrated, tiered network of IVD testing facilities to improve resource allocation and efficiency by avoiding fragmentation.

Workforce

- Creating a workforce strategy that is cognisant of the current gaps to improve the efficiency and capacity of human resources.⁹

Quality

- Focusing on quality improvement through accreditation and auditing processes to enable IVD testing facilities to attain minimum standards.²

Financing

- Approaching investment in diagnostics systems from a broad perspective, recognising that siloed approaches are usually insufficient, ineffective, or even detrimental.²

Innovation and research

- Innovation (particularly through the development of point-of-care IVDs) including innovative, scalable, and locally relevant multiplex formats, and digitalisation for remote consultations to promote democratisation of care.⁷
- A strong commitment to research and local or regional manufacturing.

Accountability and monitoring

- Reliable and updated situational analyses are needed to assess the status quo, monitor progress, track results, and modulate actions.

Policy cohesion, leadership, and governance

- Consistency of health policies and guidelines as an integral part of the political commitment to deliver health care for all is instrumental for impact-oriented health delivery.

help drive the democratisation of health care, particularly through the development of point-of-care IVDs.⁷ Primary health care can serve as a strategic delivery platform for overall health care, minimising fragmentation and inefficiency and facilitating patients' access to health-care services. Testing services should strive to meet minimum standards by focusing on quality improvement and UHC, including point-of-care tests and improved specimen transport systems.²

Health prioritisation is a political choice, and evidence-based policy guidance helps such a choice deliver notable effects. With the advent of the EDL and WHO recommendations to develop and update national EDLs,⁶ we affirm that WHO guidance should be followed. We strongly emphasise that without political commitment to high-value IVD investments in priority areas, framed within a health systems approach,

transformative outcomes will not be achieved. Research, innovation, and implementation of IVDs must be prioritised globally.

FGM, AAC, and NH are WHO employees. LY is an employee of the National Medical Products Administration. All other authors declare no competing interests. The contents of this Comment must be attributed to the authors alone, and not interpreted as official statements or positions of their institutions, organisations, and bodies.

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