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Essential diagnostics: mind the gap

This month, WHO released the latest update to its Essential Medicines List. First published in 1977, the list documents all medicines considered essential to address key public health needs globally. It was not until 2018 that WHO published its first Essential Diagnostics List (EDL). Described as the "Cinderella of health systems" in a Comment accompanying *The Lancet's* 2018 three-part Series on Pathology and Laboratory Medicine (PALM) in low-income and middle-income countries (LMICs), diagnostics are a neglected area of global health.

The importance of availability and access to highquality diagnostics has gained wider attention recently, largely due to the COVID-19 pandemic. The latest edition of the EDL, version 3, published in January, 2021, included PCR and antigen tests for SARS-CoV-2, as well as expanding the range of tests for infectious, noncommunicable, and vaccine-preventable diseases.

Not only are diagnostic tests essential for global health security, but improving diagnostic capacity globally is also key to achieving universal health coverage. While the gap in access to diagnostics in resource-poor settings is anecdotally understood, there is a paucity of data on the extent of the problem. The Lancet Commission on diagnostics, published on Oct 6, 2021, quantifies the status of diagnostics globally, reporting that 47% of the world's population has little or no access to diagnostics. There is a diagnostic gap of 35-62% for six priority medical conditions: diabetes, hypertension, HIV, tuberculosis, and hepatitis B virus infection and syphilis for pregnant women. Further, only about 19% of low-income and lower-middle-income country populations have access to the most basic diagnostic tests at the primary care level.

An accompanying Article published in this month's issue of *The Lancet Global Health* explores the availability of 16 essential laboratory and radiological diagnostics at three tiers of the health system (basic primary, advanced primary, and hospital) in ten LMICs, using data from USAID's Service Provision Assessment survey between 2004 and 2018. The authors report median availability ranging from 19·1% in basic primary care facilities to 68.4% in hospitals, and wide variation between diagnostics: from 1.2% for ultrasound to 76.7% for malaria diagnostics in the primary care setting, and from 6.1% for CT to 91.6% for malaria

diagnostics in hospitals. Availability across all tiers also varied by country, ranging from 14.9% in Bangladesh to 89.6% in Namibia.

So what are some of the barriers to access? The 2018 *Lancet* Series identified insufficient human resources and workforce capacity; inadequate education and training; poor infrastructure; and insufficient quality, standards, and accreditation as the key barriers to expanding access to PALM services in LMICs. The Commission further identifies a shortfall of up to 1 million diagnostics staff globally. It also examines the policy environment, concluding that low political prioritisation and visibility of diagnostics are the root causes of the present situation. Of note, it states that diagnostics are particularly susceptible to corruption because of the expensive equipment and supplies involved.

What can be done? The Commission estimates that 1.1 million deaths associated with the six priority conditions could be avoided annually in LMICs if the diagnostic gap were reduced to 10%. It also makes the economic case for investing in diagnostics. The commissioners call on policy makers to develop national diagnostic strategies including EDLs; improve availability and access to testing in primary care; expand and train the workforce; develop regulatory frameworks to support quality and safety of diagnostics; develop long-term financing strategies; improve affordability; expand the development of diagnostics beyond highincome countries; address the diagnostic needs of those living in fragile and conflict settings; develop advocacy programmes; and establish an International Diagnostics Alliance to support the transformation of the field.

With so many issues to address, where should we start? In a panel discussion accompanying the launch of the Commission, commentators including the Global Fund's Peter Sands, WHO's Soumya Swaminathan, and African Society for Laboratory Medicine's Pascale Ondoa agreed that focusing on the shocking gaps in primary care was a key focus. From tracking asymptomatic COVID-19 transmission to controlling the rising tide of non-communicable diseases, reliable and affordable community access to diagnostic testing is paramount. The Lancet Global Health

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For more on the EDL see https://www.who.int/news/ item/29-01-2021-whopublishes-new-essentialdiagnostics-list-and-urgescountries-to-prioritizeinvestments-in-testing

For the **Comment on the Cinderella of health systems** see **Comment** *Lancet* 2018; **391**: 1872–73

For the Series on pathology and laboratory medicine in LMICs see https://www.thelancet.com/ series/pathology-andlaboratory-medicine

For the **2021 EDL** see https://www.thelancet.com/ series/pathology-andlaboratory-medicine

For The Lancet Commission on diagnostics see Lancet 2021; published online Oct 6, 2021. https://doi.org/10.1016/ S0140-6736(21)00673-5

For the Article on availability of essential diagnostics in 10 LMICs see Articles page e1553

For the Article on access to pathology and laboratory services from The Lancet Series see Series Lancet 2018; 391: 1927-38

For the **linked Comment to the Commission** see **Comment** Lancet 2021; published online Oct 6, 2021. https://doi.org/10.1016/ S0140-6736(21)02182-6