

The Lancet: Half of the global population lack access to basic diagnostics for many common diseases

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Nearly half (47%) of the global population has limited or no access to key tests and services that are essential for diagnosing common diseases,

such as diabetes, hypertension, HIV, and tuberculosis, or basic tests for pregnant women such as hepatitis B and syphilis, according to new analysis. Without access to accurate, high-quality, and affordable diagnostics, many people will be overtreated, undertreated or not treated at all, or exposed to unnecessary and potentially harmful treatment.

The analysis was led by The Lancet Commission on Diagnostics, an in-depth report bringing together 25 experts from 16 countries to transform global access to diagnostics. The Commission highlights the centrality of diagnostics for any functioning health care system and calls on policy makers to close the diagnostic gap, improve access, and expand the development of diagnostics beyond [high income countries](#).

As the Commission notes, an early lesson of the COVID-19 pandemic was the crucial importance of timely, accurate diagnosis. Early issues developing tests hampered the understanding of, and response to the outbreak, resulting in the rapid emergence of unreliable, inaccurate (even false) tests. In high income countries, the ability to use existing public health laboratories, in addition to the private sector, was critical in ramping up testing capacity, but many low and middle income countries without access to this infrastructure were disadvantaged and left unable to reach full testing capacity.

"In much of the world, patients are treated for diseases in the absence of access to key diagnostic tests and services. This is the equivalent of practicing medicine blind. Not only is this potentially harmful to patients, but it is also a significant waste of scarce medical resources. For the first time, our analysis shows the shocking scale of the challenges we are facing, and our report offers recommendations on how we close the gap. The COVID-19 pandemic has put testing at the top of the political and global health agenda, and it must be a turning point in ensuring we prioritise diagnostics for all diseases," says Dr. Kenneth Fleming, Commission Chair, University of Oxford (UK).

Diagnostics include a collection of key tests and services that are essential to understand a patient's health. These might include blood, tissue, or urine samples collected and analysed at the bedside or in a laboratory, or diagnostic imaging such as X-rays, ultrasound, MRI, CT, or nuclear medicine.

As a part of the Commission, the authors reviewed the best available data on access to World Health Organization (WHO) recommended tests for antenatal care to provide a global estimate on access to basic diagnostics. These tests, including syphilis testing, urine dipsticks, haemoglobin testing, blood glucose testing, and ultrasounds, represent essential diagnostic tests and should be available within a two-hour travel time of the patient.

Diagnostics are fundamental to quality health care, but as the Commission states, this notion is under-recognised, leading to underfunding and inadequate resources at all levels. Globally, they estimate that nearly half (47%) of the population lack access to diagnostics. The diagnostic gap is greatest in primary care, where only about 19% of populations in low and lower-middle income countries have access to the simplest [diagnostic tests](#) (other than for HIV or malaria). The authors call for urgent investment and training to improve access to testing in primary care, especially point-of-care testing.

"There are three things that are essential for health security: diagnostics security, vaccine security, and therapeutic security. Strong health systems, and strong public health system, require all three. Equity starts with regionalizing production of health security commodities as much as possible—and this includes diagnostics," says Dr. John Nkengasong, Director of Africa Centres for Disease Control and Prevention and co-author of the Commission.

At a global level, narrowing the diagnostic gap for just six conditions

(diabetes, hypertension, HIV, and tuberculosis, plus hepatitis B and syphilis for pregnant women) from 35-62% to 10% would reduce the annual number of premature deaths in low-income and middle-income countries by 1.1 million.

Key to closing the diagnostic gap is the availability of trained staff, and the Commission estimates a global shortfall of up to 1 million diagnostics staff, which must be addressed through training and education. "Without a skilled workforce that can use its education and training to the fullest extent, countries will not be able to provide access to diagnostics that are appropriate for each level of care and achieve Universal Health Coverage," says Professor Michael Wilson, Deputy co-Chair of the Commission, Denver Health and Hospital Authority (U.S.).

The Commission further recommends that countries urgently develop national diagnostics strategies based on providing populations with access to a set of essential diagnostics that are appropriate for the local health care needs.

The past 15 years have seen extraordinary innovations in technology and informatics to transform diagnostics, but the Commission warns that the benefits are not shared equitably. The global market for in vitro diagnostics and diagnostic imaging is valued at US\$843 billion. High-income countries dominate, and just four companies in the U.S. and Europe account for half of the global supply of in vitro diagnostics, while four companies from the U.S., Europe and Japan account for three-quarters of the global supply of imaging equipment.

"The COVID-19 pandemic has illustrated the risks involved in relying on a small number of medical suppliers. Expanding the production of diagnostics by locating more research, development and production in low- and [middle-income countries](#) is a key priority," says Professor Susan Horton, Deputy co-Chair of the Commission, University of

Waterloo (Canada).

Other recommendations from the Commission include improving affordability, enhancing regulatory frameworks to oversee quality and safety of diagnostics, and democratizing diagnostics (increasing availability of point-of-care tests, self-sampling and self-testing).

Writing in a linked Comment, Dr. Sabine Kleinert, Senior Executive Editor and Dr. Richard Horton, Editor-in-Chief of *The Lancet* add: "Rapid lateral flow, PCR, and antigen tests for SARS-CoV-2 are discussed daily by politicians, journalists, and the public and available for home self-use or in public places, at least in many high-income countries. Genetic testing to identify SARS-CoV-2 variants early helps in monitoring the spread of the virus and informs vaccine strategies. This rapid need for diagnostic capacity and testing has also further increased inequity, shown the manufacturing and capability deficiencies in countries where it is needed most, and raised the ugly spectre of nationalism as a reaction to a global emergency...More attention to diagnostics as a fundamental element of health systems will not only help end the COVID-19 pandemic and strengthen preparedness to combat future pandemics, but will also be crucially important for general disease prevention, high-quality health care, and improved [health](#) outcomes globally."

More information: The Lancet Commission on diagnostics: transforming access to diagnostics, *The Lancet* (2021). DOI: [doi.org/10.1016/S0140-6736\(21\)00673-5](https://doi.org/10.1016/S0140-6736(21)00673-5)

The report will launch at a virtual event co-hosted by FIND, the global alliance for diagnostics, on Thursday Oct 7, 1pm UK time. Register for free:

https://finddx.zoom.us/webinar/register/WN_VZXIezXdTwmF6jeXnYc_gog

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