Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

The unsustainable anachronism of tuberculosis diagnosis

When approximately 40% of people who develop tuberculosis (4·2 million of an estimated 10·6 million people, in 2021, according to WHO) are not diagnosed, how can the widespread use of sputum smear microscopy for initial diagnosis—a method developed over a century ago—still be justified?

Sputum smear microscopy has been invaluable for tuberculosis diagnostics, but it has major limitations, including inadequate sensitivity, poor performance in some populations (eg, children and people living with HIV), and inability to detect antimicrobial resistance.

For over a decade, WHO guidelines have recommended the use of WHO-endorsed, rapid, primarily molecular methods (ie, WHO-recommended diagnostics [WRDs]) for initial tuberculosis testing. And yet, in 2021, only a quarter of tuberculosis diagnostic sites worldwide had WRDs. As a result, only 38% of new or relapsed diagnosed cases of tuberculosis were initially tested with a WRD, when according to the WHO End TB Strategy all people with presumptive tuberculosis should be initially tested with a WRD by 2025. Furthermore, only 70% of individuals with bacteriologically confirmed tuberculosis were tested for rifampicin-resistant infection, and even fewer for infections resistant to other antibiotics, falling short of the End TB Strategy target that all bacteriologically confirmed cases undergo drug susceptibility testing by 2020.

Recognising diagnostics as the weakest link in the continuum of care for tuberculosis, on April 18, WHO published a standard for universal access to rapid tuberculosis diagnostics. The document outlines 12 benchmarks, mapped across the diagnostic cascade, that countries should use to identify gaps and track progress as they expand access to WRDs as initial tuberculosis diagnostic, with the goals of increasing detection of bacteriologically confirmed cases and drug resistance and of reducing the diagnostic turnaround time.

WHO's standard is a useful pragmatic tool to support countries in strengthening their tuberculosis diagnostic capacity, but whether it will be employed will depend on political will and financing. In 2021, only US$5·3 billion was spent on tuberculosis (out of a $13 billion target) and less than 3% of that amount accounted for diagnostics. Funders must ramp up their investments, to bear the multifaceted costs of transitioning towards universal access to rapid tuberculosis diagnostics.

First, national tuberculosis programmes will need financial support to establish strategic plans for combating tuberculosis, starting from diagnosis. Second, available WRDs are expensive, so low-income and middle-income countries with a high tuberculosis burden will require funding to acquire the tests they need. Increased demand is expected to drive a drop in costs and to promote innovation.

Third, investment in the development of novel diagnostics is necessary. In 2021, $1 billion was made available, half of the target. Yet, existing rapid diagnostics would benefit from innovation in terms of sample type, sample collection, and multi-disease detection. One promising example is a point-of-care molecular diagnostic test that uses tongue swabs and was developed by LumiraDx (London, UK); LumiraDx has received funding from the Bill & Melinda Gates Foundation and is currently testing its platform in preclinical studies in Africa. And attempts to integrate molecular testing for tuberculosis and other diseases have been made, as exemplified in an Article by Emily Lai-Ho MacLean and colleagues in this issue, which showcases the feasibility of co-testing COVID-19 and tuberculosis using GeneXpert (Cepheid, Sunnyvale, CA, USA).

Finally, funders, alongside governments, must support decentralisation of the manufacture of tuberculosis diagnostics. High-burden countries should not be forced to rely entirely on suppliers based in high-income countries and self-sufficiency should be facilitated.

Tuberculosis is a preventable and curable disease. Accurate diagnostics are available. Efficacious treatments are available. Guidance, advocacy, approaches, and solutions to enable universal access to rapid diagnostics and care are available. Even diagnostic infrastructure, built to unprecendented magnitude for SARS-CoV-2 detection and offering repurposing opportunities, is available. The diagnostic gap that precludes individuals with tuberculosis from even accessing the continuum of care is scandalous, and a failure of governments, national tuberculosis programmes, funders, and international organisations to take action to fill this gap will be inexcusable. ■ *The Lancet Microbe*

World Health Organization 2023

For the **Global Tuberculosis Report 2022** see https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022#:~:text=The%20WHO%20Global%20Tuberculosis%20Report,TB%20commitments%2C%20strategies%20and%20targets

For the **End TB Strategy** see https://www.who.int/teams/global-tuberculosis-programme/the-end-tb-strategy

For **WHO's standard for universal access to rapid tuberculosis diagnostics** see https://www.who.int/publications/i/item/9789240071315

For more on **LumiraDx's diagnostic test** see https://www.lumiradx.com/uk-en/news-events/lumiradx-announces-new-investment-for-ongoing-development-of-its-point-of-care-molecular-tuberculosis-test

For the **Article on co-testing COVID-19 and tuberculosis** see **Articles** page e452

For more on **advocacy** see https://www.stoptb.org/news/launched-key-asks-tb-stakeholders-un-high-level-meeting-tb

For more on **approaches** see *Nat Microbiol* 2023; 8: 756–59