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T7 Task Force Global health

Policy Brief

THE ESSENTIAL ROLE OF DIAGNOSTICS IN GLOBAL HEALTH & DEVELOPMENT

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Abstract

Quality, timely diagnosis is an essential enabler of health for all, yet diagnosis remains the weakest link in the care cascade. The COVID-19 pandemic has further highlighted how access to timely, accurate diagnostics is fundamental to effective healthcare and ensuring global health security. Progress has been made during the pandemic to enhance testing and surveillance capacity, but access to testing is still highly inequitable in low- and middle-income countries. As a result, meaningful action is needed to leverage the progress made during the COVID-19 pandemic in diagnostics and close the gaps that remain. FIND, the global alliance for diagnostics, alongside the Coalition for Epidemic Preparedness Innovations, is coordinating the ambitious mission to create the tests necessary to respond to the next global threat within 100 days, as part of the 100 Days Mission. The support of the G7 will be vital in achieving these goals. This policy brief outlines our policy recommendations for the G7 to achieve the 100 Days Mission and create a future with equitable access to diagnostics and strong global health security.

Challenge

Diagnosis is the weakest link in the care cascade

Quality, timely diagnosis is an essential enabler of health for all. Early diagnosis has been consistently linked to improved health outcomes and reduced out-of-pocket spending, while disease surveillance provides critical data to inform public health action. However, diagnosis is the weakest link in the care cascade. The capacity to perform basic tests is available in just 1% of primary care clinics in low- and middle-income countries (LMICs) (Leslie, Spiegelman, Zhou, & Kruk, 2017). Worryingly, no diagnostic tests exist for 60% of the pathogens identified by the World Health Organization (WHO) as having the greatest outbreak potential (FIND, 2021). There are also no appropriate tests for half of the top 20 diseases responsible for the most lives lost (FIND, 2021).

As highlighted in the 2021 report of *The Lancet* Commission on Diagnostics, three major global health priorities—universal health coverage, antimicrobial resistance, and global health security—all require better access to diagnostics (Fleming et al., 2021). The idea that diagnostic tests are central and fundamental to quality and equitable healthcare is under-recognized, leading to underfunding, poor coordination with other disease control efforts, and inadequate resources at all levels (Fleming et al., 2021).

The key learnings from COVID-19 reveal a path to Universal Health Coverage (UHC) and the Sustainable Development Goals for health, and investing in diagnostics will be central to achieving these goals

Since the onset of the COVID-19 pandemic in January 2020, testing has had a central role in both pandemic control and politics, while the virus has swept through the world. Years of underinvestment in diagnostics research, test kit manufacturing, global laboratory systems, and global surveillance through diagnostics tools meant that both high- and low-income countries found themselves without the tests necessary to contain the spread of SARS-CoV-2. Fragile supply chains and nationalism sparked fierce competition for the procurement of the few tests available early on in the pandemic. In parallel, pandemic-related disruptions to essential health services had dire consequences for both infectious and noncommunicable diseases that might have been mitigated with a more robust and sustainable strategy for testing as a core component of healthcare delivery (Stop TB Partnership, 2021; The Global Fund, 2021).

COVID-19 has driven innovation in test development and deployment. New platforms for molecular diagnostics (PCR) have the potential to be as revolutionary for testing as mRNA platforms are for vaccines. New digital technologies, such as artificial intelligence-powered mobile apps and computerized cough analysis to differentiate between COVID-19 and tuberculosis (TB) are continuing to improve testing globally. Connectivity is paving the way for healthcare services to be accessed directly through mobile and digital apps in the farthest reaches of the world, and the rise in wearable technology and at-home tests is transforming self-monitoring and self-testing approaches (FIND, 2021).

Alongside this great progress, however, is the hard truth that the COVID-19 pandemic has exposed huge inequities in testing – of more than 4.7 billion COVID-19 tests administered globally since the beginning of the pandemic, only 0.4% have been administered in low-income countries. Currently, high-income countries

use COVID tests at 10–100 times the rate of LMICs and low-income countries, a massive inequity that is growing, not shrinking, in 2022 (FIND, 2022).

As a result, meaningful action is needed to leverage the progress made during the COVID-19 pandemic in diagnostics and close the gaps that remain – and leave us vulnerable to future pandemic threats.

Proposals

The COVID-19 pandemic has shown that access to timely, accurate diagnostics is fundamental to effective healthcare. Testing is not just for technical experts; politicians and policy makers need to understand rapid product development, regulatory issues, test kit manufacturing, healthcare capacity, guideline development, and healthcare financing at a level on par with drugs and vaccines. Strong regional and country leadership under COVID-19 has led to enhanced testing and surveillance capacity, but needs further development, collaboration and financing. In particular, the organizations leading this work to enhance diagnostic capacity – WHO; the Access to COVID-19 Tools (ACT) Accelerator and its Diagnostic Pillar; FIND, the global alliance for diagnostics; the Coalition for Epidemic Preparedness Innovations (CEPI); Unitaid; and the Global Fund – need sustained financial support.

The ambitious 100 Days Mission (100DM) aims to harness scientific innovation and public-private collaboration to ensure safe and effective diagnostics, therapeutics and vaccines are ready to be deployed within the first 100 days of a future pandemic threat being identified (GOV.UK, 2021). The 100DM has been welcomed by G7 leaders, global life science industry leaders and the G20. A key component of the 100DM is the aim is to have “accurate and approved rapid point-of-care diagnostic tests” available within 100 days (ideally sooner) of a future pandemic threat (GOV.UK, 2021).

FIND, in partnership with CEPI, will coordinate this global moonshot mission to create the tests necessary for the 100DM. Testing is the essential first step in pandemic preparedness – identifying the enemy and directing the development of vaccines and treatments.

FIND, CEPI and its global partners are working on diagnostic pandemic preparedness in five key areas:

1. diagnostic test kits for the highest priority pathogens, which can be adapted quickly to any emerging pathogen, including novel diagnostic platforms;
2. normalizing regular diagnostic testing;
3. ensuring global access to diagnostic testing through reliable local manufacturing capacity and investments in testing networks in LMICs;
4. global surveillance systems to detect and monitor emerging pandemic threats, old and new; and
5. global cooperation and coordination on areas such as testing policy, emergency regulatory authorization, and global data sharing.

FIND and CEPI will work to support global R&D to accelerate the development of prototype diagnostics against priority virus families, and strengthen engagement with LMICs to improve access and promote uptake. However, achieving equitable access to diagnostics for all and the 100DM needs the continued strong support of the G7.

Consequently, we propose the following policy recommendations that would help achieve a future with equitable access to diagnostics and strong global health security.

Short-term:

Recommendation 1: World Health Assembly (WHA) resolution – “UHC and pandemic preparedness must include appropriate and equitably accessible diagnostics”. A resolution on the importance of diagnostics, supported by WHO member states including members of the G7 and following the recommendations from this paper, would be important to establish specific policy objectives, focus and a mechanism for accountability. A WHA resolution can motivate global stakeholders to drive progress in equitable access to diagnostics and provide a framework under which initiatives to meet the resolution’s goals can be established.

Mid-term:

Recommendation 2: Establish a Global Diagnostics Alliance to drive global equity in testing for UHC and global health security. As called for by *The Lancet* Commission (Fleming et al., 2021), we must build on the successful efforts from the ACT-Accelerator Diagnostics Pillar, co-led by FIND and the Global Fund, and create a permanent diagnostics alliance. This alliance will play a key role in R&D and advocacy, and setting specific targets to reach equitable access to tests across major areas of concern in UHC and health security.

Longer-term:

Recommendation 3: Establish national diagnostics strategies to support National Health Plans, including the development and implementation of national Essential Diagnostics Lists. Diagnostic testing must be acknowledged as a key enabler for health, and supported by adequate funding, for example through national financing strategies for diagnostics, and coverage of diagnostics for key conditions in UHC benefits packages. As global leaders, G7 members can advocate for the establishment of national diagnostic strategies globally and support their development, leveraging the collective healthcare expertise of G7 members, as well as private sector and academic knowledge and resources.

Implementations

Addressing shortfalls in diagnostic testing must be an urgent priority. Deficiencies in testing affect not only people’s lives, but communities and economies, as COVID-19 clearly showed. Strong global leadership and political will is needed to accelerate change and lead the world towards a better future. Consequently, the G7 is uniquely positioned to provide the strategic leadership to address the specific policy challenges around equitable diagnostics. Moreover, the total breakdown of trade, travel, economies and societies during the COVID-19 pandemic showcases that in a globalized world, ignoring health and testing for infectious diseases

(and thus our ability to control pandemics), is one of the largest threats to prosperity. Health spending must not be seen as an expense, but rather an investment in economic, social and equitable progress.

Concrete steps to implement policy recommendations and key actors

In terms of immediate concrete steps to achieve the proposals set out here, the first is to build broad global commitment for diagnostics and testing through the G7, G20 and ultimately the WHA as outlined above. The adoption of a WHA resolution on the vital need for diagnostics, committing member countries to incorporate this into their national policies, would greatly facilitate action across the world. Accordingly, efforts are underway to assemble a broad coalition to move this forward.

The aim is to submit a draft resolution to the Executive Board of WHO by October 2022, in preparation for submission to the January 2023 Board meeting (World Health Organization, 2022a), and for approval at the May 2023 meeting of the WHA. A successful resolution needs the sponsorship of a range of countries from different regions, including countries from different income levels. This relies on leadership and commitment by Ministers as well as Director Generals of Health at the country level. Non-state actors with official standing with WHO (World Health Organization, 2022b) can also provide input at the WHA and their support will be important.

Actions that could be included in the resolution are as follows and can be already highlighted by G7 Ministers of Health through their communiqués, depending on the country priorities.

Key actions for Member States, taking into account their national circumstances, should be to:

- establish a national diagnostics strategy as part of their National Health Plan;
- develop a national Essential Diagnostics List, adapting the WHO list to local context and plans to fund gaps in access to essential diagnostics;
- make key essential diagnostics available at the primary healthcare level, and to include essential diagnostics in UHC and other community insurance benefits packages;
- invest in developing an appropriate workforce at all levels of the health system, with the skilling and upgrading needed to support advances in diagnostics;
- commit to regulatory frameworks for diagnostics; and
- commit resources to invest in research and product development and expanding manufacturing capacity for diagnostics and surveillance.

There is also an immediate need to follow up and keep momentum created through the consensus at the G7 meeting in 2021 for the 100DM. The 100DM plan to respond to and extinguish the next global threat within 100 days of WHO declaring a major outbreak or pandemic may sound like a lofty ambition, but it is achievable if:

- enhanced surveillance systems are in place for early threat detection;
- point-of-care testing platforms are developed and rolled out worldwide to diagnose disease outbreaks as they happen;
- manufacturing capacity is established globally, in a coordinated and distributive framework for rapid technology transfer to minimize over-reliance on any one source and keep supply pipelines open;

- our testing systems are linked to rapid public health interventions, breaking chains of transmission in real time – and keeping our health systems from being overwhelmed;
- worldwide testing is accompanied by accelerated development of vaccines and therapeutics, which can be similarly rolled out in 100 days; and
- global equitable access to tests, vaccines and therapeutics is guaranteed.

Close collaboration among global health agencies during the COVID-19 pandemic, alongside academia, industry, national health agencies and private sector service providers, provided a roadmap for the swift development and distribution of both vaccines and diagnostic tests and the same level of partnership and collaboration will be required to address future pathogens that threaten to overwhelm us the way SARS-CoV-2 has.

We need the world to step behind this plan and create the resourcing and collaboration network to achieve its goals, which will help us achieve UHC and stronger global health security. The support of G7 leadership is essential for this to become a success.

Disclaimer:

All authors are responsible for the content and recommendations contained within this policy brief. The policy brief has been written as part of a consultation process for the T7 Taskforce for Global Health, led by Taskforce's Co-Chairs Ilona Kickbusch, Anna-Katharina Hornidge and Githinji Gitahi, but it does not represent the official position of the Taskforce or the authors' employers.

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Dr Bill Rodriguez joined FIND as Chief Executive Officer on 1 July 2021, following an earlier tenure as Chief Medical Officer between 2015 and 2017. He was previously Managing Director at the Draper Richards Kaplan Foundation, a global venture philanthropy firm supporting early-stage, high-impact social enterprises. A physician and entrepreneur, he has extensive experience across both private and public sectors, founding his own diagnostics company, Daktari Diagnostics. As a faculty member at Harvard Medical School, he established a research programme on diagnostics and operational research in global health. He left Harvard in 2003 to become the Chief Medical Officer of the William J. Clinton Foundation, where he helped broker pricing agreements of HIV drugs and diagnostic tests between African and Asian governments and the major suppliers. Bill is a highly respected figure in the global health community, serving as advisor to the World Health Organization, Bill & Melinda Gates Foundation, national governments on global HIV, tuberculosis, Ebola and COVID-19, as well as numerous established and start-up for-profit and not-for-profit social enterprises focused on global health. Bill is a graduate of Brown University and the Yale University School of Medicine, and trained in infectious disease medicine at the Brigham & Women's Hospital in Boston, where he served as chief medical resident.

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Willo Brock joined FIND as Director of External Affairs in February 2021. In this role, he is responsible for driving stakeholder engagement, communication, advocacy, and resource mobilization. Willo has almost 30 years of global development and health experience. Previously, he was Senior Vice President External Affairs at TB Alliance for seven years and worked for large international development organizations like WWF and Habitat for Humanity. His passion is bringing together people, for-profit organizations, governments and civil society to tackle global issues of insecurity and inequality and develop effective programmes giving people opportunities for growth and development.

Willo started his career working for the Netherlands Ministry of Development in Pakistan and later moved to MDF Training & Consultancy, gaining over ten years of management consultancy, training, coaching and project management experience focused on non-profit clients. He has worked in over 90 countries globally. Willo earned a master's degree in business economics from Erasmus University Rotterdam.

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Karishma joined FIND in 2019 and is currently Senior Manager, Advocacy and Communications. She also fulfills the role of Secretariat for the Stop TB's New Diagnostics Working Group (NDWG), hosted at FIND. She has a keen interest in public health strategy, advocacy, community engagement, communications, and policy research.

Prior to joining FIND, Karishma was a TB Policy Officer at Stop TB Partnership/United Nations Office for Project Services (UNOPS) in Geneva. In her current role, Karishma is leading on advocacy, communications, and civil society engagement for the Access to COVID-19 Tools (ACT) Accelerator Diagnostics Pillar for FIND. Karishma received her BSc in Life Sciences and Biochemistry from St Xavier's College, University of Mumbai and her MSc in Global Health and Development from University College London (UCL).



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