

A CIVIL SOCIETY VISION FOR STRENGTHENING DIAGNOSTIC CAPACITY FOR ALL

INTRODUCTION: AN OPPORTUNITY TO END DIAGNOSTICS INEQUITY AND PROVIDE PERSON-CENTERED CARE

At a moment of scant resources, colliding health, climate and conflict-related priorities, the world's health systems are—overwhelmingly—flying blind: delivering care to people without access to the diagnostics needed to confirm and appropriately treat conditions, and setting policies with no data. In 2021, The **Lancet Commission on Diagnostics** found that nearly half of the world's population has “little to no access” to diagnostics¹, with the greatest gaps existing at the primary health care level in **low and lower-middle income countries**.

According to original research by The Lancet Commission on Diagnostics, diagnosis is the greatest gap in the care cascade of screening, diagnosis, treatment, and treatment completion. Every day, millions of people fail to receive care guided by a clear, confirmed answer about the source of their symptoms. People suffer and die needlessly, lacking information needed for protection of their health and their loved ones. Infectious diseases, including new pathogens, spread unchecked within households and communities, while health providers and systems waste time, energy and resources on treating without testing.

As long as nearly half the world lives in diagnostic deserts, universal health coverage and true pandemic preparedness are impossible. Detecting and responding to outbreaks of new or known pathogens depends on having accurate, affordable tests where they're needed—delivered in programs that people trust.

Today there is a new opportunity to end global diagnostics inequities. In May 2023, the World Health Assembly (WHA), the decision-making body of the World Health Organization (WHO), adopted **a resolution on strengthening diagnostics capacity**.² The resolution included fifteen recommendations for action (see Figure 1) responsive to the reality that “equitable access to diagnostics, in particular diagnostic imaging in developing countries, is particularly deficient and that targeted efforts are needed to lift these barriers.”

While the WHA resolution is a powerful tool and a critical step toward country commitments, the recommendations are not requirements. Right now, there is no accountability framework for tracking gaps and progress. This can change if civil society seizes the opportunity and demands that the resolution deliver results. A coordinated movement for diagnostics equity must span disease areas and health concerns. The tests and tools for diagnosing diseases and health conditions vary in type and in level of priority for a given country or community, depending on burdens of diseases and country health priorities. The vast diagnostics category includes everything from rapid tests for respiratory viruses like SARS CoV-2 and influenza and HIV self-tests to DNA-based PCR tests that “read” the genetic sequence of tuberculosis and other germs, allowing for identification of drug resistant pathogens. The diagnostics category also includes imaging technologies for diagnosing and treating many diseases including tuberculosis and cancer.

A **people-centered care** (PCC) approach unites all of these, and other, diagnostic needs. PCC centers people and communities and emphasizes the need to put the right services in the right places—close to communities. PCC looks different in different contexts, but it always requires communities to be involved as educated consumers, health workers and advocates for their own health and lives. Diagnostics that provide accurate information to guide self-care, care for loved ones and community action are essential to PCC.³

¹Kenneth A Fleming, Susan Horton, Michael L Wilson, Rifat Atun, Kristen DeStigter, John Flanigan, et al. **The Lancet Commission on diagnostics: transforming access to diagnostics** The Lancet, Vol. 398, No. 10315 (October 6, 2021) :[https://doi.org/10.1016/S0140-6736\(21\)00673-5](https://doi.org/10.1016/S0140-6736(21)00673-5).

²World Health Organization (2023). Seventy-sixth World Health Assembly, Agenda item 13.1: Strengthening Diagnostics Capacity. (https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R5-en.pdf, accessed 25 October 2023)

³https://www.who.int/health-topics/integrated-people-centered-care#tab=tab_3

To end diagnostics inequity and achieve people-centered care, countries, communities, and global stakeholders need to work together to close gaps and solve problems. In some regions, researchers and scientists are already developing context-specific priorities.⁴ But there is much more to be done. A local-to-global movement for diagnostics equity is needed to accelerate progress, shine light on best practices and hold accountable the duty bearers who fail to deliver.

NO PROGRESS WITHOUT ACCOUNTABILITY: A CIVIL SOCIETY CONSULTATION ON TURNING COMMITMENTS INTO ACTION

In September 2023, on the sidelines of the 78th UN General Assembly, more than forty advocates, activists and health care providers from Africa, Asia, Europe and the Americas gathered for *Diagnostics, Equity and Access*. Organized by FIND, CHAI, Open Society Foundations, PATAM and the O'Neill Institute for National and Global Health Law, the meeting engaged participants with lived and professional experience of inadequate diagnostic coverage for a range of diseases, including HIV, tuberculosis, diabetes, hypertension, cancer and other health conditions. The diverse group was united around the urgency of transforming the diagnostics landscape from grossly inequitable to globally robust. As one participant stated, “Universal health coverage remains a dream without diagnostics.”

The May 2023 WHA resolution on diagnostics provided a starting point for discussion. While it is not the first declaration of the global need to address diagnostics access,⁵ it is the first WHA resolution devoted solely to the subject—and the first since the COVID-19 pandemic brought global inequities in access to countermeasures into stark relief. According to FIND’s SARS CoV-2 Test Tracker, just over 20 percent of more than 6.5 billion tests performed worldwide since 2020 have been administered in low- and lower-middle income countries, despite those countries comprising 50.6 percent of the global population⁶.

Participants agreed that while the WHA resolution has many strong, actionable recommendations, it is not widely-known among civil society groups working on health equity and access to medicines—and risks being one of many such resolutions that governments sign, without taking any additional action. Instead of shelving the document, it needs to be turned into plans and programs. The meeting was the first global civil society-led consultation on how to make this happen.

Participants agreed on two critical, connected steps. First, existing commitments need to be paired with an accountability⁷ framework with responsibilities, milestones and metrics for assessing gaps and progress. Second, a globally coordinated, locally led, disease-agnostic diagnostics advocacy movement is needed to make sure this accountability framework is created, implemented and delivers results. One way to create this accountability framework—and to galvanize a civil society movement—is to develop and share a Diagnostics Access Agenda that drives action on all fronts.

Such an Agenda could be structured around five actions that are crucial for progress.

- **Turn plans into strategies that yield results**
- **Demonstrate diagnostics leadership at every level**
- **Gather, share and act on data**
- **Ensure affordability**
- **Create a global movement**

In the coming months, the plan is to transform these action areas into a detailed action agenda led by the Diagnostics Equity Consortium through consultation with groups from around the world. The focus will be on gaining input and buy-in from civil society from regions where the diagnostics gap is greatest. This document is a starting point for discussion, with potential actions, outcomes and civil society roles listed below. This is a draft vision. We need to work together, as civil society, to map the bold and practical steps to make it a reality. As the Lancet Commission report stated, “An advocacy programme directed at national governments to develop, fund and implement national strategic diagnostics plans is therefore vital.” As FIND Board Chair Dr Ayoade Alakija stated in her opening plenary talk, “Civil society is the sinew connecting commitments to action.”

⁴Mfuh KO, Ananda NN, Titanji BK (2023) Strengthening diagnostics capacity in Africa as a key pillar of public health and pandemic preparedness. *PLOS Glob Public Health* 3(6): e0001998. <https://doi.org/10.1371/journal.pgph.0001998>

⁵World Health Organization (2008). [The Maputo Declaration on Strengthening of Laboratory Systems](#) (accessed 26 October 2023).

⁶FIND (2023). <https://www.finddx.org/tools-and-resources/dxconnect/test-directories/covid-19-test-tracker/>

⁷Accountability refers to answerability for decisions, actions, and outcomes. Accountable stakeholders provide information, explanations and justifications (reasons), and can be held responsible for remediating gaps and shortcomings in the arenas for which they are responsible. Stakeholders may be responsible for financing, performance or political leadership, and accountability frameworks can be used to engage in each of these domains. See Brinkerhoff DW. Accountability and health systems: toward conceptual clarity and policy relevance. *Health Policy Plan.* 2004 Nov;19(6):371-9. doi: 10.1093/heapol/czh052. PMID: 15459162.

FIVE ACTION AREAS FOR AN ACCESS AGENDA

1. Turn plans into strategies that yield results

Action: All countries should develop multiyear diagnostics strategies and national essential diagnostics lists. These strategies must have milestones for achieving specific coverage levels of specific tests, looking closely at the primary healthcare level, where the largest gaps in access occur. There must be an annual review process for the national diagnostics strategy.

Outcome: National commitments that can be costed, tracked and used to assess needs, gaps and progress at local, national, regional and global levels.

Civil society role: Demand government-led planning processes, and, where needed, develop independent civil society analyses or roadmaps with ambitious milestones and priorities. Hold governments accountable for sustainable implementation of diagnostics strategic plans, development partners (where relevant) accountable for financing and WHO accountable for tracking and sharing global progress. Advocates have experience with providing input into and using National strategic plans (NSPs) for specific diseases and disease areas as tools for advocacy and accountability.

Rationale and context: The WHA resolution recommends that member states develop diagnostic strategies and essential diagnostic lists. Strategies and lists are important, but insufficient. Countries must develop and finance multi-year plans with measurable goals including coverage of priority packages of diagnostics per specific health levels, with attention to the great unmet needs at primary healthcare, and provision for annual reviews of progress. The Lancet Commission suggests that such a strategy be included in countries' universal health coverage benefits package, which will, ideally, also center people-centered care.

2. Demonstrate leadership at every level

Action: Key organizations, agencies and governments have focal people who are empowered and mandated to support implementation of the WHA diagnostics resolution, including WHO regional offices, national government ministries of health, and civil society coalitions.

Outcome: Roles and responsibilities are well-defined at multiple levels, replacing a diffuse ecosystem lacking focal people at many levels with a network of accountable individuals.

Civil society role: Push for the appointment of diagnostics focal people where they do not exist (ministry of health, district, or provincial levels); where they do exist, advocate for this individual to have mandate and resources to convene across ministries and health issues. Support the development of individual and coalition-wide diagnostics expertise, for example through the establishment of diagnostics community advisory boards (CABs), and support for diagnostics "fellows" who are resourced to build and share literacy.

Rationale and context: Expanding access to, uptake of and demand for diagnostics requires work across diseases and priority areas including pandemic preparedness and response, universal health coverage and non-communicable diseases. It also requires active engagement by ministries of finance and planning, whose support for investments in core diagnostics packages and, in some instances, manufacturing capacity, is crucial for long-term planning. Multi-sectoral and multi-issue action requires dedicated staffing. Ministries of health should have national diagnostics focal points. The WHO should have a corresponding focal point working with these leads and with relevant experts within and beyond WHO.

3. Gather, share and act on data

Action: Ensure that decision makers, particularly at country and community level, have access to accurate, timely and robust data to identify existing and emerging diagnostics needs and priorities. These data should support analyses of costs, benefits, efficiencies and optimal approaches to people-centered care.

Outcome: The benefits of expanded diagnostics coverage are understood for individuals, families, communities and in terms of return on investment and contributions to the health system; existing diagnostics capacity can be used more effectively and investments into new diagnostics and related manufacturing capacity can be informed by accurate information on need and demand.

Civil Society Role: Build knowledge and expertise in both gathering and analyzing relevant data through CABs, study clubs, diagnostics "fellows" resourced to do deep dives into context-specific issues and topics to shape and strengthen strategies.

Rationale and background: Information is oxygen for accountability work. Both the Lancet Commission Report and the WHA Resolution call for expanded data collection and sharing; however, these actions will not be taken without investments, incentives and requirements by countries, funders and global health actors. There are several types of data on diagnostics that need to be routinely collected, shared and analyzed, including (i) product specific information on cost (where available), index price, and manufacturers for existing diagnostics, which can be used to inform procurement as well as advocacy efforts. (ii) pipeline data for new diagnostics, (iii) utilization and

capacity data that can be used to inform decisions about where to place available equipment or how to problem solve for scarcities in reagents or trained staff, (iv) point of service cost data that captures client experiences and practices, as lab services are often a major source of revenue for local providers and testing algorithms, such as repeat testing for TB, may be shaped (or perceived to be shaped) by profit motives, even when the service is supposed to be free to the user, (vi) data on the impact of packages of diagnostics and expansion of coverage that can be used to inform investment cases.

4. Ensure affordability and sustainability

Action: Address the barriers to affordability and sustainability at every stage from research to roll out, through steps including transparent discussions of price, cost, licensing and technology transfer and other access provisions at the earliest stages of product development, investment cases centered on the benefits of delivering core diagnostics packages for priority diseases that drive mortality, expansion of local and regional manufacturing and other strategies.

Outcome: Cost barriers to procurement existing and emerging diagnostics are removed so that decisions can be made that realize the human right to health in all contexts and for all communities.

Civil society role: Build diagnostics literacy that shapes diagnostics access campaigns including demands that industry engage in early, open conversations about the costs and manufacturing requirements of diagnostics in development, and supply information on the costs of existing diagnostics. Discuss, develop and disseminate product profiles—looking at where and how self-test, rapid tests, multi-disease tests and other tools are needed, and at factors that affect community preferences.

Background and rationale: The WHA Resolution calls for “equitable and timely access” to new diagnostics, technology transfer guided by “voluntary and mutually agreed terms,” and “the rights and obligations of the Trade Related Intellectual Property Rights (TRIPS) agreement as amended. This language is the beginning, but by no means the extent of what is needed to end the lethal and egregious global gaps in diagnostics equity. It is essential that the private sector be impelled to share information on costs of existing diagnostics, research and development plans, and facilitating local and regional manufacturing through technology transfer and licensing agreements, potentially working with an organization such as the Medicines Patent Pool as the repository for diagnostics licenses. Incentives and conditionalities for R&D funding, procurement contracts and/or access to genomic and other information from countries may be needed to ensure that the private sector contributes the information and expertise needed.

5. Create a global movement

Action: Mobilize, fund and energize global and local advocacy for diagnostics access. *Outcome:* Siloes between disease areas and health issues are dismantled, replaced with an advocacy agenda that advances equity in access to the entire class of diagnostics including imaging technologies, with each country and community defining its essential needs.

Civil society role: Lead the movement. Develop a People’s Charter or Call to Action, using this agenda as a starting point, and adapting to local contexts. Bring diagnostics into existing advocacy efforts and push funders to support activities that expand work in this area.

Background and rationale: Diagnostics are a category of products. Specific disease areas, including tuberculosis and HIV, have cadres of informed, strategic activists and advocates focused on diagnostics—but there has yet to be a coordinated effort to link these and other efforts into the kind of powerful advocacy movement needed to ensure equity to the entire class of tools and technologies. Such work hasn’t been resourced and hasn’t been a priority. The current state of diagnostics access reflects this lack of attention and sustained, coordinated and strategic advocacy and activism. To take on this arena in all its complexity, and ensure access expands for all essential tools at all levels of the health system, advocacy is essential. It must be funded, prioritized and fueled by leaders from the most impacted communities. Moreover, the resources must support all the components of effective advocacy, including:

- *Evidence and education:* the data described in (3) need to be available in user-friendly formats accessible to the public and/or on request by civil society groups, who should also be involved in data collection and analysis. Diagnostics 101 and diagnostics literacy curricula that break down disease siloes and build a common knowledge base are also essential. Civil society groups working on UHC, HIV/TB/malaria and other issues should commit to seeking resources for and bringing time and energy to efforts to build expertise, i.e. through community advisory boards (CABs), peer-to-peer learning and incorporation of diagnostics into ongoing work.
- *Sustainable, predictable resources for civil society groups and individual advocates:* A new diagnostics movement can be launched using the expertise in existing advocacy efforts—provided there are resources for doing the work. Globally, resources for civil society advocacy and activism are shrinking. HIV-related funding, which has been a major revenue source for many groups looking at access to medicines and quality health care, continues to drop, and civic space for engaging with governments is also shrinking. Other arenas, such as

universal health coverage and PPPR, have yet to fully incorporate resources for advocacy and accountability led by and for impacted communities into their calls for proposals or strategies, and community-led monitoring and accountability is not recognized or mentioned in the UN High Level Declarations on Universal Health Coverage and Pandemic Prevention, Preparedness, and Response.

- *Global coordination and political will:* A globally coordinated coalition of informed champions is the best, if not the only, way to ensure expanded coverage of diagnostics. Diagnostics access and coverage is a global public good. An improved ability to diagnose, respond and treat advances so many interconnected health, security, and development agendas that it is rather remarkable such a coalition does not already exist. It is time to ensure that one does.

TIME FOR A CIVIL SOCIETY COALITION TO DRIVE THE DIAGNOSTICS EQUITY AGENDA

There is an unprecedented opportunity to expand diagnostics capacity for all. Putting the right tests in the right places in person-centered programs is crucial to individual and community health, efficient use of resources and long-term goals of universal health coverage, infectious and non-infectious disease control and pandemic preparedness. Working together and building on ongoing work, civil society can change diagnostics landscape. To do this, we need to develop a common agenda and systems for coordination, skill-sharing and targeted campaigns.

To support this effort, the Pan-African Treatment Access Movement (PATAM) and the O'Neill Institute for National and Global Health Law have launched The Diagnostics Equity Consortium (DEC). Initiated in 2023, the DEC aims to create a unified advocacy agenda addressing diverse country-specific needs. The DEC's goal is to catalyze civil society and affected communities to advocate for, and secure, enhanced diagnostic capabilities across various health challenges. The DEC has a global vision and a specific focus on inequities in sub-Saharan Africa, particularly those affecting primary healthcare. We need all hands for the DEC to succeed. We also need sustainable and sufficient resources for organizing accountability and education activities. Civil society must come together and as we do, global stakeholders must offer financial, political and technical partnership.

To learn more and move forward together, please visit the DEC website at <https://oneill.law.georgetown.edu/projects/diagnostics-equity-consortium/>

DIAGNOSTICS EQUITY CONSORTIUM

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