

The future of diagnostics in Africa

Received: 30 April 2025

Accepted: 26 February 2026

Published online: 22 April 2026

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Persistent gaps in access to quality diagnostic tests undermine progress toward improved health outcomes and resilience to disease outbreaks in Africa. Furthermore, resources for strengthening laboratory systems have faced growing constraints owing to recent reductions in official direct financial assistance, highlighting an urgent need to identify investments that are high impact and minimally donor reliant. In this Perspective, we present a set of priority systems strengthening interventions based on expected impact and feasibility. These include the need for efficient and integrated testing networks, the establishment and implementation of national essential diagnostic lists, modernized procurement and supply chain practices, improved digital health standards and targeted strengthening of testing infrastructure for epidemic-prone diseases. These initiatives should be customized to local contexts and supported by reliable financing, enhanced national leadership and management capacity and updated policies. We propose that collective action focused on these priorities will improve health outcomes and be cost-saving—and will be superior to existing, more fragmented efforts to close gaps in testing. This also provides a pathway to self-reliance in health security and universal healthcare in the Africa region.

Africa faces unique health challenges. It has a disproportionately high burden of endemic diseases such as HIV/AIDS, tuberculosis, malaria, viral hepatitis and cervical cancer, as well as rapidly rising burdens of noncommunicable conditions such as cardiovascular diseases and diabetes¹. In addition, Africa experiences frequent outbreaks of epidemic-prone pathogens (for example Ebola, mpox, Marburg, Dengue and Yellow Fever viruses) with the region accounting for an estimated 40% of reported global disease outbreaks^{1–3}. This constitutes a major constraint to development and is further amplified by climate change, high levels of antimicrobial resistance and socioeconomic disparities^{4–7}, political instability and recent reductions in international aid to fight HIV/AIDS, tuberculosis, malaria and other priority diseases^{8,9}.

Addressing these challenges will require major improvements in health services, including access to diagnostics. The recent Lancet Commission on Diagnostics reported that insufficient testing capacity is the largest gap in access to healthcare, with up to 80% of people living in low- and middle-income countries without access to essential diagnostics¹⁰. A World Health Assembly Resolution on Strengthening

Diagnostics Capacity, adopted in May 2023, called for action to address this gap, increase financing and improve access to new technologies¹¹.

Investments over the past 20 years in diagnostics for HIV, tuberculosis, malaria and recently for coronavirus disease 2019, improved the delivery of services for these diseases. Still, major gaps remain for these and other conditions, including epidemic-prone diseases^{12–15}. This raises the question as to whether past approaches in laboratory systems strengthening, often driven by vertical and donor-funded programs, are sufficient to close the remaining gaps, and whether a clear understanding exists of the nature of the barriers to improvement and how to overcome them. Although health targets continue to expand, testing services are falling behind the levels needed for Universal Health Coverage and effective pandemic preparedness^{16,17}. Despite this, recent innovations in diagnostic technology, data management and health systems hold much promise^{18,19}, making now a good time to carefully assess current testing gaps and their underlying causes, and to identify new, more effective and feasible pathways to close them.

The Future of Diagnostics in Africa Initiative was convened in 2023 by Africa Centers for Disease Control and Prevention (Africa

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CDC) and the African Society for Laboratory Medicine (ASLM), with the goal of identifying feasible interventions in diagnostics that could lead to a transformation in testing services and health impact. The initiative assembled a group of over 100 experts from 20 countries in Africa and over 50 organizations including national laboratory and Ministry of Health leadership, community representatives, regional and global health organizations, donors and academia. These experts reviewed regional and international recommendations, country, technical agency and donor laboratory strategy documents, and technical articles on diagnostics and health systems strengthening, to develop a set of recommended interventions. The findings for five high-priority areas—relating to essential diagnostics lists (EDLs), data systems and digital technologies, network design and integration, procurement and supply chains, and pandemic preparedness—are described below.

National EDLs

The development and implementation of national EDLs is strongly recommended by the World Health Organization (WHO)^{20–23}. The establishment of EDLs (including in vitro diagnostics, body function monitors and imaging) is considered one of the most important and feasible steps toward improved testing services and universal healthcare, and should be prioritized by every country, along the lines of Essential Medicines Lists that most countries already have. In 2022 Nigeria became the first country in Africa to develop a national EDL²⁴. The list comprised 145 diagnostic tests, including 12 general and 15 disease-specific tests required at primary health and community levels. The existence of this policy has provided clear testing commitments and a formal framework for resource allocation toward expanding basic laboratory services into communities, which in turn is supporting Nigeria's efforts in achieving its universal healthcare goals.

However, few additional low- and middle-income countries (less than ten reported as of February 2026) have national EDLs, and many countries lack policies to define what tests are part of essential health services. Even where such definitions exist, implementation is often limited due to infrastructure, financial limitations, supply chain issues and other systemic challenges^{20,25,26}. The absence of defined lists limits resource allocation for testing within national health and hospital budgets.

There are ways to overcome these barriers and catalyze a major shift in EDL development (Fig. 1). First, advocacy at regional level by Africa CDC, WHO, ASLM and others can help elevate the importance of national EDLs as a foundation for universal healthcare and pandemic preparedness. This should be complemented by advocacy from community representatives to ensure that closing gaps in access to essential diagnostics remains high on the agenda of policymakers and funding bodies. Second, countries should establish multidisciplinary teams with diagnostic, clinical, epidemiological and health finance expertise to develop and periodically update national EDLs. These teams should also be responsible for developing implementation plans and proposed budgets to translate policy into equitable access to testing. Third, national EDLs should be aligned with national essential medicines lists with concerted efforts to ensure that appropriate tests are covered by national health budgets and insurance schemes. Finally, regular monitoring of EDL development and implementation, supported by national and regional dashboards, will be key to tracking progress and ensuring accountability.

The implementation of expanded lists of essential tests will take time and needs to be done in stages, starting with high-priority tests. National EDLs should be published and disseminated by governments, and used to inform investment in testing capacity and the mapping of access to tests. To enable national adoption of new diagnostics, support from a regional regulatory harmonization body for Africa, such as the African Medicines Agency, and from the WHO is considered a priority²⁷. Africa CDC, with national and global experts, is well poised to provide guidance on priority diagnostic tests for the region, while aligning with

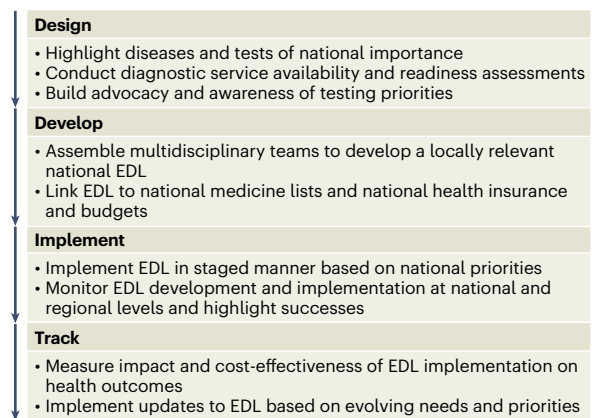


Fig. 1 | A staged process for national EDLs. The development and implementation of an EDL require several steps that align testing services with delivery of national health services. The list should inform national testing strategies and programs aimed at strengthening the access and quality of both existing and new testing services. Essential test implementation should be regularly tracked to identify and close gaps in access.

WHO recommendations, to support countries developing their own national lists. In fact, the Africa CDC and African Union Development Agency - New Partnership for Africa's Development have already established a Diagnostic Advisory Committee to support harmonization of regulatory processes for diagnostic tests, and have been tasked to develop a list of diagnostics for priority diseases in Africa for evaluation and regulatory approval²⁸.

During EDL implementation, training programs will be needed to engage and capacitate healthcare workers, in particular at primary care and community levels, on when and how to use essential tests. It will also be useful for governments and researchers to evaluate the rollout across national and community levels by conducting surveys on the availability and accessibility of diagnostic tests at different health system tiers, and studies on the impact and cost-effectiveness of EDL implementation. This will help inform ongoing updates to national EDLs, as well as future policy and resource allocation decisions.

Data systems and digital innovation

The effective integration of diagnostics and data systems has the potential to transform the delivery of health services to fight endemic diseases and prevent epidemics. Data systems provide the underlying infrastructure and technology to capture, analyze and communicate data from diagnostic and other health system platforms for use in evidence-based clinical decision-making, surveillance and management, preferably in real time^{29–32}. Ideally, a connected diagnostic ecosystem would transform access to healthcare through the use of industry-standard digital and analytic systems integrated with cutting-edge innovations, such as AI-enabled screening tools and medical devices, telemedicine services, electronic forms and records, digitized supply chains and other applications^{33–35}. This includes digital systems to monitor the quality, access and delivery of testing services, an important tool for tracking access to universal healthcare, particularly at primary healthcare levels, and for pandemic preparedness.

The utility of improved data systems for diagnostics was illustrated recently by mpox surveillance programs in Uganda. DHIS2 (<https://dhis2.org/>), a widely used digital platform for collecting, analyzing and visualizing health data, was connected to electronic integrated disease surveillance and response forms used at health facilities and in communities to capture reports of mpox and other epidemic-prone diseases³⁶. This allowed surveillance data to be communicated and visualized in real time within outbreak response units, which in turn

Table 1 | Framework for improving digital data systems for diagnostics

| Area | Interventions |
|--|--|
| Data governance and security | Establish a process of managing data to ensure that availability, usability, quality, security and privacy concerns are adequately addressed. |
| Infrastructure and technology | Establish a framework of existing digital systems that is interoperable and adaptable to change, and uptake of cost-effective new technologies and digital innovations. This also includes the IT infrastructure required for data systems to run. |
| Workforce capacity | Build and maintain a well-trained and well-resourced workforce to ensure the efficient and effective use of data systems and tools to deliver diagnostic services. |
| Market shaping | Invest in digital solutions with initiatives to ensure affordability and sustainability. Includes service-based and all-inclusive pricing models. |
| Sustainability, funding, resource mobilization | Identify new approaches to unlock funding and investments for the long-term sustainability of effective digital systems. |
| Knowledge exchange and sharing | Develop systems and processes to share lessons and transfer knowledge between local, regional and global stakeholders as new data systems and digital innovations are deployed. |

enabled more agile mpox control efforts, including rapid case identification, contact tracing and cluster vaccination.

However, barriers to the expansion of integrated diagnostic and data systems exist, including poor interoperability between digital systems, high costs and unsustainable market models. Data systems in particular have been impacted by reductions in donor aid, highlighting the need for more affordable and sustainable systems. Inadequate governance around data ownership and cybersecurity, skilled workforce shortages and limited digital literacy are also constraints. These threaten to expand the digital divide and gaps in access to healthcare in less-resourced settings.

There are several immediate opportunities to address these barriers (Table 1). Steps should be taken to establish national best practice data policies and standards that ensure cybersecurity and interoperability between diagnostic products and digital tools, and broader health data systems. This will enable safe and seamless integration of existing and new products, reduce future adaptation costs, and enable further impact through increased use of these tools. It will be important to avoid implementing too many different digital systems that don't connect with each other, thereby reducing costs and increasing efficiency. National-level working groups of key stakeholders (that is, government, end users, industry) can help develop data governance policies that define data system standardization and interoperability requirements, data ownership and management standards that are relevant to the country context. They can also help provide clear cybersecurity mechanisms that continuously incorporate new security standards, processes and policies that meet country needs as technology and best practices evolve.

To support this, knowledge gaps around optimal policies and best practices for data systems, governance, interoperability and security should be addressed. An accessible repository of existing data-related policies, lessons and best practices from digital system implementation across African countries should be established and shared, for example through peer-to-peer forums and communities of practice. Such a regional effort could be led by Africa CDC, WHO and ASLM in collaboration with countries, and could leverage existing sources such as Digital Square's Global Goods for Health, the WHO's Implementome (<https://github.unige.ch/implementome/main/>) and the Global Laboratory eTools repository (<https://www.lab-etools.org/>), a Global Fund and APHL initiative^{28,35–41}. These sources provide

exemplars of implementation of both global and locally developed digital tools⁴⁰. WHO's Implementome is a particularly useful resource for countries needing to assess which global public digital goods can be adapted to their context⁴¹.

It will also be important to conduct targeted training and capacity building for key members of the workforce to build institutional knowledge, and to preserve critical skillsets in digital systems and the use of digital data, governance and security. Training should be provided to data scientists, health informaticians, IT, healthcare and laboratory professionals to develop, implement and maintain data systems, and to promote the adoption of harmonized data standards. Lessons from work by organizations such as Transform Health (<https://transformhealthcoalition.org/partnerships/>) can inform national policy development⁴². Training programs and educational resources can empower local talent to develop innovative solutions tailored to the local context. It will also be necessary to strengthen and maintain ongoing training and support for the healthcare workforce, especially online training resources that are low cost, easily accessible and adaptable, given that data systems evolve every few years.

In addition, more adaptable procurement approaches for digital systems are needed, including a shift toward service-based vendors and the use of local digital providers. Service-based rather than product-based contracts have become a standard procurement model in other healthcare sectors and could help improve the reliability of digital health services. Under this model, suppliers provide digital services (instead of software products alone) and are accountable for the functionality and efficiency of the service. This will be relevant for diagnostic data systems as the inclusion of private sector services in the public sector digital health ecosystem is already underway and likely to grow. Investing in scalable products that use local digital capabilities and networks of organizations working on the ground should also be encouraged^{30,41,43}.

Many of the challenges and opportunities discussed above are not specific to diagnostics; hence, needs for diagnostics should be incorporated into health system-wide strategies to ensure investments in digital systems. In addition to implementing more cost-effective infrastructure and technologies, essential digital systems will need to be positioned as a priority investment supported by both traditional and innovative financing models.

SNDI

Strategic network design and integration (SNDI, also known as diagnostic network optimization) is a tool for effective deployment of available diagnostic capacity to close testing gaps and lower costs^{44–47}. By creating efficient linkages between hospitals and laboratories and optimizing the deployment of point-of-care testing, SNDI is one of the most powerful tools for managing national testing services and ensuring universal access to essential diagnostics, especially at primary care and community levels. It can also be used to ensure adequate capacity for epidemic disease detection, and to inform how and where to introduce new technologies. As resources for testing services grow more constrained, well designed and managed networks of laboratories and clinics can improve healthcare delivery, reduce costs and ensure access and continuity of testing services^{47–49}. For example, several SNDI initiatives have recently been implemented in Kenya^{50,51}. These built more efficient and reliable linkages between hospitals and laboratories for bacteriology testing for antimicrobial resistance and molecular testing for HIV viral load and infant diagnosis, human papillomavirus and hepatitis B virus, taking into account patient volumes, laboratory capacity and sample transport routes. This led to substantially reduced test turnaround times, lower logistics costs, and improved test access and health outcomes for communities.

The SNDI process (Fig. 2) often uses geospatial mapping and analytical software; however, simpler tools can also be used^{45,46,52,53}. Despite extensive network mapping and analyses in recent years in



Fig. 2 | The SNDI process. Diagnostic network optimization involves a multi-stage process from design to implementation, supported by stakeholder consensus building and network management systems. Testing network design should be updated regularly to account for changes in health priorities, advances in healthcare delivery and the availability of new technologies.

some countries, the implementation of improved network designs has been limited^{47–57}. This is partly because network optimization is often not included in government policies, processes and metrics, and not considered during strategic health system decision-making and national health budgets. National laboratory departments often lack the guidelines, training, tools and data systems needed to lead and implement SNDI activities⁵⁸. This is compounded by the fact that diagnostic services frequently function in a siloed and fragmented manner, aligned with national health structures, disease programs and funding streams. Prior efforts have also focused mainly on selected molecular tests (mostly HIV or tuberculosis), rather than a wider set of essential tests. In addition, the data collection and analysis needed for SNDI can be resource intensive and time-consuming.

There are feasible near-term opportunities to address this. First, governments can make policy updates to adopt and prioritize SNDI for essential tests as a part of routine health service delivery and optimization, and as a tool for achieving universal healthcare. This can be achieved by building awareness among national policymakers of the strategic and programmatic relevance of geospatial mapping of testing capacity and network optimization, supported by evidence of the benefits and feasibility of SNDI. It will be important to establish network and procurement policies that not only are based on efficiency and performance criteria, but also are patient and community centric and cover a wider set of essential diagnostics, especially at primary healthcare levels. Particular focus should be placed on integrating various testing services within network design and using existing infrastructure and technologies for multiple diseases instead of maintaining disease-specific diagnostic capacity (for example, integrated HIV, tuberculosis, human papillomavirus and hepatitis testing) to improve efficiency and test access.

Second, it will be important to strengthen national capacity to routinely implement SNDI and monitor testing network performance. This can be achieved by supporting training, technical assistance and dedicated teams mandated to run SNDI activities, coupled with the establishment of tools for SNDI (for example, optimization and geolocation software). As government staff turnover can be high, access to regular training opportunities will be important to maintain key expertise and motivation for sustainable SNDI functions. Ongoing training on SNDI tools should become easily accessible for healthcare workers and ideally be institutionalized within pre-service laboratory training.

A coordinating mechanism will be needed to provide governance and to align national stakeholders on priorities and plans across disease programs. It would also be useful to develop and widely disseminate guidance on SNDI know-how, operational tools and key performance indicators and benchmarks for functional networks. Best practices and case studies on network design and management should be developed and made accessible between countries through communities of practice.

Third, in the near to medium term, it will be important to map laboratory capacity in relation to health service delivery sites at national and subnational levels. For this, more affordable and easy-to-use data collection and SNDI tools are needed. Information might also be drawn from other health system and service delivery assessments. National systems for routine SNDI exercises should be established by incorporating network assessments as part of regular laboratory system strengthening activities toward the delivery of universal healthcare, and to improve efficiency and reduce costs. Importantly, once network analyses have been conducted, they should be used to make actual changes to laboratories in the network, and the national departments responsible for SNDI should be given the formal mandate to make these changes.

Procurement, supply chain management and market access

Diagnostics procurement in many countries faces formidable challenges due to funding limitations, fragmented procurement practices, lack of pricing transparency, complex supply chains and gaps in contract management expertise^{59–70}. Tools such as global access pricing (GAP; whereby costs are adjusted based on economic status) and more inclusive pricing models are promising but have seen limited adoption beyond HIV viral load and tuberculosis testing⁷¹. Weak supply chains can halt the delivery of health services and dramatically increase costs for any test, including laboratory-based and point-of-care diagnostics, imaging and other diagnostic products and services.

To address this, several fundamental conditions need to be in place (Box 1). Important (and perhaps hardest) to achieve is the expansion and diversification of funding for testing services, to ensure reasonable and predictable budgets. This includes increased domestic funding for diagnostics, through national health budgets, health insurance schemes, public–private partnerships and other models for financial self-reliance. Testing programs also need to pursue the most impactful ways of reducing testing costs while still ensuring reliable services.

Quick wins can be achieved here through established best practices. First, steps can be taken to improve access to GAPs by widely disseminating GAP agreements and reference prices, for example through the publication of GAP lists by global and regional agencies. This will increase the transparency of end-user pricing and the comparability of prices across diagnostic products and services. Coordinated or pooled procurement that aggregates volumes across buyers and across diseases helps make GAPs more feasible, reduces prices and ensures reliable supply. However, procurement for testing programs may become more fragmented across national and subnational buyers, as international funding and procurement systems change. Integrated testing and greater use of multi-disease diagnostic technologies can avoid duplication of testing capacity across disease silos. Approaches that strengthen coordination between buyers, for example

BOX 1

Priority interventions to strengthen diagnostics procurement and supply chain

Diagnostics procurement is challenged by inadequate funding, fragmented procurement, inconsistent and nontransparent pricing, and complex and costly supply chain processes. Recommended interventions to address these include the following.

1. Finance: establish reliable funding for essential diagnostics (including from domestic and health insurance sources) to support sustainable testing demand.
2. Forecasts: develop clearer and more predictable diagnostics forecasts and coordinated procurement.
3. Alternate procurement models: implement innovative procurement approaches, including a shift from product to service-based procurement, for example all-inclusive pricing, and pooled procurement mechanisms.
4. Pricing: negotiate more competitive, standardized and inclusive pricing terms and establish service-level agreements. Establish transparency of end-user pricing and comparability of pricing, and access global pricing agreements.
5. Training: conduct training on service-level agreements and contract management.
6. Data systems: implement digital solutions to improve visibility over supply chain and service provision.
7. Policy: review and update procurement policies and governance structures to optimize new procurement approaches.

the Africa CDC pooled procurement mechanism (<https://africacdc.org/apm/>) and the Integrated Diagnostics Consortium (<https://aslm.org/our-expertise/integrated-diagnostics-consortium/>), could help address this and provide forums for buyers to pursue better pricing and terms. Similarly, shifting procurement increasingly to local or regional manufacturers and products designed to cater to regional needs will also provide a pathway toward self-reliance.

Second, increased efforts are needed to shift from traditional product-based procurement to service-based procurement agreements. These provide suppliers with greater responsibility for supply chain and delivery of testing services; they allow for reductions in pricing and price variability, and free users from supply chain complexity. This includes innovative procurement approaches and mechanisms, such as all-inclusive agreements, vendor-managed inventory, standardized distributor margins and pooled procurement, ideally based on testing networks that have been optimized using SNDI processes. Service-level agreements with stringent and comprehensive key performance indicators should become standard public sector procurement tools. More inclusive pricing for as many essential products and services as possible should be available from suppliers across all countries, including countries with access issues (that is, small island nations) and for all buyers within a country. To support this, more reliable forecasts for essential diagnostics are needed to inform national and global volume-based pricing negotiations and the use of alternate procurement models.

The implementation of all-inclusive pricing models has driven substantial cost savings and more reliable testing services for HIV viral load in patients on antiretroviral treatment, and for the diagnosis of HIV in infants in countries across Africa. In 2020, all-inclusive pricing and comprehensive service-level agreements for molecular HIV

testing were introduced in Kenya, Mozambique, Nigeria, Tanzania, Uganda and Zambia⁷¹. These included leased instruments and all test reagents, consumables, trainings and instrument services, supplied under a single price per test and governed by service-level agreements, with key performance indicators for both suppliers and end users. These new procurement approaches had benefits that were fast and meaningful, leading to an overall improvement in the delivery of HIV services, improved supply security and lower costs. Specific improvements included expanded and more reliable test availability, reduced stock shortages and instrument downtimes, fewer testing backlogs and shortened turnaround times for test results. Price transparency and negotiation led to savings of >US\$130 million within 3 years. These improvements enabled HIV programs in these countries to expand testing services by more than twofold between 2020 and 2023, while simultaneously improving the quality of patient care and lowering costs. Based on these successes, the all-inclusive pricing model had begun to be implemented in an additional 22 countries in Africa⁷¹.

Implementing the above recommendations requires robust processes for diagnostic procurement. This includes strengthening procurement working groups, guided by carefully designed procurement strategies for coordination and oversight, and annual national forecasting and quantification exercises. Procurement legislation and policies may need to be updated, and vendors will need to adjust practices. It will also be important to strengthen skills and training for diagnostics procurement and supply chain operations. Advanced skills in the design and management of service-level agreements and other procurement contract negotiation and oversight skills are vital. Dedicated teams to manage performance-based service-level agreements and to ensure efficiency and accountability are needed. These teams should also play a substantial role in SNDI oversight and management, by aligning the key performance indicators of service-level agreements with the performance indicators of optimized diagnostic networks.

Pandemic preparedness, response and surveillance

Diagnostics are critical for early, precise detection and response to localized disease threats, preventing them from escalating into epidemics or pandemics^{15,72–74}. In addition, diagnostics are needed to limit the spread of antimicrobial resistance and to enable effective One Health disease management strategies^{75–78}. However, surveillance systems are often difficult to sustain and are at particular risk when resources are limited. Many countries have limited capacity to test for epidemic-prone diseases and antimicrobial resistance, and do not conduct sufficient active or passive surveillance for diseases of concern^{79–84}. Gaps in diagnostic capacity are often greatest at primary health and community levels, precisely where the risk of emergence of an outbreak is high. The sharing of information across health sectors (human, animal, food, environmental) and across borders is also inadequate to mitigate international disease spread^{85–89}.

Several steps can help develop sustainable capacity (Table 2) in the face of resource constraints. First, national testing policies should be updated to ensure that a list of priority epidemic-prone diseases and the necessary testing systems needed for surveillance and outbreak response are well defined. These can draw on regional and international guidance, and from local and regional disease epidemiology and assessments of risk. Within this, the role of national laboratory departments and public health institutes should be strengthened to enable them to contribute effectively to National Emergency Operating Centers and Pandemic Preparedness Task Forces in the event of an outbreak. It is also important to update or develop policies and guidelines relevant to the accelerated regulatory approval of novel technologies needed for epidemic control during outbreaks (for example, rapid tests and surveillance tools), and the use of advanced tools such as genomic sequencing. For example, during the recent mpox outbreak, Africa CDC quickly developed a list of approved diagnostic tests

Table 2 | Four pillars to improve testing for pandemic preparedness, response and surveillance

| Area | Interventions |
|---------------------------------------|--|
| Policy and governance | Strengthen coordination, developing multisectoral policies, enhancing data oversight and securing sustainable funding—all aimed at promoting collaborative multisectoral efforts and avoiding fragmented approaches to pandemic preparedness. |
| Testing access, networks and capacity | Map lab networks, optimizing testing access, investing in capacity building for healthcare personnel to ensure efficient testing and surveillance capabilities across different levels and settings. |
| Testing supplies | Establish a robust diagnostics supply chain, negotiating improved access and pricing, expanding microbiology laboratory capacity and ensuring the availability of essential testing products to support effective disease detection and response efforts. |
| Data management | Map existing data systems, enhancing analytical capabilities, strengthening surveillance and promoting interoperable data transmission and sharing to facilitate informed decision-making. Also, exploring innovative technologies such as AI to further enhance data analysis and early outbreak detection. |

(<https://africacdc.org/news-item/new-test-added-to-recommended-list-of-molecular-diagnostic-tests-for-mpox/>) to guide response efforts. This list provided countries with easily accessible insights on which tests were reliable and included both laboratory and point-of-care tests that met key performance criteria. Also important are outbreak-specific policies around the procurement and priority access to testing equipment, the use of locally manufactured products, and on testing data sharing and use. It will be important to mitigate policy or operational barriers to cross-sector and cross-border sample referral and information exchange^{81–83}, including provisions for improved collaboration, aligned approaches and data sharing on disease outbreaks across health sectors and countries.

Second, it will be important to map the national diagnostic capacity for priority diseases of epidemic potential, including genomic sequencing and basic testing capacity at primary healthcare and community levels, sample referral and data systems. This can be done using a targeted assessment or as part of SNDI activities. A budgeted plan for the strengthening of this capacity should be developed and implemented using a staged approach. Priority should be given to strengthening testing and surveillance in high-risk areas such as densely populated urban centers, remote communities and borders, to ensure the early detection of emerging pathogens and rapid communication and response.

Third, over the medium term and in a stepwise manner depending on resources, local epidemiology and international risk, broader national testing capacity for relevant priority pathogens should be strengthened. The design of these testing systems should be done to ensure capability is maintained between outbreaks with ‘always on’ readiness to detect and respond to new threats^{89,90}. This includes targeted improvements in testing capacity and efficiency at the point of care, high-throughput laboratory nucleic acid testing, genomic sequencing capacity and digital systems to relay testing data to outbreak response units. The use of locally or regionally manufactured products may help reduce costs and mitigate international supply disruptions during outbreaks⁹¹.

The successful control of two recent outbreaks—the Ebola Virus Sudan Strain outbreak in Uganda and the Marburg virus outbreak in Rwanda—illustrate the value-strengthened diagnostics capacity and close integration of testing within national outbreak response

systems. In Uganda, the Sudan Ebola virus was confirmed with PCR and genomic sequencing within 24 h of the first case, and this enabled rapid outbreak declaration and a well-targeted public health response that brought the outbreak quickly under control⁹². Sequencing data helped to identify the origin and transmission chain, further enhancing ongoing and future control measures. In Rwanda, PCR testing and genomic sequencing for Marburg virus were essential for outbreak detection and swift implementation of control efforts through surveillance, contact tracing and vaccination that rapidly brought the outbreak under control and prevented further spread^{93,94}. Rapid availability of testing kits and genomic sequencing ensured that the index case and likely source of exposure were identified, as well as the transmission chain of 100% of the cases. In addition, data sharing and testing ensured international alertness, which was able to quickly rule out the spread of suspect cases to Europe.

A key consideration in the design of testing capacity is that current tools for surveillance and outbreak response often require substantial resources to implement and maintain. Innovation in diagnostic tools should be promoted to allow new approaches that reduce costs and simplify deployment to be explored. These include, for example, enhanced access to self-screening, artificial intelligence and predictive modeling, pop-up labs and new systems for early detection of zoonotic diseases, and tracking disease dynamics linked to climate, travel patterns and other factors⁹⁰.

Limitations and future directions

The recommendations provided above include a prioritized set of interventions that countries can use to close critical gaps in testing, but this list is not intended to be comprehensive. Additional interventions will be undoubtedly needed to ensure a reliable and sustainable ecosystem exists for the delivery of laboratory services. Also, priorities and interventions will evolve over time, highlighting the importance of adaptability; therefore, updates to this analysis based on country gap assessments will likely be important.

Several additional considerations are worth highlighting. Particular attention must be paid to strengthening diagnostics at primary healthcare and community levels, including the use of point-of-care tests as tools to help achieve universal healthcare. Related to this, the strengthening of human resources through training and retention systems, especially at community and primary healthcare levels, will be a critical investment to ensure the capacity to deliver these testing services with the required standards and quality. The private sector can also play an important role in delivering testing services through public–private partnerships and supportive services such as equipment maintenance, data management and digital systems, sample transportation and training. Additionally, regional manufacturing and research should be supported with national and international investment and technology transfers, coupled with a supportive regulatory environment. Regional manufacturing holds particular promise given Africa’s rapidly growing biomedical industry and the presence of manufacturers of high quality in vitro diagnostic test kits, general laboratory consumables and reagents. To complement the recommendations on pandemic preparedness, especially the evaluation of new diagnostics tools, establishing a regional biobank has strategic importance. Africa CDC is establishing and strengthening the biobanking network in Africa, which will place the continent in a better position to contribute to the Pathogen Access and Benefit Sharing mechanism under the new WHO Pandemic Agreement^{95,96}. Africa CDC has also launched the first Africa-owned genomics data archiving and sharing platform to promote the use of data for public health decision-making and local manufacturing of medical countermeasures⁸⁷.

In terms of next steps, African countries (specifically national laboratory departments within Ministries of Health) will take the lead on advancing priority interventions, tailoring efforts based on local gaps and needs. A number of tools exist to support this, including a

new tool for tracking the maturity of laboratory systems and measuring country-specific gaps, recently developed under Africa CDC and WHO-AFRO with support from The Global Fund (<https://africacdc.org/download/the-laboratory-systems-maturity-monitoring-lmm/>). These tools and the priority intervention areas identified above will provide a way to measure gaps within national laboratory services, and link these to country-specific implementation plans and budgets that are owned and led by national governments. It will be important for governments to mobilize reasonable and predictable national funding for these implementation plans, to mitigate the effects of declining international aid. National laboratory directorates will need to play a greater role in managing these assessments, implementation plans and budgets, and in coordinating support from donors and partners. Africa CDC and ASLM will oversee efforts to mobilize better coordinated international support and activities for key interventions across the wider community, in coordination with other agencies such as WHO, The Global Fund, the West African Health Organization and the East, Central and Southern Health Community, other regional economic blocks, donors and nongovernmental organizations.

Advancing recommendations that require multiple organizations (for example, governments, donors and technical agencies) to work together will not be easy to achieve because collective action requires dedicated effort. Structures for collective action exist, such as national technical working groups that provide forums for coordinated action on the ground. There are also regional and international working groups and consortia, including the Africa CDC-led Africa Laboratory Technical Working Group, the ASLM-convened Laboratory Systems Strengthening Community of Practice (LabCOP; <https://aslm.org/our-expertise/laboratory-systems-strengthening-community-of-practice/>) and National Laboratory Directors Forum (<https://aslm.org/aslm-launches-the-laboratory-directors-forum-to-transform-laboratory-best-practice-in-africa/>), the Integrated Diagnostics Consortium, WHO's new Global Diagnostics Coalition (<https://www.who.int/initiatives/global-diagnostics-coalition/>) and community representative groups such as the African Community Advisory Board (AFRO-CAB; <https://www.afrocab.org/>) and the O'Neill Institute Diagnostics Equity Consortium (<https://oneill.law.georgetown.edu/projects/diagnostics-equity-consortium/>). These forums provide opportunities for better aligned efforts across organizations and more efficient use of available resources in the face of constraints.

Conclusion

A recent 2-year progress update on the Lancet Commission on Diagnostics highlights the need for more efficient approaches and country-level commitments to diagnostics strengthening⁹⁷. At the same time, recent reductions in global aid pose a risk to the delivery of testing services for both high-burden endemic and epidemic-prone diseases in many African countries^{8,9}. To mitigate the impact of these changes, countries will need to find ways to be more self-reliant and efficient with available resources. The recommendations presented above offer a step in this direction, providing a path toward cost-effective testing services, greater self-reliance and meaningful progress toward national and regional health goals.

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Acknowledgements

This work was supported by the Gates Foundation and Unitaid.

Author contributions

All authors contributed to the analysis and development of recommendations for one or more of the topic areas described in this Perspective, as well as reviewed the manuscript. Y.K. and T.P. drafted the manuscript based on the reports developed by all authors.

Competing interests

The authors declare no competing interests.

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Peer review information *Nature Medicine* thanks Palwasha Khan and Peter Waiswa for their contribution to the peer review of this work. Primary Handling Editor: Karen O'Leary, in collaboration with the *Nature Medicine* team.

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