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Understanding the Costs and Benefits of Investing in Laboratory Systems in African Countries

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Abstract

Laboratories are fundamental components of health systems, critical in routine and emergency contexts for both disease surveillance and health services for communicable and non-communicable diseases. Although laboratories are a core national competency for providing quality clinical care, responding to international mandates, and setting priorities, investments in strengthening laboratory systems have often been inconsistent and inadequate in African countries. This underinvestment has left vulnerabilities which came to light during recent health emergencies, including the COVID-19 pandemic, and highlight the need for long-term investments with benefits that extend beyond individual country borders.

This paper qualitatively establishes the complex costs and benefits of strengthening laboratory capacity and systems within and across national borders. Costs are presented as direct and indirect, while benefits are presented at the individual, population, and health-system levels. Each cost and benefit grouping is further divided into thematic subcategories. This paper demonstrates that investments in laboratory systems can yield considerable and wide-ranging benefits. While these investments require comprehensive financing, their impacts are potentially transformative.

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Summary

Laboratories are a fundamental component of national public health institutes and health systems (1). They are critical in routine and emergency contexts to enable both disease surveillance and health services for communicable and non-communicable diseases. Laboratories are a core national competency for providing quality clinical care (2), responding to international mandates (3), and setting priorities (4).

Despite the importance of laboratory systems, investments in strengthening them have often been inconsistent and inadequate in African countries. This underinvestment has left vulnerabilities which came to light during recent health emergencies, including the COVID-19 pandemic, and highlight the need for long-term investments with benefits that extend beyond individual country borders.

This paper outlines the costs and benefits of strengthening laboratory capacity and systems within and across national borders. It is not strictly an economic evaluation, but it borrows from economic evaluation frameworks to qualitatively establish the complex costs and benefits of investing in laboratory systems and wider diagnostics capacities. Costs are presented as direct and indirect, while benefits are presented at the individual, population, and health-systems level. Each cost and benefit grouping are further divided into thematic subcategories.

Dedicated analysis is needed to understand the specific balance of costs and consequences for particular policy decisions, but this paper clearly demonstrates that investments in laboratory systems can yield considerable and wide-ranging benefits. While these investments require comprehensive financing, their impacts are likely to be wide ranging and potentially transformative.

Background

Over the past 15 to 20 years, national and regional leaders have made coordinated efforts to strengthen laboratory systems in African countries, often in response to specific disease crises. Key efforts to drive support for laboratory needs like the Maputo Declaration (2008) (5), the World Health Organization Regional Office for Africa (WHO AFRO) resolution (2008) (6), and the African Society for Laboratory Medicine's Ministerial Call for Action (2012) (7), and Freetown Declaration (2015) (8) have prompted momentous regional advances in laboratory capacity and performance. Chief among these are the development of standards such as the Stepwise Laboratory Quality Improvement Process Towards Accreditation (9) and related initiatives such as the Strengthening Laboratory Management Toward Accreditation (SLMTA) programme (10). Since 2013, 237 SLMTA-supported laboratories in 17 African countries have received accreditation, with nearly half of those occurring in the last two years (11). Better parity among countries has been achieved—in 2013, 91 percent of accredited laboratories in sub-Saharan Africa were in South Africa, and almost all of these were entirely private facilities or for clinical research (12). Since then, nearly

90 percent of newly accredited African SLMTA laboratories have been outside of South Africa (11). The establishment of leading regional institutions and networks like the African Society for Laboratory Medicine (13) and the East African Public Health Laboratory Network (14) have led to much-needed collaboration among countries. Major investments to address disease-specific crises including HIV/AIDS, TB, and Ebola have facilitated broader laboratory system progress, such as the creation of the African Centre for Integrated Laboratory Training, (15) which has supported laboratory workforce trainings in over 20 countries in Africa and beyond.

But improvements have been uneven, sporadic, and insufficient. Before the COVID-19 pandemic, laboratory investments in low-resource settings were limited and often focused on individual diseases rather than holistic strategies for comprehensive, integrated national laboratory systems that can both manage routine needs and respond to public health emergencies. Despite significant investment in laboratory services for specific diseases, laboratory systems in Africa were not ready to address epidemics, as witnessed during COVID-19. Only two African countries had COVID-19 testing capabilities when COVID-19 was declared a public health emergency of international concern.

The pandemic starkly illustrates how significant laboratory capacity gaps have not only been a key driver of response performance, but also left countries vulnerable to existing global inequities. Throughout the pandemic, most African countries have lagged in testing volume (16), due to restrictive testing strategies (17), limited availability of PCR tests, and little capacity for genomic sequencing (18). Despite improvements—including regional initiatives to rapidly introduce and/or expand PCR testing, point-of-care technologies, and rapid antigen tests to the subnational level and establishment of pathogen genomics surveillance network—African countries today are still performing over 100–300 times fewer daily COVID-19 tests per population compared to high-income countries (17). The true picture of disease on the continent remains incomplete, with significant undercounting of cases (19)(20) and deaths (21), and limited surveillance of genomic and viral evolution trends (22). This has hindered the development and application of appropriate and evidence-informed strategies and has often disadvantaged the region in international policies that rely on comparative assessment frameworks (e.g., travel measures that assess national testing and sequencing regimes).

With COVID-19 moving from "emergency" to endemicity, new considerations arise. COVID-19 will likely persist as an endemic disease with regular or recurring risk of outbreaks. Though the urgency and severity of the threat will likely diminish over time, in part through the application of technologies (i.e., vaccines, therapeutics, and diagnostics), monitoring and mitigating its impact remains critical. But despite rapid progress made thus far in the pandemic, national public health institutes and other health stakeholders across Africa continue to highlight laboratory and sequencing capacity as key gaps in their ability to manage the protracted direct and indirect burdens of COVID-19 (23). Crises like the West Africa Ebola outbreak (24) underscores the need for long-term strategies to apply the capacities developed during emergencies through to the

recovery and rehabilitation phases. Yet while regional and international commitments have grown in response to COVID-19, they remain insufficient to support the permanent increase in laboratory capacity needed to manage COVID-19 alongside laboratory diagnostic services for other priority diseases. Further investments demand novel cross-cutting examinations of how, where, and to what degree such strategies impact health.

Objectives

This paper outlines the rationale for laboratory investments in African countries by laying out the costs, benefits, and other considerations associated with strengthening laboratory capacity and systems to deliver necessary functions both within and across national borders.

Costs and benefits of laboratory systems

Because returns on laboratory investments largely accrue to other health functions, these investments may appear a poor financial value, especially as costs increase in line with expanding capacity. The nature of laboratory investments means that many of their benefits accrue to outcomes measured by other parts of the health system, and also continue to accumulate beyond the initial investment for future populations. Economic evaluations should ideally look across the entire health economy to evaluate the full value chain, though this may not be practical. Key performance indicators of laboratory functions (e.g., results turnaround time, equipment downtime) do not represent their ultimate added value across the range of benefits. Economic evaluations that attempt this often make methodological assumptions that hugely reduce the accuracy of estimates (25) (26), while studies that aim to evaluate clinical, surveillance, and laboratory systems in their entirety often inaccurately allocate total laboratory costs. Moreover, the absence of aligned horizontal financing structures in some low-income countries often means relying on multiple funding and data sources across health system functions, and therefore it is very difficult to square the savings in clinical and public health outcomes with rising laboratory costs on the same balance sheet.

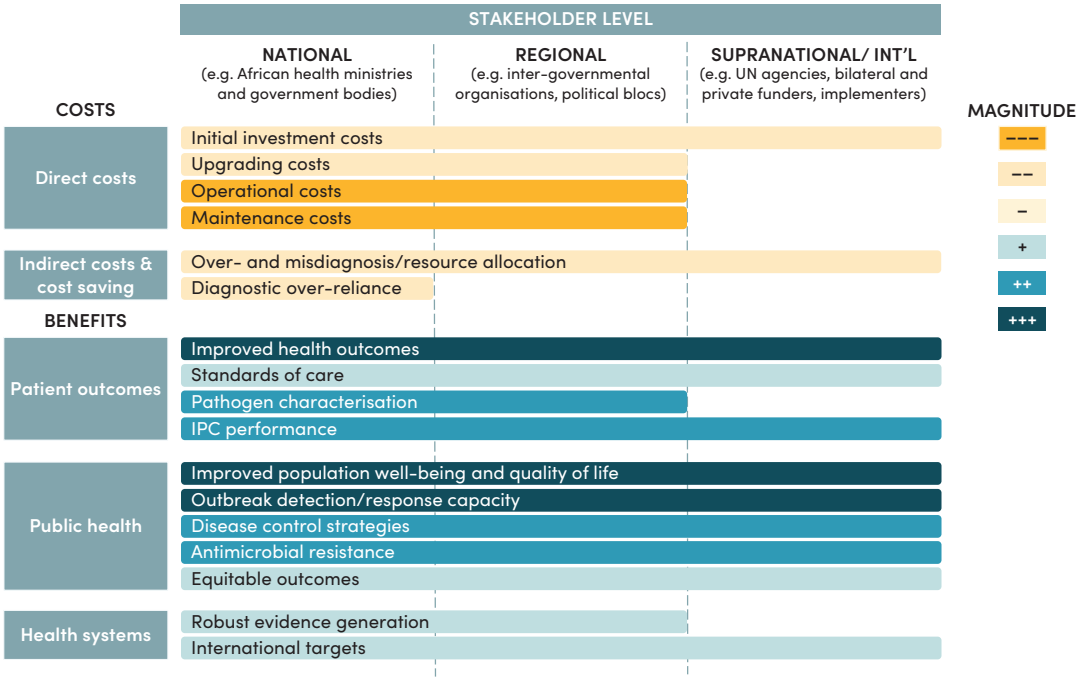
Laboratory investments demand a holistic assessment which looks beyond the laboratory system to the health system as a whole. Traditional economic evaluations have a limited ability to comprehensively assess investment impacts in cross-sectoral thematic areas such as laboratories (27). Analyses of discrete interventions narrowly define returns as responding to laboratory performance indicators rather than wider health outcomes. Even the most direct clinical effects typically require subsequent actions and other health technologies to maximise impact, and trigger further downstream benefits beyond improved patient care. Cost estimates are also complex—many evaluations solely consider the financial costs of tests and direct laboratory needs, rather than the wider range of personnel and resources (beyond the traditional laboratory "system") needed to deliver full diagnostic capability. Such indirect costs and savings are commonly excluded in assessments.

This assessment considers the value generated by laboratory capability holistically, in a structure that reflects the level at which primary benefits are realised and considers costs beyond direct expenditures.[1] The effect of benefits can be both iterative and cross-cutting (e.g., improving individual outcomes also advances population well-being and potentially system performance). However, this framework links each benefit to a single corresponding level based on where the most immediate and greatest relative impact is realised, while recognising that the benefit may be generated at a different level.[2] The levels are defined as:

Costs	Direct Costs
	Indirect costs or cost savings
Benefits	Individual—patient outcomes
	Public health
	Health systems (and beyond)

Figure 1 illustrates these types of costs and benefit, and also the broad range of beneficiaries and stakeholders which these costs and benefits most relate to. The figure designates a crude magnitude to each cost and benefit, hypothesising the relative size of their impact. Box 1 applies this framework using examples from Zambia.

FIGURE 1. Conceptual map of the costs and benefits of lab investments



1 This is not a a systematic review or evidence synthesis. Rather, it is a thorough consideration of critical cross-sectoral issues implicated in this topic using diverse evidence including published research, white and grey literature, situational assessments, and normative guidance.

2 Consider, for example, the benefits of sentinel surveillance, where increasing capacity is delivered via clinical sites at the individual level, but the primary benefit is realised through strengthened disease surveillance at the population level.

Costs

A. Direct Costs

1. **Initial investment costs.** Establishing laboratories and laboratory systems demands significant capital implementation costs, especially at the comprehensive scale needed to fully realise investment benefits. Laboratory cost considerations vary significantly across health system levels, from centralised reference laboratories to point-of-care services. Levels vary in scope and services, resulting in a wide range of component needs, including equipment, human resources, training, infrastructure, and information systems. Comprehensive costing for a single laboratory structure is complex due to the overlapping nature of laboratory and clinical services and how costs, particularly personnel, are attributed to the laboratory system or other parts of the health system.

   Most economic analyses of laboratories investment focus on costing of vertical disease-specific services (e.g., HIV) and are not fully representative of structures that provide horizontal services. However, they can provide some insight into the costs of establishing full-service laboratories. For instance, estimated establishment (including equipment) and first-year operational costs in a multi-tiered model to fully cover CD4 HIV testing services in South Africa were $21,654, $60,354, and $3,462 per site for services in Tiers 1, 2, and 3–5[3] respectively (28). While burden of disease and care needs for HIV are significant in South Africa, the cost considerations for equipment alone are substantial and likely to be even higher in other African countries with more limited procurement mechanisms. Broader capability also comes with increased cost; the cost for accreditation alone can range from $50,000–115,000 per lab (29).
2. **Upgrading costs.** All technologies eventually become outdated, meaning reinvestment to update the platform is periodically required to yield improvements to the system or simply to maintain the same functionality. Marginal costs for upgrading can be substantial; many countries have been left unable to further develop facilities after initial investments from international aid providers. These costs further increase as both service provision and population coverage expand because of scaling up of services. A lack of market intelligence in low-resource contexts hinders accurate estimates of cost structures in the mid- to long-term, preventing international stakeholders from appreciating the size of the funding gap.
3. **Operational costs.** Regular usage services generate some of the highest costs of laboratory services and tend to only increase as coverage of diseases and populations expand. Analyses of single-disease surveillance systems such as meningitis suggest over double the amount of current annual operating costs is needed in some countries merely to continue meeting standards, let alone to increase performance (30). While such use costs consist of a variety of needs, from consumables to technological

3 Tier 1 = health clinic providing ART, Tier 2 = sub-district health facility, Tier 3 = community laboratory, Tier 4 = district laboratory, Tier 5 = centralised laboratory

infrastructures and quality assurance and stock management (including time-sensitive materials), most assessments indicate personnel salary costs are one of the more difficult and expensive resources to maintain within the operating budget. In particular, a lack of consistent funding leads to a significant dip in service delivery performance from understaffing and turnover, which requires frequent recruitment and training (30).

4. **Maintenance costs.** Costs to sustain high-quality delivery over time and for different health threats are significant but difficult to quantify. Good clinical laboratory practice requires regular and reliable financing to prevent misuse and disrepair of equipment and facilities. The impacts of the lack of maintenance have been well-documented in Africa, from instrument malfunctions, delayed servicing, and outsourced suppliers for commodities (31). Maintaining capacity necessitates recurring cost-associated activities including equipment, physical and technological infrastructure maintenance, and workforce capacity building. Supporting end-to-end processes involves laboratory functions and specialists at multiple time points and guaranteeing capacity across all system components can be complex (32). As such, comprehensive estimates are again difficult to quantify—however, individual estimates suggest that for a model clinical laboratory in resource-limited settings, nearly a third of direct laboratory expenses are spent on activities needed to maintain capacity often requiring up to $600,000 per year for quality maintenance[4] alone (33).

B. Indirect Costs or Cost Savings

1. **Over and misdiagnosis.** Improved laboratory capacity increases health system cost-effectiveness by reducing over- and misdiagnosis and better informing resource allocation needs. Tests are necessary inputs for care provision, without which substantial costs are incurred from clinically and financially ineffective care. Inaccurate or incomplete diagnoses result in increased frequency and duration of healthcare visits with accompanying costs (34). Further indirect costs are sustained from consequent shifts in behaviour including delayed care-seeking and decreased utilisation of preventive services. Strategies to minimise misdiagnosis are assessed to have significant long-term savings from averted treatment costs; for example, in HIV, a retesting strategy to verify diagnosis prior to ART was estimated to save African countries $717 million over 10 years (35). New diagnostic innovations also present opportunities to improve care through a variety of testing metrics—modelling suggests that the value of such tools would largely be realised from reductions in over-treatment due to increased test specificity (36), which would also further reduce the costs of wider challenges such as antimicrobial resistance. At the health system level, improved disease surveillance increases accuracy of needs assessments, enabling better prioritisation and resource allocation strategies.

4 Including but not limited to costs for prevention (e.g., QA personnel and training, preventive equipment maintenance, etc.) and appraisal (e.g., inspection, QC testing, external QA and validation, etc.).

2. **Diagnostic over-reliance.** Over-reliance on diagnostic tools can lead to increased costs. The ultimate cost-effectiveness of a diagnostic approach depends not only on the test validity, but also on appropriate clinician behaviour in utilizing test results (37). Yet failure to train clinicians to understand the range of use cases and accurately interpret results can lead them to perceive tests as a diagnostic panacea. The clinical significance of results is not uniform across all contexts; consider the malaria "test and treat" approach, where the value of an RDT result varies significantly across differences in disease prevalence. Subsequently, clinical care is often compromised by clinicians neglecting to consider non-malaria underlying causes (38). This can result in substantial cost escalation that rapidly reduces the marginal benefit of the strategy.

Benefits

A. Individual—Patient Outcomes

1. **Improved health outcomes.** Increased diagnostic capability improves health outcomes through more precise, timely, and appropriate clinical action. The greatest gap in care pathways in all settings is the diagnostic step. Analyses from high-income countries suggest over two-thirds of significant clinical decisions are informed by laboratory results (39). Evidence from low-resource settings is more limited, but failure to detect disease and misdiagnosis are both globally recognised as barriers to providing proper treatment, particularly for communicable diseases and infections, where the potential for medical harm due to diagnostic error is high. Better clinical management relies on diagnostic differentiation, which is challenging in many African countries where many circulating pathogens have non-specific symptoms, such as fever (40); reducing inappropriate treatments could also save health systems money. Laboratory capacity can also address emerging acute threats, such as H1N1, where clinical laboratory usage was associated with a 69 percent decrease in mortality of hospitalised patients and reduced time between symptom onset and disease identification (41). Treatment of noncommunicable diseases can also be improved (42); gaps in care for breast cancer have included significant delays in diagnosis and treatment and disruptions in quality of care (43), which could be addressed by strengthened capacity for and integration of timely diagnostic services. While quantifying the total impact of diagnostics on patient outcomes is challenging, there can be little doubt that laboratory systems are a critical foundational platform for effective patient care.
2. **Standards of care.** Diagnostic technologies inform the development and practice of context-appropriate care pathways, including strategies designed for limited-resource settings. Approved diagnostic and treatment protocols often have limited generalisability and can carry recommendations that may have reduced benefit in some populations. While all clinical guidance is living and is regularly adjusted to reflect an increasing knowledge base, capturing such data to better elucidate

heterogeneity of treatment effects and facilitate development of more specific care pathways requires strong diagnostic capacity. For example, the transition from using interferon drugs (Peg-IFN) as antivirals for hepatitis C treatment in African countries was due to the identification of a genotype commonly found in individuals with African ancestry which was associated with a significantly reduced response to Peg-IFN therapies (44). The successful implementation of new protocols resulting from such discoveries also depends heavily on diagnostics, for instance, the shift in global malaria treatment recommendations from presumptive treatment (i.e., giving drugs based on fever) to a "test and treat" paradigm (45) which significantly improves health outcomes (46). Without RDTs or microscopy capability, clinicians fall back on proxy indicators to diagnose (including rainfall and other nonspecific clinical signs and symptoms) (47).

3. **Pathogen characterisation.** Recent developments in pathogen and patient characterisation technologies can improve patient outcomes. Modifying and adhering to care pathways depend not only on pathogen identification, but also on a specific understanding of pathogen and patient profiles. This capability has been greatly enhanced by the advent of human and pathogen genomics technologies, including whole-genome and next-generation sequencing. These approaches have led to significant pharmacogenomics findings with huge potential impact. For example, improvements to treatment for malaria caused by *Plasmodium vivax* could be gained through G6PD screening for primaquine usage, which could prevent 6.1 million cases and save $266 million worldwide (48), but many low-resource settings are unable to implement and use these technologies at scale without existing baseline diagnostics capability and infrastructure.
4. **IPC performance.** Consistent and appropriate use of laboratory services minimises the risk of secondary health threats associated with poor clinical care, including hospital-acquired infections (HAIs). Infection prevention and control (IPC) strategies depend on functioning laboratories to inform surveillance and control of facility-based spread, especially for drug-resistant microorganisms. Global burden of HAIs is heavily concentrated in limited-resource settings, with evidence suggesting a prevalence two to three times that of in Europe or the US (49). In Africa, estimates indicate HAIs occur in 2–15 percent of patients in hospitals (50), but actual detection and documentation of outbreaks is far lower and suggests significant under-detection (51). Despite some progress, clinical sites continue to struggle with delivering adequate IPC measures, especially at peripheral and subnational facilities, increasing the risk for nosocomial infection of all pathogens, which prolongs and worsens patient care. Lab capacity to diagnose, culture, and type pathogens to inform IPC protocols is critical to appropriately identify risk, provide effective treatment, and mitigate facility-based spread and associated healthcare costs.

B. Public Health

1. **Improved population well-being and quality of life.** Diagnostics usage increases population well-being in part by reducing overall population mortality and contributing to the reduction in burden of disease across all diseases. A wealth of evidence highlights the bidirectional association between quality of life and overall reductions in morbidity and mortality of all disease (52). Laboratories contribute significantly to achieving these improvements, with crude modelling estimates for six priority diseases suggesting that bridging the "diagnostic gap" (i.e., ensuring 90 percent of all true cases are diagnosed) may prevent over 1 million premature deaths annually in low- and middle-income countries. When the effects from appropriate treatment based on diagnosis is included, the reduction in mortality rises by 50 percent (53). Diagnostics may actually *appear* to increase morbidity due to improved detection—on average, half of all true cases for a range of diseases (including diabetes, hypertension, TB, and malaria) in low-resource settings go undiagnosed (53). Evidence suggests that better diagnostics for a variety of conditions would have the greatest overall benefit on reducing disease burden in Africa (compared to other low- or middle-income regions), due to the significant gaps in disease detection (54).
2. **Outbreak detection and response capacity.** Laboratories facilitate public health capacity to prevent, predict, respond to, and mitigate disease outbreaks. Laboratories are a key pillar in both preparedness and response to infectious hazards (55,56). This includes capacity to detect and identify a pathogen, communicate the result to the necessary stakeholders in a timely manner, and support control of further spread. Surveillance strategies like Integrated Disease Surveillance and Response hinge on laboratory capability to accurately and timely characterise the threat. Consequently, weak laboratory systems in many African countries limit national, subnational, and regional capacity for outbreak management. This not only affects the response to novel or emerging pandemic threats, including delayed detection (57) and pathogen misidentification, but also significantly hinders effective control of common or endemic high-burden diseases like cholera (58).
3. **Disease control strategies.** Stronger disease surveillance improves disease control strategies and facilitate monitoring of health threats. Developing context-specific, population-based approaches for disease control (including disease-specific strategies such as ending HIV/AIDS and controlling malaria) depends on accurate detection of diseases to target response strategies. While accurate detection can be challenging in all countries regardless of capacity (59), the degree of underestimation in low-income countries is far more substantial. Estimates suggest reported COVID-19 deaths in many low-income settings have represented less than 10 percent of true deaths, compared to upwards of 75 percent in most high-income countries (60). In the absence of robust routine or emergency surveillance systems to accurately characterise disease burden, analytical tools like modelling and population surveys can overcome some of this difference, but they involve a significant degree of uncertainty and limited granularity

for subnational trends. Some innovative approaches using unconventional data sources have emerged (61), but traditional passive and active surveillance systems (including sentinel surveillance) still form the backbone of understanding and characterising health of populations. Laboratories are also identified as a core International Health Regulation (IHR) capacity and a specific action in the Global Health Security Agenda (62), yet virtually all assessment frameworks and real-world experiences of African countries indicate significant gaps in laboratory systems and broader outbreak management capability (63). IHR progress monitoring shows the WHO African region consistently ranking last globally across most core capacities (64). Increased national capability boosts resilience globally, as investment benefits accrue beyond individual countries as pathogens do not respect borders.

4. **Antimicrobial resistance.** Laboratory services are critical to mitigating the emergence and spread of antimicrobial resistance. Failure to detect and characterise drug-resistant pathogens not only prevents appropriate clinical treatment, but also promotes the survival, persistence, and evolutionary selection of resistance genotypes. Insufficient usage of susceptibility testing and diagnostics leads to substantial mistreatment (65), fostering the rise and spread of resistance and rapidly diminishing the potential impact of therapeutic options. Historic examples include inappropriate and delayed application of artemisinin-based therapies for malaria in the face of widespread artemisinin-resistance (66), reducing the envisioned lifespan of artemisinin treatments. Misdiagnosis and mischaracterisation are significant drivers of resistance across a broad range of antimicrobials, including those against HIV (67), tuberculosis (68), and bacterial pathogens (69). Resistance trends can also be induced across multiple antimicrobials, often because of over-prescribing one treatment for another (e.g., antimalarials vs antibiotics) (70).
5. **Equitable outcomes.** Access to and appropriate usage of diagnostics improves health equity. Hard-to-reach populations and vulnerable and marginalised groups traditionally suffer the most from inconsistent access to health services. While access varies across settings and diagnostic type, a recent evaluation of a selection of low- and middle-income countries suggested that only 19 percent of basic primary care facilities (which serve rural and remote populations) had immediate access to essential diagnostics, compared to 68 percent of hospitals. For specific diseases, facilities were even more limited—few facilities were able to process referral to larger laboratories, and disease-specific diagnostics (such as those for HIV and malaria) were more frequently available than other technologies that have greater economies of scale to address a wide range of diseases (71). Additionally, the poorest and most vulnerable populations have lower financial resilience to the increased costs from periods of poor health (including lost wages and care-seeking costs) (72). Strengthening laboratory capacity—both broadly and targeted towards vulnerable groups—with traditional and new diagnostic innovations will have the greatest impact on populations in greatest need.

C. Health Systems (and beyond)

1. **Robust evidence generation.** Better disease data increases robustness of evidence generation to improve public health decision-making. Predictive analytical modelling can assess potential scenario outcomes and counterfactuals are valuable to inform policymaking especially in the face of high uncertainty. However, the applicability of such analyses depends on the appropriateness of selected parameters to the population they aim to represent (73, 74). For instance, despite the acknowledged heterogeneity in COVID-19 spread, many early epidemiological modelling forecasts applied a generic baseline model to a range of countries to provide rapid evidence to inform urgent policy decisions. More granular country-specific models (such as those developed in high-income countries) could have improved these projects by accounting for differences between contexts by incorporating factors like public health measures and contact patterns. However, this is heavily dependent on the availability of high-quality data, including disaggregated surveillance data (before and during the pandemic) and rapid research evidence, both of which were scarce in most African countries. Even the value of using basic epidemiological data for intra-country comparative analyses was limited and required substantial methodological adjustment to account for the variation in under-detection (19).
2. **International targets.** Diagnostic capability is critical to defining international benchmarks and targets on health outcomes and galvanising and shaping efforts towards progress. Key targets in frameworks for global commitments like achieving universal health coverage (UHC) and the Sustainable Development Goals (SDGs) rely on diagnostics to screen, prevent, and treat several priority diseases. A quarter of the indicators in both the WHO UHC and SDG frameworks need laboratory capacity, including incidence of multiple diseases, treatment for TB and HIV, mortality and treatment of selected chronic diseases, and cervical cancer screening (75, 76). Many other indicators indirectly implicate laboratory services, including IHR compliance and mortality attributed to air pollution and exposure to unsafe sanitation. Despite progress in recent years, most African countries still lag in several priorities, including HIV, TB, and malaria, and have struggled to expand service delivery to meet the growing needs of the population. Assessing, addressing, and monitoring these changing patterns depend on diagnostic capacity. More precise monitoring is necessary to inform appropriate financing strategies, especially with recent trends of stagnating national funding in the health sector compared to rising support from international development funds (77). Quantifying and achieving progress on these goals demand laboratory capacity, ultimately also increasing national governance in the region and ability to lobby for international support.

Additional considerations

Assessing the true value of laboratory investment returns involves considerations in addition to the costs and benefits described above. Externalities may moderate the effect of costs or benefits or deliver them in a manner that may be undesirable. While these elements may not be easily fiscally quantified, they illustrate the importance of considerations not captured by traditional evaluations.

1. **Lack of available costing data in African countries limits the generation and applicability of robust analyses, most often resulting in underestimating costs and misrepresenting benefits.** A recent review of economic evaluations for vaccine-preventable disease surveillance (78) found less than half of studies identified were able to collect financial estimates on lab costs. Of these, most only provided limited data with significant gaps in costing estimates, valuation of human resources, and other associated costs (e.g., overhead). Most analyses also only considered returns for a specific disease rather than taking a broad health systems scope, resulting in underestimates of horizontal laboratory system costs (79). Quantifying the impact of increased lab capacity on health outcomes remains challenging, not least because of a lack of data to inform counterfactuals. Even the most robust evaluations often misrepresent real-world cost thresholds; a recent study evaluating GeneXpert for TB diagnosis in South Africa found that contrary to most theoretical evaluations, there was no demonstrable evidence for greater cost-effectiveness compared to traditional microscopy, in part due to costs incurred from additional necessary steps in treatment and diagnostic pathways when using GeneXpert (80). However, other potential benefits and costs (e.g., reducing time to treatment vs. the cost of treating without sufficient susceptibility testing) are still unaccounted for in even the most robust analyses.
2. **International stakeholders' financing priorities are often misaligned with the greatest needs in low-resource settings.** Global interests are largely focused on emerging infectious diseases and high-impact diseases with pandemic potential, yet low-income countries continue to suffer most regularly and to the greatest overall degree from so-called "diseases of poverty", including cholera and diarrhoeal diseases, pneumonia, and tuberculosis, for which there are demonstrably effective control strategies and measures. A narrow financing focus that prioritises international interests (e.g., emerging threats) and fails to address the breadth of laboratory functions as a common good, risks backsliding on development and health progress to address routine, persistent disease priorities.
3. **Outcomes will not be immediately realised, and only maximised with sustained comprehensive commitments.** Progress will be slow and often difficult to quantify, which can jeopardise impact assessments and future commitments. Even with increased access, actual uptake in low-resource settings may take years without investments to overcome other delivery barriers, including weak health systems, insufficient national policy prioritisation, and limited delivery mechanisms (81). Misaligned approaches that fail to comprehensively consider both laboratory and supporting system components have often

resulted in solutions lacking sustainability. For example, in the aftermath of the Ebola outbreak, Sierra Leone lost much of its laboratory strengthening capacity built during the crisis (82). Support to enabling infrastructure and health systems are necessary to maximise diagnostics impact (83), and a narrow view of performance may mischaracterise the true potential and effect of investments, decreasing stakeholder confidence in value. Dedicated financing of vertical solutions (e.g., rapid diagnostics for a specific disease) can also hinder long-term progress towards sustainable strategies that rely on tools with better economies of scale (e.g., genomics technologies with breadth across a range of diseases).

Conclusions

The benefits of laboratory systems and diagnostics are myriad and extend far beyond immediate improvements to patient outcomes in single diseases. However, investments can be costly to be fully effective. Conventional economic evaluations underestimate the true value of laboratory strengthening by neglecting to consider all levels of the health system, including national to international impacts. Collective consideration of these effects can provide a wider perspective of laboratory value chains, despite the complexity in quantifying the returns. Specific disease crises like the COVID-19 pandemic can provide a window of opportunity to encourage high-impact investments, including the usage of collaborative cross-sectoral financing strategies with non-traditional funding sources. To maximise benefits, strategies must be maintained, context-appropriate, and developed using both national and regional investment cases that consider scale-up and maintenance needs. While investments must by nature satisfy a wide range of stakeholder interests, the most urgent priority is to achieve enduring, sustainable outcomes that address longstanding development health objectives.

Recommendations

Several recommendations for stakeholders investing in laboratories emerge from this paper:

- National, regional, and international decision-makers should look for opportunities to invest in laboratory and diagnostics services in African countries.
- Specific strategies should be informed by appropriate and available evidence, while still reflecting the wider holistic scope of costs and benefits.
- Investments should be sufficiently comprehensive across health sectors and be sustained long term to yield and maximise these wider benefits.
- Unique financing partnership approaches should be considered to reflect and address the disproportionate costs borne by different stakeholders.
- Investment objectives should focus on moderate- and long-term returns, with monitoring structures which are more indicative of development progress.

BOX 1. Examples from Zambia

While laboratory capacity in Zambia has increased, historic capability to conduct essential tests has been low—in 2016, estimates indicated that only 12 percent of health facilities nationally had full capacity for key diagnostics (84). The following examples from Zambia illustrate the costs and benefits of investments in clinical and public health laboratories, using the framework set out in this paper.

Costs example

This example illustrates the costs of investing in decentralised laboratory testing in Zambia's Southern Province using Xpert HIV-1 Qual performed on the GeneXpert IV, a point-of-care technology that provides Early Infant Diagnosis, HIV viral load testing, and tuberculosis testing. Due to challenges with centralised testing results turnaround time, only 60 percent of infants born to HIV-positive mothers were tested by the age of two months in 2019 in Zambia. Decentralised testing requires lower levels of training and resources after the initial investment and could therefore be scaled up to reach more families. The initial investment and ongoing costs below are based on testing in 40 facilities over a five-year period (85).

Cost Category	Cost Description	Cost (2018 US$)
Initial Investment Cost	Cost required to change systems from the previous standard of care to GeneXpert Initial investment costs associated with the purchase of the GeneXpert technology include the cost of the platform, maintenance, freight, insurance, inspection, handling, and clearance, shipping, and distribution. Additional set-up costs will include the revision of clinical guidelines; the adaptation processes such as supply chains and information management; and the training of staff to use the new technology.	The initial investment costs for 40 facilities were estimated to be $30,130 This includes (but is not limited to): 1. The GeneXpert machines—$17,000 2. Cost of set up (including initial training)—$4,800 3. Other equipment and shipping—$1,490
Upgrading Cost	As technology ages and new versions of the adopted GeneXpert platform become available, it may be desirable or necessary to replace the GeneXpert machines with new models.	Unknown at point of investment but should be factored in to total cost considerations

Cost Category	Cost Description	Cost (2018 US$)
Operational Costs	Costs include reagents and supplies for testing and specimen collection, sample transportation, salaries, processing, and testing, and waste management, result distribution	Recurrent costs—$27.91 per test Including (but not limited to): 1. Staff time 2. Reagents 3. Blood Collection 4. Other supplies (e.g., cotton roll, gloves, etc) 5. Other costs (e.g., storage)
Maintenance Costs	Cost of maintenance and repair of GeneXpert platform for faults and errors	3 Year Warranty Extension—$6,840 Cost per repair outside warranty for remaining lifespan—$250

Benefits examples

A. Patient Outcomes: Tuberculosis Care Quality Improvements. One of Zambia's 10 legacy health sector goals is to reduce tuberculosis (TB) incidence and eventually eliminate it (86). As part of the efforts to achieve this, a quality-of-care improvement approach was implemented at the Mulenga Urban Health Post in Copperbelt Province (87). It aimed to improve TB health outcomes and standard screening practices by investing in a coordinated quality management system, including support for increased bacteriologically confirmed diagnostic capacity of pulmonary TB through introduction of a GeneXpert system. The holistic approach also involved strengthening the TB registry and laboratory documentation, integrating antiretroviral therapy (ART) provision to better manage TB-HIV coinfections, and increasing workforce capacity to facilitate TB treatment completion and patient follow-ups. After only one year of implementation, treatment success rate increased from 35 percent to 50 percent, with no patients lost to follow-up despite the long monitoring period. While only 52 percent of cases receiving treatment had bacteriological confirmation, qualitative feedback suggested increased workforce understanding of the importance of diagnostics for better clinical outcomes and personnel capacity was cited as a key reason for the evidenced success. In March 2019, the facility adopted GeneXpert (in addition to microscopy) as a standard screening practice for TB confirmation.

B. Public Health: Cholera Re-emergence. After a five-year period with little to no cholera incidence in Zambia, a significant resurgence in 2016 reinstated cholera as an active public health threat. Retrospective laboratory investigation was performed on samples from the past three outbreaks to understand the phenotypic characteristics and genetic diversity of *V. cholerae* strains to aid in disease control and prevention efforts (88). Findings suggested that the outbreaks in 2009 and 2010 were related but switched serotypes. The 2016 outbreak was unrelated to the other two outbreaks but appeared to have been driven by multiple infection sources rather than a single source, suggesting a need for wider surveillance measures. Antimicrobial resistance trends were

characterised in all three outbreaks, including multi-drug resistance in 2016. Fortunately, chosen treatment options matched susceptibility traits despite the lack of testing during the outbreaks, but evidence suggested further evolving resistance patterns and the importance of real-time characterisation for treatment. During a subsequent outbreak in October 2017, this molecular and biochemical laboratory approach was integrated into the active public health response to inform control measures. Samples were regularly tested and characterised at a national reference laboratory, strengthening surveillance and informing the Ministry of Health-coordinated response structure (89).

C. Health System (and beyond): Robust evidence generation using RDTs and health management information System (HMIS). Increasing diagnostic capability improves health outcomes through providing better treatments, and Zambia has been scaling up diagnosis at point-of-care with Rapid Diagnostic Tests (RDTs) since 2006 (90), which has allowed for confirmed diagnosis at the majority of facilities nationally since 2009 (91). In addition, the health management information system (HMIS) in Zambia was revised in 2008, which contributed to improved routine reporting and data collection. Enhancing the link between diagnostic results and HMIS systems allows routine incidence data to be used for rigorous evaluation of malaria control programs. A study using data from the Zambia HMIS for 2009–2011 linked insecticide-treated net (ITN) intensity and malaria incidence to show that an increase in one ITN for each household was associated with 27 percent reduction in confirmed malaria case incidence and 41 percent in areas with lower malaria burden (92). Programme evaluation can yield greater programme effectiveness and contribute to better clinical management and care pathways, particularly in resource constrained contexts such as Zambia. Linking diagnostics and HMIS systems means Zambia could use real-time data to monitor trends in confirmed cases and deaths. This incidence data from RDTs is highly useful for tracking cases and emerging threats, and assist with timely decision making for malaria interventions. In this way Zambia's consistent RDTs and strong linkages with HMIS data will improve infection prevention and control strategies.

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