Laboratory Medicine in Sub-Saharan Africa:

Strengthening Systems for Sustainable Healthcare

Thesis on Development Policy

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1 Executive Summary

Together with the medical field of pathology, laboratory medicine plays an integral role in delivering quality patient care in any health system, influencing approximately 70% of clinical decision-making at least in high-income countries. Likewise, laboratory system strengthening is required for the sustainable strengthening of health systems as a whole. Robust, resilient laboratory networks will not only support the delivery of adequate healthcare services to patients to deal with existing health issues; moreover, they will also lead to a responsiveness of the health sector that will allow for emerging threats to health – and to international health security – to be dealt with before new epidemics grow out of control. Finally, they will enable the collection of routine data, which can then inform public health specialists and policymakers.

In the past, the field of diagnostics was heavily neglected in the global health agenda. Where diagnostic systems were needed, there was a preference either for simple rapid tests (needing little infrastructure or know-how) or for laboratories geared towards specific diseases (notably HIV/AIDS). Neither of these approaches contributed to a broader, sustainable system strengthening. However, the World Health Organisation Regional Office for Africa (WHO AFRO), the recently-founded Africa Centres for Disease Control and Prevention (Africa CDC) and, notably, the African Society for Laboratory Medicine (ASLM) are now taking the lead in coordinating and facilitating system strengthening across the region.

This essay reviews the current state of laboratory medicine in sub-Saharan Africa and highlights five types of gaps: physical (equipment and infrastructure); professional (human resources, including training and retention); policy (national and supra-national planning); management (quality, maintenance, and supply chain management); and trust and knowledge gaps (poor communication between clinical and diagnostic personnel). On the other hand, this essay also highlights the major successes achieved in recent years. These include the leadership and advocacy of ASLM; the new support systems facilitating accreditation; and the more holistic approach to health system strengthening in the era of the Sustainable Development Goals. Furthermore, a very recent development is lauded: More than four decades after the first Essential Medicines List, in May 2018 the WHO published an Essential Diagnostics List, a catalogue of 113 tests needed to detect, diagnose and monitor the most common medical conditions as well as a number of global priority diseases.

Based on these findings, this essay makes recommendations towards strengthening medical laboratories across sub-Saharan Africa. Recommendations are made at three geographic levels – international/regional, national, and local – and are addressed to international/regional multilateral organisations, national governments and Ministries of Health, and local implementors, respectively.
At the international level, funding for diagnostic systems must increase. Though it is true that sub-Saharan African countries face constraints in terms of their absolute spending power, many have also failed to adhere to mutually agreed relative spending targets for health. Tied to the question of funding, it is essential that diagnostic technologies be made available at fair prices. Here, regulations that limit the scope of patent laws may play an important role. In this respect, countries across the region will be able to greatly increase their negotiating power by harmonising and standardising their systems. This will also save costs, facilitate accreditation, and ultimately contribute to better patient care. Finally, African leadership and South-South partnerships must be strengthened in order to leverage the ever-growing pool of knowledge within the region and generate true ownership.

At the national level, there have been many calls for the establishment of tiered laboratory networks, in which the range and complexity of available diagnostic tests increases from “low”- (e.g. small local laboratories) to “high”-tier laboratories (e.g. national or supranational reference laboratories). The goal is that effective referral systems should allow universal access to specialised diagnostic services. In this context, the author suggests that staff and trainee rotations between and within the respective tiers of the laboratory system will be hugely beneficial. Such rotations will contribute to a natural knowledge transfer, facilitate harmonisation, and likely increase staff retention by generating new opportunities for professional development. To further address staff shortages, the feasibility of task shifting, i.e. the delegation of duties to lesser-trained personnel, should be assessed. This practice is already common in clinical care in low-income countries. In addition, national governments should incentivise the accreditation of laboratories and invest in the digitalisation of medical records. Accreditation provides a means by which laboratories can attest to their quality standards, and the process provides them with regular feedback and clear targets for improvement. Meanwhile, transitioning from paper-based to electronic storage of medical records will benefit patients (improved clinical decision-making), clinical and laboratory staff (time saved), health systems (reduced costs), and the general population (health policies informed by aggregated medical data).

At the local level, laboratories are encouraged to engage in partnerships, be it with non-profit organisations or with the private sector. However, it is crucial that the mutual responsibilities of all involved parties are clearly defined from the start. In order to ensure sustainability, risk analyses, maintenance plans, and response plans for events that would endanger the project should be in place. Individual laboratories should strive to work within the broader health system in order to create synergies and foster national ownership. Finally, laboratories are encouraged to actively participate in research, since public health data is severely lacking for many countries.

Laboratory system strengthening in sub-Saharan Africa is rapidly gaining momentum. By tapping into key opportunities, remarkable improvements to patient care at last appear within reach.
2 Abbreviations

**Africa CDC**  
African Centres for Disease Control and Prevention (Addis Ababa, Ethiopia)

**AIDS**  
Acquired immune deficiency syndrome

**AJLM**  
African Journal of Laboratory Medicine

**ASLM**  
African Society for Laboratory Medicine

**AU**  
African Union

**EML**  
WHO Model List of Essential Medicines

**EDL**  
WHO Model List of Essential In Vitro Diagnostics

**EPC**  
European Patent Convention

**HIV**  
Human immunodeficiency virus

**IHR**  
International Health Regulations

**IPR**  
Intellectual property rights

**ISO**  
International Organization for Standardization

**MDGs**  
Millennium Development Goals

**NCD**  
Non-communicable disease

**POC**  
Point of care

**SDGs**  
Sustainable Development Goals

**SLIPTA**  
Stepwise Laboratory Quality Improvement Process Towards Accreditation

**SLMTA**  
Strengthening Laboratory Management Toward Accreditation

**TRIPS**  
Agreement on Trade-Related Aspects of Intellectual Property Rights

**UHC**  
Universal health coverage

**WHO**  
World Health Organisation

**WTO**  
World Trade Organisation
3 Introduction

The World Health Organisation (WHO) Constitution defines health as a fundamental human right (1, 2); however, half of the world’s population still lacks access to essential health services (3). While there is a general understanding of the importance of medicines and vaccines, there has long been a lesser focus on diagnosis (4–9) – that is, the identification, staging, and monitoring of a disease. Laboratory medicine enables diagnostic testing and is a crucial element in any health system (4, 10). This essay aims at reviewing the status of medical laboratory\(^1\) systems in sub-Saharan Africa by addressing the following key questions:

i) Which key actors and agreements shape the efforts to strengthen laboratory systems in sub-Saharan Africa;

ii) What is the current status of laboratory diagnostics throughout the regions, and what shifts have taken place in recent years;

iii) What are the major barriers, opportunities and priorities for achieving sustainable solutions; and

iv) Based on the previous point, what recommendations can be made for policymakers and implementors alike.

This essay will start by highlighting the role of medical laboratory systems within the context of public health, focusing on sub-Saharan Africa (Chapter 4.1). Next, it will review recent developments as well as current priorities in this region (addressing questions i—iii; Chapter 4.2). Based on these insights, possible strategies for laboratory system strengthening throughout the region will be discussed (question iv; Chapter 5). These recommendations will draw on existing literature, current trends, as well as personal experience. The recommendations will fall into three categories: the international level, addressing international (global or regional) multilateral organisations or intergovernmental collaborations; the national level, addressing national governments and Ministries of Health (MoHs); and the local level, directed at managers of individual laboratories or locally-acting NGOs.

Finally, the conclusion will summarize the recent developments that laboratory diagnostics have undergone, highlighting the power of international development goals in shaping even highly specific and specialised fields of development, and will make a cautious prognosis of the road ahead.

\(^1\) Note: For the purpose of this thesis, the terms “medical laboratory”, “clinical laboratory”, and “diagnostic laboratory” are used interchangeably.
4 Background

4.1 The Role of Medical Laboratories in Global and Public Health

Laboratory medicine fulfills multiple functions that are relevant to all levels of public health. At the individual level, medical laboratories enable the detection and diagnosis of disease, as well as the monitoring of treatment success and disease progression. At the population level, laboratory systems assist in disease screening and public health surveillance, generating data that contribute to identifying health priorities and creating sound public health policies. Finally, at a regional and global level, medical laboratory systems are essential to minimizing global health security risks. Early detection of new disease outbreaks allows for rapid response, while having strong laboratory systems already in place allows for a more robust management of new threats, thus reducing the spread of disease. These functions are described in greater detail below.

4.1.1 A Medical Requirement

Together with the medical field of pathology, laboratory medicine enables “the accurate diagnosis and detection of disease, informing prognosis and guiding treatment, contributing to disease screening, public health surveillance and disease registries, and supporting medical-legal systems”, as was recently described by Wilson et al. (4). In addition, the rapid diagnosis of infection or therapy failure can prevent the spread of disease, as is reflected by the prominent “treatment as prevention” strategy in HIV management, in which treating HIV-positive individuals not only protects their own health, but also prevents them from being infectious to others (11).

The establishment of strong public health laboratory networks has been described as one of six core functions of public health with the greatest influence on the effectiveness of the health system and on the public’s health (5, 12). Furthermore, it has often been stated that at least in high-income settings, approximately 70% of clinical decisions are influenced by data from laboratory medicine (13–15). While this claim is difficult to validate (16), the importance of this field in health systems in undisputed. In African countries, Best and Sakande claim that nearly half of medical decision making is influenced by laboratory testing (6). Nevertheless, diagnostic systems have often been neglected in the effort to strengthen global health systems (6, 8). For instance, out of 49 countries evaluated in sub-Saharan Africa in 2013, 37 did not have medical laboratories that met international quality standards (9, 17).

In 2014, the World Health Organisation (WHO) cited a “lack of access to quality medicines and appropriate health technologies, in particular in vitro diagnostics [i.e., tests performed on bodily
samples such as blood, tissue or urine] and laboratory services”, as a cause for the slow progress towards achieving the Millennium Development Goals (MDGs) related to health\(^2\), going on to state that “without diagnostic tools, safe and effective drug treatment, prevention of resistance to antiretroviral therapy [i.e. treatment for HIV/AIDS] and monitoring of resistance are not possible” (8, 18). This view was echoed, among others, by Wilson et al., who view access to quality laboratory medicine as a precondition to sustainably controlling disease and reducing mortality, stating that “any attempts to reduce disease burden and decrease premature mortality rates will not succeed unless clinicians have access to the high-quality [pathology and laboratory medicine] services necessary for diagnosis, prognosis, and guidance of therapy” (4). Especially in the case of HIV, a disease that continues to claim one million lives annually mostly in sub-Saharan Africa (19), the lack of a cure necessitates lifelong monitoring of therapy success through laboratory testing.

### 4.1.2 A Requirement for Sustainability

Early attempts at setting up diagnostic laboratories applied a “vertical” approach focusing on select diseases – a reflection of the insular foci of the Millennium Development Goals (5, 6). In this context, many HIV/AIDS laboratories were set up, though this did not sufficiently lead to a general strengthening of laboratory systems (20, 21). According to the WHO, “antiretroviral [i.e. anti-HIV] therapy, tuberculosis treatment and anti-malarial therapy are becoming increasingly available in many resource-limited settings as a result of global efforts, however, the same attention has not been given to the provision of appropriate and affordable in vitro diagnostics” (8).

Compared with the MDGs, the Sustainable Development Goals (SDGs) place an increased focus on sustainable and resilient infrastructure development with equitable access for all (SDG 9) (22). With respect to health, the SDGs incorporate not only infectious diseases (such as AIDS, tuberculosis, malaria, and others; SDG 3.3), but also recognise the growing importance of non-communicable diseases (NCDs; SDG 3.4). Many NCDs, such as diabetes, hyperlipemia, and cancer, require laboratory diagnostics for detection, diagnosis, staging, prognosis, and/or treatment planning (4).

One alternative to laboratory system strengthening would be an increased reliance on rapid tests that circumvent the need for sophisticated laboratory infrastructure or trained staff (23). So-called point-of-care (POC) tests, with which the results become available still during patient consultation, additionally eliminate the need to transport samples from healthcare facilities to central laboratories (23). Accordingly, some have argued that POC testing is more important – and more realistic – in many low-income settings (23). Indeed, benefits of this test method can include the immediate availability

\(^2\) MDG 4, Reduce Child Mortality; MDG 5, Improve Maternal Health; and MDG 6, Combat HIV/AIDS, Malaria and Other Diseases (18).
of test results, optimized treatment decision-making, avoiding referrals, and potentially more efficient care (24).

However, though POC tests can certainly bring added value to the diagnostic system, solely relying on such testing would also have major drawbacks: For one, POC tools are not available (nor necessarily feasible) to replace many established laboratory-based tests. This is particularly relevant in the era of the SDGs, which greatly increased the number of priority diseases compared to former public health goals, thereby also increasing the variety and complexity of necessary tests. Horton et al. go so far as to say that “[bypassing poorly functioning laboratory systems with POC testing] hinders the development of a sustainable solution, and this approach has proved to be inadequate in the management of new threats such as Ebola virus and the emerging burden of non-communicable diseases” (24).

Certainly, investments in diagnostic laboratories have the advantage of working to strengthen the health system (24). Ideally, POC tools and more complex laboratory testing will be used together towards holistic healthcare solutions.

4.1.3 A Requirement for Health Security

In addition to the moral imperative of advancing sustainable diagnostic systems in low- and middle-income countries, there is also a level of reasonable self-interest even for wealthier nations, namely global health security. The WHO Strategic Framework for Strengthening Health Laboratory Services 2016—2020 states that “the modern world is threatened with growing outbreaks of known, emerging or unknown diseases. […] In our preparedness and response to these threats, the role of public health laboratories is crucial” (10).

As Kluge and colleagues recently noted, health system strengthening and health security enhancement go hand in hand and are mutually reinforcing (25). For instance, the resilience of health systems can be increased by promoting universal health coverage, which can also have a major impact on health security by “preventing outbreaks through high immunisation coverage, providing early alert by rapid access of all patients to healthcare, better response thanks to reliable infrastructure and healthcare workforce for case management” (25). Indeed, it is believed that poor preparedness and responsiveness of health systems have been enabling factors in disease outbreaks, including the recent Ebola and Zika epidemics (10, 25).

In addition, results gained from routine testing can be used to gauge disease trends and inform health policy (4). Therefore, diagnostic results inform decision-making relevant to both health security and national development (10).
4.2 The State of Medical Laboratories in Sub-Saharan Africa

4.2.1 A Shift of Focus: Leadership, Agreements and Recent Advances

Many sources agree that laboratory medicine, and indeed broader health system strengthening, was ignored for too long while international organisations instead focused on individual diseases. However, awareness has been increasing significantly: In 2011, the African Society for Laboratory Medicine (ASLM), a non-profit organisation endorsed by the African Union (AU), was founded to “advocate for the critical role and needs of laboratory medicine and networks throughout Africa” (26). The same year, the ASLM co-launched the African Journal of Laboratory Medicine (AJLM), striving to “[encourage] scholarly exchange amongst biomedical scientists and clinicians, public health officials, the medical community and policy makers across Africa” (27). Similarly, recent activity of other key actors such as the World Health Organisation (WHO) and the newly-founded Africa Centres for Disease Control and Prevention (Africa CDC) reflect a fledgling shift of focus (10, 28–30).

Indeed, the ASLM and the WHO, among others, are establishing themselves as important players in the push towards creating resilient and functional medical laboratory systems throughout sub-Saharan Africa (26, 31). They have been involved in the formulation of seminal agreements to guide the strengthening of healthcare systems, such as the World Health Organization’s International Health Regulations (IHR) 2005, as well as the Maputo Declaration (2008) (20) and later Freetown Declaration (2015) on Strengthening of Laboratory Systems.

A further significant development occurred in May 2018: More than four decades after the original Essential Medicines List (EML), the WHO has now published its first Essential Diagnostics List (EDL), encompassing 113 tests or products “needed to diagnose the most common conditions as well as a number of global priority diseases” (32). This list contains a balance of rapid tests requiring little infrastructure or training, which are particularly suitable for primary healthcare, and more complex tests intended for use in clinical laboratories (32, 33). The goal is that the EDL, which will be updated regularly, will serve as a reference which countries can adapt to the local context in order to develop their own national lists (32).

4.2.2 Current Gaps

Although legally binding to all 194 WHO Member States, the above-mentioned IHR 2005 requirements for laboratory core capacities have not been met in many countries (10, 25). According to the WHO, reasons for its poor implementation include “weak or non-existent regulatory frameworks for laboratory services, insufficient funding and inadequate access, quality of testing, equipment and
supplies, and competence of the workforce”, as well as the fact that “laboratories are given low priority and recognition in most national health care systems” (10).

Similar aspects are raised in the Maputo Declaration, as well as in more recent academic publications. Broadly speaking, the current shortcomings can be categorised into five types:

**Physical gaps:** On the physical level, there are deficiencies in terms of physical infrastructure (4, 5, 20), including equipment (5). These gaps are closely linked to managerial (e.g. having good maintenance plans that prolong the lifespan of equipment and increase sustainability) and professional (e.g. having qualified personnel handling the equipment correctly) challenges.

**Professional gaps:** On a professional level, insufficient education and training programmes (4) as well as poor career development prospects together lead to poor staff retention and a lack of human resources (4, 5, 20). Solving this issue will only be possible through African-based training institutions and programmes tailored specifically towards the regional and local needs (5).

**Policy gaps:** On a political level, budgetary and policy shortcomings lead to weak national laboratory policies and poor strategic planning (20). Perhaps most importantly, individual laboratories are not yet sufficiently integrated into national and supranational laboratory networks with referral systems (4) – which would allow people living in remote areas to share the benefits of medical advances not (yet) accessible in their areas.

**Management gaps:** Together with the resource constraints experienced by individual laboratories, and the inadequate supply of trained personnel, organisational and policy shortcomings promote weak maintenance systems (5), quality management systems (4, 20), and supply chain management (5, 20). Furthermore, laboratories often lack the support they would need to attain accreditation, which would increase their credibility and serve as a certificate for the quality of their results (4).

**Trust and knowledge gaps:** All of these challenges negatively impact the quality of laboratory results. Herein lies another challenge: physicians may lack trust in these results, rather relying purely on clinical judgement and empirical therapy (5). The consequence is that the strengthening of laboratory systems may not automatically and immediately translate into improved outcomes. Rather, improved communication between clinicians and laboratories will be required in order to build confidence and improve patient care (5).

### 4.2.3 New Opportunities

Despite the above-mentioned challenges, the past years have brought about some remarkable improvements. Recent advances bring new opportunities, some of which are detailed here.
**Policy and advocacy**: Some authors believe that the apparent lack of political will in the past was caused in part by a lack of leadership and advocacy (20, 24): indeed, laboratory medicine is less “visible” to the public than many other medical disciplines. Alemnji *et al.* argue: “Developing strategies to raise awareness on the impact and importance of improved laboratory quality systems in Africa has been a huge challenge because the impact of laboratory errors on health services has not been systematically analysed and presented to policymakers.” (5). However, in parallel with an increased focus from the WHO (8, 32), younger organisations such as the ASLM and the Africa CDC are rising to the challenge, and will both facilitate supranational coordination and support governments in developing their own national programmes (26, 28, 30).

**Vertical approach vs. integration**: Previously, investments in diagnostic laboratories – where they did happen – were focused on specific diseases. Most notably, there were investments in specialised HIV/AIDS laboratories. However, this approach did not optimally strengthen the broader diagnostic and health systems, and may even have aggravated competition for resources within the healthcare framework (6). Conversely, integrating this existing infrastructure into laboratory networks is expected to cost-effectively strengthen the broader health system (5, 6, 20, 21).

**Accreditation and the SLIPTA/SLMTA processes**: Accreditation entails the “external validation of quality, with both technical and management components” (34). Ultimately, the goal at least for larger reference laboratories must be to achieve international accreditation (according to the ISO 15189 standards); however, this is still far out of reach in many settings. As per April 2017, the vast majority (n=326; 73.6%) of internationally accredited African medical laboratories are located in South Africa (35). All other African countries combined have just 135 ISO-accredited medical laboratories, with the highest numbers in Kenya (n=31) and Egypt (n=27) (35).

One of the major achievements of WHO AFRO and the ASLM has been the development and implementation of two frameworks to facilitate quality improvement of African laboratories: the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) process (36), an auditing process evaluating the quality of laboratories below the level of international accreditation; and the Strengthening Laboratory Management Toward Accreditation (SLMTA) toolkit (37), a mentoring and training programme for laboratory personnel.

In essence, SLIPTA awards laboratories not yet ready for full accreditation with zero to five stars, with five-star laboratories ready to apply for accreditation under international (ISO 15189) standards (5). These new tools provide a user-friendly path for individual laboratories and laboratory networks to consistently improve their quality.
**Tipping point:** The HIV/AIDS epidemic exposed the need for laboratory systems to support prevention, monitoring and optimal treatment of disease (5). More recently, outbreaks of Ebola in West Africa (4, 6, 7) and Zika in Central and South America (4) have further exposed the fragility of current systems as well as positioning this fragility as a global security threat (25). This, together with the broader and more sustainable approach of the SDGs when compared with previous global health policy, may have brought about a crucial tipping point in the history of laboratory medicine.

### 4.2.4 Official Priorities for Laboratory System Strengthening across Africa

In recognition of the current gaps and opportunities, the major relevant international organisations have laid out their priorities towards strengthening laboratory medicine across Africa. **Error! Reference source not found.** in the Annex (Chapter 8) provides an overview of these targets, which pertain mostly to the international (i.e. pan-African or regional) and national level. They broadly fall into ten categories:

i) **National laboratory policies and plans** as a prerequisite for the sustainable strengthening of medical laboratory systems in each country (10, 20, 30, 31, 38).

ii) **Tiered laboratory networks and referral systems** (20, 31) both within nations (10, 26, 30, 38) and at the supra-national level (10, 38).

iii) **Capacity-building** in terms of breadth of diagnostic tests available, as well as in the volume thereof (30, 31, 38).

iv) **Human resources**, including training, retention, and adequate financing (10, 20, 26, 30, 31, 38).

v) **Quality management systems**, which should ideally be harmonised within and between countries (10, 26, 30, 31).

vi) **Regulations and safety measures**, ideally harmonised within and between countries (10, 26, 30, 38).

vii) **Harmonisation** of systems within and between countries, including clinical guidelines, procurement, quality management, maintenance systems, and regulations (20, 26, 38).

viii) **National ownership** as a prerequisite to ensuring sustainability (20).

ix) **Private industry, research and development;** specifically, the potential of public-private-partnerships (20), the need for new diagnostic systems that are better suited to low-income countries (20, 38), and the promotion of evidence-based decision-making (10).

x) **Leadership and advocacy** of international organisations (31) and national governments (10).
5 Discussion

In the following, recommendations and suggestions are made that address three levels in laboratory system planning: international and regional coordination; national planning; and local implementation – though some interventions by their nature apply to more than one category. These recommendations take into account the priorities identified by the WHO, ASLM and other international organizations (20, 28, 30, 31, 38) and the analyses of representatives of key professional groups (24, 34, 39, 40) or other expert opinion (5–7, 41), as well as drawing from the author’s experience with HIV-related diagnostics in southern Africa. Rather than adding to the priorities listed in Chapter 4.2.4, these recommendations can be seen as a set of practical suggestions towards addressing them.

5.1 The International Level

5.1.1 Funding of Pathology and Laboratory Medicine

Perhaps unsurprisingly, many of the main barriers to establishing functioning laboratory systems in resource-limited settings – from infrastructure to human resources to quality management (4, 10, 20) – directly reflect the impact of budgetary constraints.

Pathology and laboratory system strengthening must be viewed within the greater framework of health system strengthening, where major shortcomings can be observed especially in sub-Saharan Africa. This is exemplified by the outcome of the 2001 Abuja Declaration, in which AU Member States pledged to allocate at least 15% of their annual budget to health (42); however, over the following decade health budgets remained stagnant or even dropped in nine (19.6% of AU countries with interpretable data) and 11 (23.9%) countries, respectively (43). A decade later, only six countries (Rwanda, Liberia, Malawi, Zambia, Togo, Madagascar) had reached this goal, with four more countries coming close (44). To achieve sustainable progress, it will be important that countries respect their commitments in the Abuja Declaration and make healthcare spending a priority.

Within healthcare spending, pathology and laboratory medicine have a somewhat disadvantaged position in that they suffer from a lack of visibility. For this reason, Horton et al. argue that pathologists must take on an increased leadership role in the global health arena, and call for increased advocacy for pathology and laboratory medicine (24).
5.1.2 Fair Pricing for Laboratory Medicine

The above-mentioned financial constraints are also affected by the direct cost of diagnostic tests. These costs, in turn, will depend on the regulatory landscape with respect to intellectual property rights (IPR).

Many industries argue that IPR are needed to incentivise research; however, an excess of regulation can also hinder innovation by preventing access to methods or materials needed for research (45), strengthening the position of monopolies, and making it difficult for smaller companies to navigate the complex regulatory landscape. In addition, IPRs tend to skew biomedical research to products that will yield high profits – that is, products that will be sold primarily in high-income countries (45).

Today, patent laws on pharmaceutical products are relatively clear (46): The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in force since of 1995, lays down minimal standards for the regulation of intellectual property to which all World Trade Organisation (WTO) Member Nations must adhere (47). This extension of IPR contains a paragraph allowing Members to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from patentability. Still, this did not fully resolve the question of access to essential medicines in poorer nations (48), and the Agreement was often viewed as benefitting the pharmaceutical industry and wealthy countries (49). In consequence, the 2001 Doha Declaration on the TRIPS Agreement and Public Health introduced certain flexibilities, listing several measures that countries can take to ensure the provision of essential medication (50).

By contrast, the patentability of medical devices is less clear (45, 46). While more than 80 countries exclude medical procedures from patentability, the United States and Australia have taken a more liberal approach (46, 49). In addition, Oguanobi notes that although the European Patent Convention (EPC) in theory excludes the patenting of methods “directed toward surgery, therapy, or diagnosis”, it does allow patenting in certain “exceptional cases [that] depend on the technical details of the device, and the EPC decides on a case-by-case basis (46).

Diagnostic systems of increasing complexity are finding use in poorer countries. In order to ensure universal access not only to essential medicines, but also to essential diagnostics, it will be important that the regulatory landscape surrounding medical diagnostics is inclusive to low- and middle-income countries. This issue must be on the agenda of organisations like the ASLM and the WHO, and of leaders of poorer nations, and must equally be recognised by the WTO and leaders of wealthy nations as a priority.
5.1.3 International Harmonisation

One important strategy to reduce the burden on individual health systems and increase efficiency is to increase the degree of harmonisation across the region (6, 24, 34, 41). Potential targets for international harmonisation include aligning clinical guidelines, regulatory frameworks (24, 26), quality management systems (6, 7), and accreditation systems, to name just a few.

There are many benefits to standardisation. On a clinical level, standardisation allows for uniform and consistent case management and increases the comparability of results (51). On a programmatic level, standardisation facilitates maintenance, training and transferability of human resources, and quality assurance (51). Finally, standardisation of specific equipment and diagnostic tests greatly simplifies supply chain management by creating leaner systems (6, 20, 41, 51). This will further allow for mutual support between laboratories through redistribution during local stock-outs (51). Furthermore, aligning procurement will allow for bulk purchasing and may create a dynamic of group pressure in which African nations are in a stronger position to negotiate fair prices (51). It is conceivable that a lean, well-defined and reliable procurement structure may help to incentivise greater investments of medical, pharmaceutical, and biotechnological companies to the region (51).

Naturally, harmonisation between countries should not replace the need for national laboratory plans and strategies, adapted to the national context. After all, one major challenge to implementing standardisation after the Maputo Declaration was a misalignment of laboratory procurement policies with national treatment guidelines (41). Nevertheless, having blueprints in place can serve as a good baseline which countries can easily adjust according to their needs. The ASLM and WHO AFRO are well-positioned to continue to facilitate harmonisation and standardisation across the region, as well as to advise countries in similar settings (7). Certainly, the SLIPTA/SLMTA process is a major step in this direction with regards to accreditation, and the EDL – though it does not recommend specific products or suppliers – should be embraced by countries as a useful benchmark.

5.1.4 Promotion of African Leadership and South-South Partnerships

Already today, there are 511 ISO accredited laboratories across Africa (35). To fully benefit from this expertise, accredited laboratories should be given a platform and incentives to share their knowledge and foster improvements across the region.

South-South or triangular collaborations to strengthen laboratory medicine have proved successful in the Caribbean (52), and would likewise bring multiple benefits to sub-Saharan Africa. These could include i) enabling mutual learning with regards to both technical and managerial issues; ii) facilitating harmonisation (of standards, clinical guidelines, quality management, etc.) through regular exchanges;
iii) cost reductions through shared use of resources, e.g. use of same suppliers (enabling scale-ups and bulk ordering) and shared cold chains; and iv) the establishment of regional centres of excellence. When compared with the use of experts from further afield, regional experts will have a better understanding of the medical priorities in their geographic region, of the local availability of reliable suppliers (with whom they will already have established connections), and of technical challenges (such as unstable power supply, difficult road conditions, etc.) specific to the region and how best to overcome them.

One way to facilitate such knowledge transfer would be the establishment of multiple regional centres of excellence, with training centres offering specialised short courses for laboratory personnel from different countries. Regional centres could also be used to negotiate prices and arrange procurement for multiple countries that have aligned their tests and clinical guidelines. This would likely be especially valuable to smaller or less developed nations who who could benefit from the buying power and expertise of larger or wealthier neighbours. Additionally, these centres of excellence could collaborate with biotechnological companies through public-private partnerships. For example, it is conceivable that biotechnological companies provide training and equipment at a reduced cost as part of their Corporate Social Responsibility agenda, potentially in return for preferential access to these emerging markets. Finally, these centres could encompass supranational reference laboratories in which tests that exceed a member nation’s laboratory capacity could be performed.

Lastly, South-South partnerships could also take the form of more intense, bilateral agreements between countries (or their national reference laboratories), in which know-how and technologies already available in one country could be transferred to another where these technologies are being newly implemented.

5.2 The National Level

The urgent need for national laboratory policies setting out the vision of the laboratory system, and of national strategic laboratory plans providing a roadmap to guide the implementation of this vision, is broadly accepted and recognised (4–7, 10, 20, 24, 30, 31, 34, 38). The same is true of the need for tiered laboratory networks with strong referral systems (5, 6, 10, 20, 24, 26, 30, 31, 34, 38, 41). A tiered laboratory strategy essentially means that different tiers of laboratories (e.g. laboratories at the level of the community health centre, district hospital, provincial hospital, and national reference laboratories) should exist (6, 34). Laboratories within these tiers should have increasing technical capacity and testing complexity at each successive tier, with regular referral of more complex tests to the next level, thus enabling even remotely living people to access complex diagnostic testing (6, 34).
Specific models for designing tiered laboratory networks have been suggested elsewhere (6, 34). The following suggestions are designed to address this and further aforementioned priorities simultaneously and in a synergistic fashion.

5.2.1 National Harmonisation

Harmonisation and standardisation play a role not just at the international, but also at the national level, where the benefits described in Chapter 5.1.3. equally apply.

One example of a successful harmonisation effort is the 2007 Ethiopian Public Health Laboratory System Master Plan, formulated in response to frequent logistic challenges including stockouts, weak logistic and distribution systems, long waiting times for test results, and machine failures. The strategy included designing a standardised laboratory logistics system, including standardised test menus, test techniques, operating procedures, and laboratory equipment, and then providing training for these specific systems. As a consequence, problems with stockouts were largely resolved, wastage was reduced, and waiting times for test results were in some cases reduced from two to three months to just days (53). Standardisation facilitated laboratory commodity management, forecasting, quantification, procurement, and has thus enabled more rational decision-making (53).

Similarly, Zambia was able to reduce the stockout rate at the central warehouse from 70% to 2% through standardisation, while the cost of procurement also declined (51).

In Lesotho, both medicines and medical consumables (including those for diagnostic testing) are procured, stored and distributed by the National Drug Service Organisation (54). For individual laboratory procedures, the Ministry of Health issues Standard Operating Procedures to the respective laboratories and monitors their implementation. While certain challenges, including occasional stockouts, have yet to be overcome (personal experience), this model has the potential to increase efficiency, facilitate knowledge sharing, and promote the implementation of universal quality standards.

5.2.2 Staff Rotations for Effective Exchanges within Tiered Networks

Staff rotations between laboratories within the national (and supranational) laboratory network – especially between different tiers within the network – would be a powerful tool to facilitate a number of stated priorities (see Chapter 4.2.4) for laboratory system strengthening. First and foremost, regular rotations would facilitate knowledge exchange. Laboratory personnel rotating from “lower”- (i.e. generally smaller, more remote laboratories with a lower capacity) to “higher”-tier laboratories would benefit from learning additional procedures in an environment that is likely to be more stringent with
respect to quality management standards. Conversely, staff rotating from higher- to lower-tier laboratories could provide training, allowing technical and managerial know-how to reach even the more remote areas and the level of primary healthcare. This approach would strengthen the concept of the tiered laboratory system, since personnel from lower tiers would have a better understanding of tests performed in higher-tier laboratories and be less hesitant to refer samples onwards. Staff rotations would also facilitate the harmonisation of tests, management procedures and accreditation processes, since staff would already be familiar with the processes in settings somewhat different from their own. Furthermore, it is easily conceivable that the increased mobility of personnel between different (tiers of) laboratories would provide new job opportunities. This might help mitigate some of the problems of retention of laboratory personnel. Finally, those representatives of the diagnostic system that move on to work in the Ministry of Health or similar political functions would have a better understanding of the nation’s laboratory system as a whole, and the challenges faced in different settings, and thus would be in a better position to assess the real needs and find holistic solutions.

There are various ways in which a certain degree of exchange could be implemented. Incorporating mandatory internships in various laboratory tiers as part of the study curriculum would be a good way to confront students with the realities in different contexts from the start. By working first in lower-tiered laboratories and then progressing to higher-tiered facilities, students would be exposed to a naturally increasing number and complexity of tasks. Conversely, if the opposite route were chosen, students would first gain insight into an “optimal” setting before learning to deal with less regulated scenarios.

To enable ongoing professional development, higher-tier laboratories could receive financial incentives for participating in knowledge transfer programs to lower-tier laboratories – be this by sending out their staff to provide trainings locally, or by accepting external staff to their facilities for short courses. Finally, knowledge exchange between laboratories (including laboratories of the same tier) could be facilitated through peer accreditation. This practice is applied, for example, in Lesotho: in addition to participating in the external SLITPA process for accreditation, representatives of individual laboratories conduct visits to other facilities to provide a form of peer assessment and feedback from which both parties can learn, in a rotational fashion.

Although such considerations can be implemented at any stage, their early inclusion in national planning will greatly facilitate broad implementation.
5.2.3 Consider Task Shifting to Combat Shortages in Human Resources

Davies et al. write: “Laboratory professionals continue to figure prominently among neglected health cadres across sub-Saharan Africa. There are often insufficient numbers, a skewed distribution, low level of qualifications, and limited career opportunities [and personnel] do not systematically respect safety standards” (9). Accordingly, an increased focus on the training as well as retention of laboratory personnel is a major and often-mentioned concern (10, 20, 26, 30, 31, 38).

As mentioned above, staff rotations between laboratories as well as increased representation of laboratory technologists in Ministries of Health and other public health functions may increase the potential for career development and, therefore, the attractiveness of this career path. Another strategy would be to assess a potential role for task shifting, i.e. the delegation of certain duties to lesser-qualified personnel, in the diagnostic setting. This practice is already common on the clinical side of the medical field in resource-limited settings (55), often with positive results (56–58). So far, little information is available regarding a potential role of task shifting to laboratory settings. However, in Afghanistan the performance of trained but non-certified versus certified technicians in a test to diagnose pulmonary tuberculosis was comparable (59). Furthermore, it has previously been suggested that pharmacists would be ideally poised to take on additional functions including laboratory diagnostics (60). Controlled trials would be needed to assess the feasibility and outcomes of such strategic interventions.

5.2.4 Incentivise Progress towards Accreditation

The importance of achieving high standards of quality within diagnostic laboratories, including the prevention of sample mix-ups and the reliability of results, is self-evident. National governments can support high quality standards by not just enabling, but incentivising individual laboratories to strive for accreditation – be this international accreditation, or progression along the SLIPTA process. Three suggestions are made here as to how this may be achieved:

The first suggestion involves financial incentives, with the most successful laboratories receiving rewards in the form of additional funding and recognition. This would allow them to develop into local centres of excellence. In return, they might be expected to take on training capacities, including both the training of students and offering specialised support to less successful facilities.

Secondly, highly trained laboratory professionals might be offered incentives in the form of higher salaries or other benefits for agreeing to work in poorly performing laboratories.
Thirdly, at the level of political decision-making to support accreditation, focus groups with representatives of both highly accredited laboratories and staff from more difficult settings should be consulted. While the former would provide technical knowledge and have a good understanding of the ultimate goals, the latter would provide a realistic view on the most challenging settings.

5.2.5 Invest in Digitalisation of Medical Records

There is a range of opportunities for the application of information and communication technology to address problems in resource-limited settings. Potential applications include telepathology (the use of telecommunications to transfer diagnostic data and provide pathology services from a distance) (24, 61), automated patient reminders via text messaging (62), or systems to support clinical decision-making (63), to name just a few. In the view of the author, one of the most valuable investments in information technology for healthcare would be a conceptually simple one (though not necessarily being simple to implement), namely the digitalisation of medical records. Electronic medical records (EMR) are lacking in many countries in sub-Saharan Africa, especially outside of larger specialist hospitals (64). This can lead to loss of patient data and incomplete medical histories, delayed or no clinical response to new diagnostic information from laboratory testing (effectively wasting the resources used for this testing), wasting the time of clinicians and laboratory personnel in settings where these human resources are already scarce, and subsequently, worse patient outcomes. Beyond being a necessity for effective patient management and monitoring (65), EMR can make health data easier to extract, allowing for more informed decision-making with relevance to diagnostics as well as public health in general.

Multiple initiatives have shown that transitioning to EMR can be feasible across different settings in sub-Saharan Africa (65–69). This intervention would also be cost-effective: e.g. for Malawi, modelled estimates have indicated that the implementation of hospital-wide electronic medical records would financially break even by the third year of operation, and save over half a million US dollars over the first five years (70).

In Chapter 4.1, the importance and potential benefits of medical laboratories and diagnostic testing were described. However, these benefits will remain hypothetical if results do not reach clinicians in a timely manner, and if they are not utilised for informed clinical decision-making. Digitalised systems would be a powerful tool to help bridge this gap.
5.3 The Local Level

Many of the above-mentioned suggestions and recommendations for laboratory management at the national level either directly impact or can be conceptually transferred to local laboratories. Some further considerations that impact mostly the local level of individual laboratories are listed below.

5.3.1 Engage in Partnerships – of the Right Kind

Some of the challenges that laboratories low-income countries face, including budgetary constraints and lacking know-how, could be effectively overcome by engaging in partnerships with non-profit organisations (NPOs) or with the private sector (5). Ideally, the government would provide the regulatory framework and cover the cost of diagnostic testing (at least insofar as it is conducted in accordance with the national clinical guidelines). Oftentimes, this funding would originate from major organisations (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria) but be channelled through and managed by the Ministry of Health. Meanwhile, the contribution of the private partner may depend on the nature of the company or organisation; for instance, whether or not it operates for profit. A non-profit partner may for instance provide additional funding needed for investments that the government could not afford, or funding towards reaching rural populations that would not otherwise be able to profit from diagnostic services. A for-profit partner such as a large, international biotechnological company may be willing to provide equipment, training or maintenance at a reduced cost in order to profit from corporate social responsibility marketing – as well as to get a “foot in the door” to emerging markets.

However, there are also certain concerns that should be addressed at the early stages of engaging in such partnerships, including those listed below.

Defining responsibilities and vision: The expectations between the partners should be defined as clearly as possible from the start. Critically, this should include not only initial and “regular” funding, but also the liability to fund unexpected costs. Similarly, the vision behind the partnership, including longer-term goals as well as approximate timeframes, should be addressed. Wherever possible, long-term financing plans should be instantiated, preferably in the form of binding agreements. These should be made in writing, at least in the form of a Memorandum of Understanding, or potentially through more formal contracts.

Investing in maintenance and insurance: Compared with initial investments, the cost of regular maintenance – or the responsibility for unforeseen costs in the absence of maintenance contracts – is more often neglected. Accordingly, maintenance of equipment is a recurring challenge to laboratory systems (41). Sayed et al. suggest “equipment leasing and reagent-based contracts that incorporate
inbuilt maintenance clauses rather than outright purchase” in order to increase sustainability (34). Indeed, regular, foreseeable costs are easier to budget – especially for NPOs whose finances may be subject to stringent auditing. Thus, maintenance and service contracts for laboratory equipment should be prioritised from the start (41).

Ownership: The importance of working within the health system is addressed in the next chapter. However, working closely with the Ministry of Health and (where possible and morally feasible) within the national healthcare guidelines is particularly important where non-national (public or private) parties are involved. African countries have relied heavily on donor funding to provide healthcare, making clear transition plans to local ownership all the more important (5). This may be achieved by an external entity providing the means (equipment, training, etc.) for certain testing under the condition that the government commits to purchasing these services. Making government funding of the most essential diagnostic tests a requirement would necessitate collaboration, strengthen national ownership, prevent the formation of parallel structures, and compel donor organisations to focus on the country’s most pressing health concerns and align their projects with the national healthcare policy.

5.3.2 Work Within the Health System

Some forms of medical support, such as vaccination programmes or immediate relief services, can provide benefits even in the absence of government cooperation. However, broader system strengthening cannot be successful in isolation. Without national guidance and participation, the imposition of isolated solutions by external donors would most likely lead to the formation of multiple parallel structures.

This concept can be expanded to already existing private laboratories. In South Africa, where almost three quarters of all ISO accredited medical laboratories in Africa are located (35), in 2014 78% of accredited clinical laboratories were private, compared to just 17% public and 5% research laboratories (17). This shows that private laboratories are a major potential resource that could provide know-how on quality standards, effective management, and accreditation procedures. Furthermore, their services could be purchased for the referral of more complex tests where the national public laboratory system is overwhelmed. To fully tap into this resource, efforts should be made to facilitate collaboration and knowledge transfer between public and private laboratories.

5.3.3 Collaborate for Research

Despite the medical need, research on many diseases affecting the lives of people living in sub-Saharan is scarce. Just as importantly, implementation research to find the best policies and strategies to bring
existing healthcare services to the population in need is lacking. Decentralised laboratories are thus at the heart of a wealth of information that would desperately be needed to inform policymakers, implementors, and funding bodies on the real-life priorities. However, staff in these laboratories are often too far removed from the world of scientific research and academic publishing to effectively disseminate this information. Inclusive partnerships between academia and clinics could generate mutual benefits: the academic institutes would gain access to highly sought-after and publishable information; staff in local laboratories would benefit from additional external support and training, be initiated into academic reporting, and gain recognition through co-authorship; the laboratories themselves would likely be strengthened, which would also benefit the local population; and the population at large would benefit from better reporting of the realities in their setting and from more informed decision-making.

6 Conclusion

Like other development fields, laboratory system strengthening has undergone major ideological changes over the last decades.

In the past, complex systems were often deemed unfeasible for low-income countries, and the strengthening of broader laboratory systems was long neglected (4, 5, 7). This former neglect has multiple causes. For one, there has been a lack of leadership by pathologists and laboratory professionals (24). This made it difficult for policymakers to understand the significance of strong laboratory systems within the broader public health framework (5). Meanwhile, the era of the Millennium Development Goals (MDGs) had a mixed impact on medical laboratories. On the one hand, health featured heavily within the MDGs, contributing three of the seven goals3. Especially MDG6, “Combat HIV/AIDS, malaria and other diseases” necessitated a major scale-up of diagnostic laboratory services. After all, the HIV/AIDS epidemic had demonstrated how fragile existing laboratory systems had been, and how ill-equipped they were to rise to new major health threats (5, 6, 20). However, the ensuing investment in laboratory diagnostics did not translate well into broader health or even broader laboratory system strengthening: instead, a so-called “vertical approach” was used in which isolated, disease-specific laboratories (especially HIV laboratories) were generated (5, 6, 21). This strategy proved inadequate, as it led to competition for resources (6) and overwhelmed public health laboratory services (5) without necessarily translating to a broader system strengthening. Thus, there

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3 MDG 4, Reduce Child Mortality; MDG 5, Improve Maternal Health; and MDG 6, Combat HIV/AIDS, Malaria and Other Diseases (18).
have been many calls for the laboratory support that was provided for tuberculosis, malaria and HIV disease programs during the MDG era to be integrated into a broader public health system (5, 6, 20).

Indeed today, in the era of the SDGs, such an insular approach is no longer timely. Rather, achieving the SDGs will necessitate the availability of a greater range and complexity of tests, along with the required infrastructure, personnel, know-how, management, and policies to create resilient systems that will be able to adapt to a changing health landscape and overcome new threats.

Resilience is not easy to achieve, but will require improvements at all levels of the laboratory (and healthcare) system: investments in infrastructure and equipment; integration of formerly isolated laboratory services into a tiered laboratory network; referral systems within nations and across regions that will allow remote or marginalised people to access advanced diagnostic functions; access to the necessary tests, reagents and consumables and suitable supply chain management; strong investments in maintenance as well as quality control; ongoing training, motivation and retention of human resources at all levels (e.g. pathologists, medical technologists, administrative and logistical personnel, and informed policymakers within the Ministries of Health, to name just a few); advocacy to policymakers; sound public health policies at the national and international level; strategic planning, including the establishment and implementation of national laboratory plans; as well as appropriate integration of the private and not-for-profit sectors (including the establishment of public-private partnerships).

Progressing in all these fields will naturally be a momentous undertaking and will require strong leadership and partnerships both within nations and across the region. However, the developments of recent years appear to be hugely promising: Seminal agreements such as the Maputo and Freetown Declarations were important in terms of increasing visibility and generating momentum, as well as generating focus and points of reference. The establishment of ASLM marked the birth of a new authority in the field of laboratory system strengthening in Africa that, together with WHO-AFRO and the newly established Africa CDC, is well poised to take on a leadership role. The establishment of the SLIPTA and SLMTA frameworks will be practical tools and enablers for countries in establishing resilient, functional, and equitable laboratory networks. Finally, the AJLM, apart from being an important source of information for researchers, implementors and policymakers alike, possibly also reflects a growing self-confidence of the fields of pathology and laboratory medicine within the global health arena, and also of pan-African leadership.
7 Literature


47. WTO | Ministerial conferences - Doha 4th Ministerial - TRIPS declaration, (available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).


49. P. Rastogi, World Wide Legal Status Of Medical Method Patents: An Overview (2014), (available at http://www.mondaq.com/india/x/311404/Patent/World%26%2300B1;Wide%26%2300B1;Legal%26%2300B1;Status%26%2300B1;Of%26%2300B1;Medical%26%2300B1;Method%26%2300B1;Patents%26%2300B1;An%26%2300B1;Overview).


# Annex

## Table 1: Priorities for Medical Laboratory Strengthening in Africa

This table lists and categorises the goals, objectives and calls of major relevant organizations or Declarations towards strengthening laboratory systems in Africa. The individual points have been shortened for clarity and brevity.

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<tr>
<td><strong>National laboratory policies and plans</strong></td>
<td>Goal 1: Strengthen national laboratory system policies and strategic plans</td>
<td>Objective 2: Assist countries in developing comprehensive national laboratory strategic and implementation plans and enabling policies, which include regulations of laboratory diagnostic testing and secure and safe handling of highly dangerous pathogens</td>
<td>Goal 1: Strengthen leadership and governance of the national laboratory systems</td>
<td>Call 1: Call on national governments to [develop] [...] a national [...] policy [...] [implement] a national strategic laboratory plan, [...] [and] establish a department of laboratory systems within the Ministry of Health;</td>
<td>Call 1: Call on national governments to [develop] [...] a national [...] policy [...] [implement] a national strategic laboratory plan, [...] [and] establish a department of laboratory systems within the Ministry of Health;</td>
<td>Call 3: Call on ASLM and WHO AFRO to help [...] establish national laboratory strategic plans and policies that support and strengthen functional tiered laboratory networks [...], and a score card to measure progress of implementation and improvements of the networks</td>
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<td><strong>Laboratory networking</strong></td>
<td>Goal 3: Enhance networking between laboratories with public health responsibility and with surveillance and response systems</td>
<td>Goal 4: Building a network of national public health reference laboratories to improve early disease detection and collaborative research</td>
<td>Objective 1: Support countries and regions to map existing laboratory systems to defined requirements of a tiered national laboratory system (specifically quality, standards, and biosafety) and networks [...]</td>
<td>Goal 5: Promote effective laboratory referral networking (in-country and among countries) and enhance coordination</td>
<td>Call 5: Call on donors and development partners to [...] [collaborate] with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated laboratory network [...] [and] seek to build public private partnerships</td>
<td>Call 5: Call on national governments, nongovernmental organisations, donors, and partners to [...] [support] laboratory-based</td>
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<tr>
<td><strong>Capacity-building (excl)</strong></td>
<td>Goal 4: Increase domestic testing capacity in range and volume</td>
<td>Objective 3: Support Africa CDC Regional Collaborating Centres and national-level laboratory networks to implement modern advanced molecular technologies and multiplex pathogen assays</td>
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| **Human resources** | **Goal 1:** Strengthening laboratory workforce by training and certifying laboratory professionals and clinicians through standardised frameworks | **Objective 6:** Support laboratory workforce development, which may include the creation of a Field Laboratory Training Programme | **Goal 3:** Establish sustainable, sufficient and competent human resources for laboratory service delivery | **Call 4:** Call on countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing | **Call 4:** Call on national governments, nongovernmental organisations, donors, partners and the private sector to develop innovative strategies for laboratory workforce development to support functional tiered laboratory networks, especially at the primary healthcare level |
| **Quality** | **Goal 2:** Transforming laboratory testing quality by enrolling laboratories in quality improvement programmes to achieve accreditation by international standards | **Objective 1:** Support countries and regions to map existing laboratory systems to defined requirements of a tiered national laboratory system (specifically quality, standards, and biosafety) and networks [...] | **Goal 2:** Strengthen the organization and management of the national laboratory systems towards quality |  |  |
| **Regulation and safety** | **Goal 3:** Develop strong, harmonised regulatory systems for diagnostic products as defined by the Global Harmonization Taskforce | **Objective 1:** Support countries and regions to map existing laboratory systems to defined requirements of a tiered national laboratory system (specifically quality, standards, and biosafety) and networks [...]; Objective 2: Assist countries in developing comprehensive national laboratory strategic and implementation plans and enabling policies, which include regulations of laboratory diagnostic testing and secure and safe handling of highly dangerous pathogens | **Goal 4:** Ensure safe and secure laboratory environments | **Call 7:** Call on national governments, nongovernmental organisations, donors, and partners [...] [guide] evaluation and regulation of diagnostics, especially in outbreak settings; **Call 8:** Call on national governments and regional bodies to [...] streamline regulations governing diagnostic tests to ensure quick, reliable access to services for [all] |  |
| Harmonisation | Goal 3: Develop strong, harmonised regulatory systems for diagnostic products as defined by the Global Harmonization Taskforce | Objectives 1-3: to standardize or harmonize the used tests (Objective 1), equipment (Objective 2) and maintenance (Objective 3) at each level of an integrated tiered laboratory network; Call 5: Call on donors and development partners to [...] collaborate with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated laboratory network [...] (and) seek to build public private partnerships |
| National ownership | Goal 1: Strengthen leadership and governance of the national laboratory systems | Call 2: Call on national governments, nongovernmental organisations, donors, partners, and the private sector to support the implementation of a standardised score card to routinely assess the preparedness and capacity of functional laboratory networks to prevent, detect, and respond to current and future global health threats |
| Private industry, research and development | Goal 6: Promote rational and evidence-based use of laboratory services | Call 5: Call on donors and development partners to [...] collaborate with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated laboratory network [...] (and) seek to build public private partnerships |
| Leadership and advocacy | Goal 6: Contribute to WHO leadership and coordination role in global laboratory strengthening forums | Call 8: Call on private industry and research and development institutions [...] to accelerate development of innovative diagnostic tools for resource-limited settings |