

# **Utilization of diagnostic laboratories in sub-Saharan Africa: Changing roles and increasing need for inter- professional collaboration**

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Master in International Health  
September 2010 – September 2015

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## Key words

Laboratory capacity building, laboratory strengthening, laboratory utilization, diagnostics, inter-professional collaboration, inter-professional interface, sub-Saharan Africa

## 1. Abstract

Despite a surge in international interest in laboratory systems for sub-Saharan Africa (SSA) in recent years, the state of many laboratories in the region has remained unchanged for decades. This thesis describes the changing regional and global context with regard to the diagnostic landscape and how this changes the roles of diagnostic laboratories. A special focus has been on the inter-professional collaboration between laboratory and clinical staff. The results are based on a literature study, supplemented by semi-structured interviews with key informants and own experiences.

From the study a picture emerges that laboratory systems suffer from a lack of recognition and sense of priority, which causes laboratory staff to feel undervalued. The technological, social and biological developments addressed here warrant a change in the way the role of diagnostic laboratories is viewed. Local policy makers should recognize the increased need for laboratory infrastructure, ensure adequate numbers of laboratory specialists are available which are trained according to future needs and change job descriptions accordingly.

However, investing in laboratories alone may not be enough. Clinicians are often still inclined to base their diagnosis on clinical symptoms alone, despite the availability of novel diagnostics. A lack of experience in communication with other cadres and a sense of complacency towards the efforts of diagnostic laboratories may be in part to blame for this. A more inter-professional approach is advocated, in which laboratory specialists actively participate as well-trained professionals that orchestrate the various efforts related to diagnostics.

The results of the study were retrospectively fitted into a previously described analytical model, in an attempt to create a theoretical framework that may prove useful for future discussions on the role of the laboratory in SSA.

*Where other people's work has been used (either from a printed source, internet or any other source) this has been carefully acknowledged and referenced in accordance with departmental requirements.*

*The thesis "Utilization of diagnostic laboratories in sub-Saharan Africa: Changing roles and increasing need for inter-professional collaboration" is my own work.*

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Total word count: 9774

Date: August 2015

## 2. Introduction and objectives

Diagnostic laboratory services are an essential part of any health system. In sub-Saharan Africa (SSA), where infectious diseases are abundant, a well-functioning laboratory is especially important. Despite significant technical advances in laboratory sciences, the state of many diagnostic labs in developing countries hasn't changed for decades. However, due to several developments, laboratory medicine can be expected to slowly move towards the forefront in global health.

Firstly, ongoing technical developments have hugely increased capabilities to detect and monitor disease. This is definitely also true for lower tier laboratories, as technical advances have made it possible to perform certain tests in typical field settings that were previously restricted to national or regional laboratories.

Secondly, acquired resistance to various drugs is increasing, which can only be definitively demonstrated in the lab, will also add significantly to most laboratory's workload. The increase of this largely manmade phenomenon will require substantial laboratory involvement to combat.

Thirdly, demographic changes and increased travel worldwide have resulted in shifting patterns of disease in large parts of Africa and are putting new demands on surveillance systems, for which laboratory services are essential. The current outbreak of Ebola virus disease will certainly add to the momentum for establishing better laboratory-based surveillance.

In recent years, the above considerations have led to increased awareness concerning the need for better laboratory systems. In the WHO Maputo declaration of 2008, member nations clearly express their intention to end the neglect of laboratory services in developing countries [1].

Since then, attempts to improve the level of laboratories have been implemented and although results have been encouraging, there are several obstacles that need to be overcome. Obvious challenges such as a lack of qualified staff and substandard education are largely due to economical factors. However, as noted by Petti et al., the barriers for laboratory testing in sub-Saharan Africa extend far beyond economical barriers [2].

It is my personal belief, based on experiences working as a lab manager and advisor in SSA, that many of the problems facing the efficient utilization of African laboratories are the result of the sub-standard collaboration between producing party (lab staff) and the end-user (clinical staff).

An effective laboratory system requires intricate collaboration between various components of the health system, a fact often overlooked by policy makers. Furthermore, as discussed in a separate chapter, empirical treatment remains commonplace in large parts of SSA, resulting in a high level of misdiagnoses and concomitant morbidity and mortality.

The main goal of this thesis is to describe the changing role of the diagnostic laboratories in SSA in light of recent developments in global health, in general, and laboratory science, in particular. As a starting point for exploring the need for efficient use of laboratory-based results in the clinical management of patients, a separate chapter is dedicated to the impact of diagnostic laboratories, preceding chapters on recent social, biological and technological trends and developments.

A secondary objective is to explore the way the lab communicates with the clinic (and vice versa) and to describe future needs for inter-professional collaboration between these two cadres.

Thirdly, the issues identified here will be discussed according to an analytical model for policy making in the health sector, in an attempt to provide a comprehensive framework for future studies regarding the role of diagnostic laboratories in SSA.

Ultimately, several recommendations will be provided to increase the impact laboratory testing may have on public health in general, and on clinical management in particular.

### 3. Methodology

Most of the information for this thesis was gathered from literature. However, important insights were provided by three key informants during semi-structured interviews. Their comments have been used as anecdotal evidence throughout this thesis. Due to the fact that own experiences have played a large role in the materialization of this thesis, they have also been incorporated here.

#### 3.1 Literature search

In order to obtain a comprehensive literature database, Pubmed.com was used as the primary literature database, although general web-based searches were also performed.

Queries used in the searches included, but were not limited to: “inter-professional collaboration, laboratory system strengthening, laboratory health system, communication in health care, empirical treatment, laboratory use, laboratory (test) utilization, inter-professional education, laboratory planning, laboratory strategic plan, task shifting (in) diagnostics, human resources health laboratory”. Combinations of the above terms were also used.

Often the words “perception, communication, development, diagnostic” or similar were included to obtain more specific results. Likewise, the terms “sub-Saharan Africa”, “developing”, “Africa” were frequently added to obtain results more relevant to the region.

In order to obtain relevant information from grey literature, the websites of WHO, several NGOs and governmental bodies such as Ministries of Health of various African nations were screened for useful publications.

In addition to online searches, previously gathered literature on topics relating to diagnostics in tropical medicine was screened for information.

Snowballing was frequently used to gather all information that was deemed relevant. Studies older than 10 years were usually omitted, unless considered to be of extraordinary relevance. In addition, issues of journals covering a topic of particular interest, as well as the WHO website, were screened for articles. The literature review was of a non-systematic nature and continued during the preparation of the manuscript.

#### 3.2 Interviews and personal experiences

Especially on the topic of “Inter-professional collaboration between laboratory and clinical staff”, little information was available from literature. Furthermore, a more qualitative approach was considered appropriate, as the concept of collaboration deals to a great extent with perceptions and opinions.

Therefore, secondary to information obtained in literature, semi-structured interviews were conducted with both clinical as well as laboratory staff. In addition, interviews were scheduled with “neutral” informants, i.e. health professionals not directly belonging to one of the cadres.

Ultimately, interviews were performed with 3 informants: a Malawian clinical officer with over five years of experience (via Skype), an international laboratory advisor with many years of experience working for a large NGO, and an experienced consultant in Human Resource (HR) Development; all have spent many years working in sub-Saharan Africa.

Guidance for conducting the interview was provided by a book on Qualitative Methods in Health Research by Green and Thorogood (chapter 4 on interviews) [4].

Questions asked were based on a previously drafted Interview guide (See also Appendix I). However, since the information was used as anecdotal evidence rather than data for qualitative analysis, the list of questions was used as a guide only.

After clearly obtaining oral consent for the interview, the interviews were recorded and subsequently transcribed literally. Passages of special importance were underlined and have been incorporated into the results in subsequent chapters.

In addition to the opinions of the key-informants, I have occasionally included own experiences, from episodes of working as a laboratory manager in Malawi, Ethiopia and laboratory advisor in Nigeria. In all cases, this is clearly indicated.

### 3.3 Analytical framework

Although dated, an analytical framework by Gill Walt and Lucy Gilson proved to offer guidance for defining the relationships between the various themes arising from the literature study [3]. In their article they discuss health policy reform in developing countries, and argue that policy makers wrongly focus almost exclusively on the content of reform, with little regard for the actors involved and the context in which the reform is to take place.

Using a simple analytical model, they provide a very comprehensive means to situational analysis, which, according to them, can be done either prospectively or retrospectively. Central to their model are the concepts of Context, Content, Actors and Process (figure 1). As pointed out by Walt and Gilson, these should not be viewed as independent entities; rather the interaction between the four components is of particular interest.

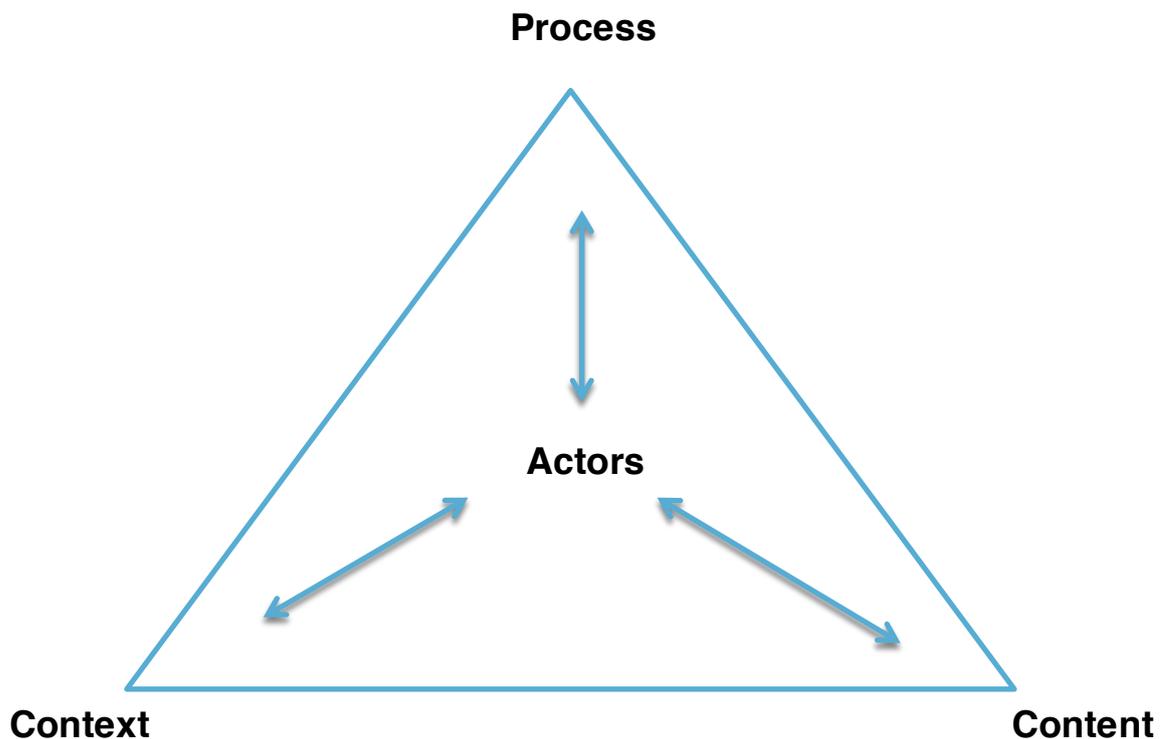


Figure 1: Simplified analytical model for health policy analysis; adapted from [3].

Although perhaps overly simplistic at a first glance, these concepts can be conveniently and usefully applied to the topic at hand.

*Process* was defined as the “Utilization of laboratory results for clinical management”. The *Actors* discussed here are the staff members that share a responsibility for the *Process*, i.e. laboratory and clinical staff.

The *Context* was defined as the “changing social, demographic and biological circumstances” relating to the efforts of the lab. These can be regarded as more public health-related, rather than laboratory- or clinical medicine-specific.

The *Content* refers to the “changing diagnostic technology and practice”, the ability to perform laboratory diagnoses and the way they are performed.

These four will be discussed in separate chapters. In addition, interactions have also been identified.

The topics identified from literature were fitted in the model retrospectively, and therefore did not have an influence on the themes identified from the study, nor on the order in which they are presented. In the final draft of the manuscript, however, labels in chapter titles (process, context, content, actors and interactions) have been added in order to provide more structure to the reader.

#### 4. Process: Utilization of laboratory results

Any mature health system will employ medical laboratories for, at least, the following tasks: to provide a laboratory diagnosis to aid clinical management, to provide essential public health information and to assist in surveillance of disease.

Although all three of these classical roles will be addressed in this thesis, the scope of this chapter, as well as the emphasis of the entire thesis, will be on laboratories that serve to aid in clinical management of individual patients. It should be remembered however, that these roles can be highly related and may be performed sequentially in certain laboratories.

For instance, with regard to tuberculosis, testing will be initially directed at identifying the presence of *Mycobacterium tuberculosis*. The combination with subsequent testing for resistance, either by culture or molecular methods, will give information not only vital to the patient, but also of importance from a Public Health perspective.

In contrast, for cholera, laboratories may perform a sentinel-role, since even one positive test (if consistent with clinical symptoms) should trigger immediate action from Public Health authorities, thus providing essential surveillance for the disease.

Public Health laboratories are therefore involved in all key processes in disease prevention, control and curative medicine and may be viewed as one of the three pillars in combatting disease, next to Public Health and clinical medicine.

However, as postulated by John Ngenkasong [5], laboratory medicine is the most neglected of the three. In search for explanations, we must first establish the impact laboratory testing has on clinical management.

##### 4.1 Role of the laboratory in clinical management

*Empiricism is a theory that states that knowledge comes only or primarily from sensory experience. Extrapolated to clinical medicine, empirical treatment (in this thesis also generally referred to as empiricism) is the use of treatment as a means to provide a clinical diagnosis. If the treatment is perceived as successful, is it usually assumed it was adequate for the underlying illness.*

Compared to other scientific disciplines, medical science is relatively new. Knowledge concerning basic physiology and the cause of diseases was largely absent until only around 200 years ago.

In fact, some discoveries in laboratory science actually precede that of evidence-based medicine, such as the invention of the microscope for the study of cells and microorganisms by van Leeuwenhoek in the 17th century.

Only in the second half of the 19th century did laboratory science and medical knowledge come together to allow for the first clinical laboratories, largely fueled by an increased understanding of the life cycle of microorganisms due to the work of Louis Pasteur, Robert Koch and others [6].

Nowadays, laboratory investigations are known to be required for a large proportion (60 to 80%) of medical decisions in the developed world [7]. Laboratory investigations are usually more sensitive and specific compared to diagnosis based on clinical symptoms alone. The two are interdependent: certain symptoms will prompt laboratory testing whereas lab results may also place clinical findings in a different light. For infectious diseases in a tropical setting with a high

prevalence of infectious diseases (most notably malaria), laboratory testing is especially useful due to the often aspecific nature of the symptoms; fever being the most common.

The benefits of laboratory testing over a purely clinically obtained diagnosis is supported by a large body of evidence, as reviewed by Petti et al. [2]. In the case of malaria, there is a well-established tendency for empirical treatment resulting in over-diagnosis and -treatment, frequently missing other life threatening infections [8]. Part of the reason malaria is over-diagnosed may be cultural and/or historical: as one of the interviewees pointed out, in several African languages the word for malaria is the same as the word used for fever.

A study of particular interest showed that the effective use of laboratory tests significantly improves treatment outcomes in Primary Health Care facilities in rural Kenya [9].

Similarly, Polage et al. additionally found in Ghana that incorporation of laboratory tests in the diagnostic algorithm to result in a decrease in the prescription of antibiotics. Strikingly, this decrease was to such an extent that patient cost for antibiotics was up to 20 times higher than the costs of laboratory testing [10].

The same study elegantly addresses the potential reasons for clinicians not to involve the lab in clinical decision-making. Interestingly, among all potential barriers for efficient use of the lab, the clinicians tendency to rely on their own clinical judgment rather than test results was identified as a key factor: “When specifically asked about malaria and tuberculosis, physicians stated that they were more likely to rely on their clinical impression rather than tests to diagnose these infections.”

In my own experience from Malawi and Ethiopia, treatment based on purely clinical symptoms is very common, especially for malaria and tuberculosis, but depends highly on the clinician in question. Older clinicians seemed less inclined to involve the laboratory, which suggests a (perhaps logical) trend, however I have not been able to find any supporting literature. During one of the interviews, when asked if he often relies on clinical symptoms only, one (young) clinician interviewee responded that he needed to have very good reasons to do so.

Among the challenges related to the use of laboratories is the frequently observed under-requesting by clinicians. Often the clinical staff is not aware of the full repertoire of tests that is offered by the lab, and only order what they deem important.

In a meta-analysis on appropriate laboratory testing in developed settings, Zhi et al. identify under-requesting as one of the most common, yet understudied, phenomena [11]. The importance of the use of Clinical Practice Guidelines (CPGs) in assuring proper test utilization was underlined by Alonso-Cerez et al. [12]. According to them clinicians are often overwhelmed by the choice of tests, and don't have the time to acquaint themselves to CPGs. They also claim that laboratory professionals have the appropriate knowledge and can improve the quality and efficacy of health care.

From the above the picture emerges that challenges relating to the lab are not only related to practical barriers, but often have to do with believes and behavioral patterns.

## 5. **Context: an increased need for laboratory testing in SSA**

The role of diagnostic laboratories has to be considered in light of both man-made and natural developments in recent years. The reality of a changing world will need to be translated into policies in any truly responsive health system.

The phenomenon of drug resistance has reached alarming levels in large parts of the world (see [13] for a recent WHO report on antimicrobial resistance). In SSA, acquired resistance to drugs combatting what was classically known as the “big three” of tropical diseases, malaria, HIV/AIDS and tuberculosis has been a reality for decades.

Luckily, life expectancies are rising among people living with HIV/AIDS (PLWHA). In South-Africa for instance, overall life expectancy has risen by 11.3 years between 2003 and 2011, claimed to be exclusively due to successful roll-out of ART (Anti Retroviral Treatment) programs [14]. Because of this, laboratories are burdened more and more with monitoring therapy performing CD4 count and HIV viral load (VL), next to solely diagnosing the presence of an HIV infection. In light of a multitude of Prevention of Mother to Child Transmission (PMTCT) programs, in most SSA countries, there has been a significant scale-up of Early Infant Diagnosis (EID), further adding to the laboratory’s workload. Luckily, as outlined further on, novel laboratory techniques for determining VL, CD4-count and EID are becoming increasingly available.

In SSA, the epidemiology of tuberculosis (TB) is invariably linked to that of HIV/AIDS, due to the high co-infection rate. This necessitates a shift in the use of diagnostics, as diagnosis of the disease by microscopy lacks sensitivity, especially in co-infected patients.

Although the percentages of Multi-Drug Resistant TB (MDR-TB) in new patients are low in SSA compared to other countries ( $\pm 2-3\%$  compared to  $\pm 20-30\%$  in several former Soviet states) [15], it is on the increase, further adding to the need for novel TB diagnostics, as microscopy alone cannot identify drug resistant strains of mycobacteria.

Although resistance to the most common anti-malarial drugs (artemisinin and its derivatives) has, up to date, fortunately not set foot in SSA, the occurrence of resistance in other parts of the world (South-East Asia and, possibly, South-America) warrants a conservative approach with regard to empirical prescription. The laboratory involvement in detection of resistance to artemisinin-based drugs is therefore largely limited to surveillance efforts. However, as described in the preceding chapter, prescription of antimalarials in the absence of a laboratory diagnosis remains commonplace, which may ultimately result in acquired drug resistance. The dreaded spread of artemisinin-related drug resistance from South-East Asia to Africa is also a definite possibility. In the future drug susceptibility testing (DST) for single cases of malaria may therefore be required.

Developments other than the increase in levels of drug resistance may also add to the future role of Public Health laboratories. The population density is increasing enormously in large parts of SSA, with implications for the epidemiology of infectious diseases. Increased (air-)travel will further add to the risk of outbreaks. These factors are thought to have played a large role in determining the outbreak dynamics in the current Ebola epidemic. In order to eliminate Ebola from West-African communities, laboratory capacity to diagnose the disease has recently been established. Subsequent to the current outbreak, these efforts will be most likely scaled down to maintain efficient surveillance capacity.

Other diseases for which laboratory surveillance is expected to be scaled up include vector-borne diseases. The last decade has seen an increase in the numbers of Chikungunya outbreaks, a

disease with a high attack rate. Partly due to the considerable recent global spread of suitable vectors (most notably *Aedes albopictus*), dengue fever, a disease with fairly aspecific symptoms, is also of particular concern, which will require laboratory capacitation.

Since outbreaks of vector-borne diseases may be combatted with a range of measures for vector-control, efficient laboratory surveillance plays a large role in the outbreak response.

Other infectious diseases for which the laboratory capacity has been or is likely to be scaled up include polio (declared a “programmatic emergency for global public health” by the World Health Assembly in 2012) and zoonoses such as Lassa fever, in order to distinguish from other febrile illnesses.

A change in laboratory roles is also predicted for non-communicable disease. Urbanization, changing dietary practices and an aging population in large parts of Africa are having a major impact on health. Most notably, incidences of diabetes type II have reached alarming levels [16]. Since diabetes has had a tremendous effect on morbidity in the Western world the past decades, technology had become available for monitoring of patients that may also be suitable for use in SSA, as will be discussed in the next section.

## 6. **Content: recent technological advances in laboratory medicine**

Globally, the market for diagnostics (usually referred to as IVDs, In-Vitro Diagnostics) is among the fastest growing; for comparison, the annual growth rate is roughly twice that of the pharmaceutical industry [17]. “Personalized medicine”, the diabetes pandemic, aging populations, scientific progress and technological advances such as robotics significantly add to this growth.

Sub-Saharan Africa, however, contributes only marginally, as much of the burden of disease is still related to infectious diseases and important restrictions apply related to finance, infrastructure and workforce. In light of this, much focus has been on so-called Point-of-Care (POC) tests, that do not require sophisticated laboratories but may be performed bed-side, in order to provide information directly to treating clinicians in possibly remote areas.

The WHO developed the ASSURED criteria of affordability, sensitivity, specificity, user-friendliness, rapid results, equipment-free and delivered to patients to describe the ideal POC diagnostic, which would bring the test to the patient in a timely fashion (reviewed in [18]).

One particular type of POC test is the Rapid Diagnostic Test (RDT), a term usually restricted to a chromatographic device that detects anti-bodies in response to an infection (in detection of HIV infection, for instance) or directly detects antigens present (e.g. in malaria).

These tests often fulfill most, if not all, of the ASSURED criteria and are therefore the test of choice in many parts of SSA. They do, however, supply a “yes or no” answer which make them limited in suitability for monitoring patients on treatment, for species identification (in the case of malaria) or for assessment of the severity of infection.

In the past, the lack of RDTs for various diseases didn't necessarily reflect a biological limitation (most infections will result in detectable antibodies and/or antigens) but rather a lack of financial incentive for the IVD industry for development. As a result of an increase in number of cases for various infectious diseases, combined with technological and scientific advances, rapid tests have recently become available or are in later stages of development for: Dengue, Cholera, Ebola, Lassa fever, Tuberculosis, Influenza, Typhoid fever, Hepatitis C, among others.

Importantly, each test has its own limitations, with often important implications for clinical management. For instance, the HIV rapid test cannot be used on neonates born from HIV-positive mothers, as it will respond to maternal antibodies and is therefore likely to be falsely positive. Although this may be regarded as basic knowledge concerning the use of the test, many clinicians are unaware of this fact, as I've noticed from my own experience.

Similarly, a malaria test detects an antigen that may stay in circulation and therefore detectable for up to two months. A positive test may therefore also be indicative of a past infection, and does not always warrant immediate treatment. Again, this knowledge appears to be absent by many clinicians.

This lack of knowledge adds to the workload of laboratory specialists: they are (or should be) in charge of effectively communicating the limitations of any test to clinicians that order it.

Perhaps the most interesting development in recent years is the increased availability of “cartridge-PCR” tests. PCR (Polymerase Chain Reaction) is a Nobel-prize winning technique that is used to amplify minute amounts of genetic material. Although the principal technique has not changed over the years, technological advances have enormously facilitated the procedure. A decade ago, a PCR was difficult to perform and labor-intensive, even in the most sophisticated laboratories. Every step was performed manually, with a significant risk for contamination and subsequent false positive results. In a cartridge PCR, all steps are performed in a closed container, thereby

minimizing chances of contamination and hugely broadening application possibilities. This development has meant the end of the dogma “PCR is not suitable for field-settings”.

The GeneXpert is currently the most used platform for cartridge-PCR testing. Roughly 15 tests are currently available that detect genetic material belonging to various commonly bacteria and viruses. In addition to merely detecting its presence, the test can also detect mutations that may have resulted in (multi-)drug resistance, significantly aiding in clinical management of the disease. The GeneXpert is not a POC test but can be employed at lower level health facilities, although a significant number of conditions need to be met, including the availability of a steady power supply. A recent study suggests task shifting of the test from laboratory staff to nurses may be feasible [19].

In SSA, the GeneXpert is mostly used for detection of tuberculosis; the MTB/RIF test (developed by biotech company Cepheid in collaboration with FIND (Foundation for Innovative New Diagnostics, a non-profit organization based in Geneva)), has the additional benefit of detecting mutations that confer Rifampicin resistance, which is a proxy for MDR-TB. Although the tests are expensive, discount prices have been negotiated for developing countries. Of special interest will be the launch of both qualitative (EID) and quantitative test (VL) for HIV on the GeneXpert platform, expected later this year.

Even more easy to use molecular diagnostic tests are currently in the pipeline, which include the LAMP (Loop-mediated Amplification) test for various pathogens. LAMP also amplifies genetic material, but has the advantage over PCR that less sophisticated equipment is necessary.

Other developments in laboratory science include novel biochemistry kits and equipment, automated systems for liquid cultures (including those for TB) and even microscopy (employing software that detects pathogens from microscopy images).

The increased phone network coverage of large parts of Africa has also been exploited for diagnostic purposes. Although major bottlenecks exist, systems are in place to send lab results directly to clinicians, and to collect data centrally for purposes of surveillance and Monitoring and Evaluation.

Global Fund and other large donors that support countries in SSA have clearly indicated their intention to invest in these novel systems, and we may therefore expect many such instruments and techniques to be implemented in the coming years. Comprehensive information concerning diagnostic products for malaria, TB and HIV/AIDS, both on the market and in the pipeline may be found on the site of UNITAID (see [20] for the HIV/AIDS document).

The developments highlighted here, in my view, place new demands not only on the staff performing the test but also on the clinicians that will use need to translate the test results into effective treatment.

## 7. **Actors: human resources involved in laboratory test utilization**

According to the WHO, Human Resources for Health (HRH) are the people who make health care happen. These include all professionals working at health facility that have enjoyed some sort of vocational training.

Work in diagnostic laboratories is performed by staff with varying level of education. Although regional differences exist, usually we can distinguish laboratory scientists, lab technicians and lab assistants who have had usually had 5, 3 and 2 years of training, respectively. Specialty training (usually 5 years) may also lead to a BSc or MSc in a particular biological field. Laboratory scientists are often the most in demand, and are therefore rare to find in smaller clinics, especially in rural settings. The same is true to a lesser extent for lab techs. In some instances, non-specialist personnel such as cleaners are trained on-the-job to perform diagnostics in the laboratory. Although I've witnessed some of them to be quite proficient in the practical work, the ability to adequately interpret the results is usually completely missing.

On the clinical side, in large parts of SSA most of the work is not performed by medical doctors (MDs) but rather by clinical officers (COs), who have received 3 to 4 year training, usually complemented with a 1-year internship. In a country like Malawi, there are many times more COs than there are MDs; not out of choice but rather necessity as MDs are simply not available. COs are therefore responsible for the majority of clinical procedures, including surgery. In the Malawian mission hospital where I worked for a period over a year, there was no MD present or even available in an advisory or supervisory role.

When comparing the level of education between lab and clinical staff in such a setting, it can be concluded that the difference, if any, is not very large.

It must be noted, however, that there are significant regional differences with regard to both availability and job descriptions of clinicians. To the best of my knowledge, a country like Nigeria with a high level of education, all clinical procedures must be performed by MDs.

Shortages of laboratory staff can be very high. A WHO publication of particular interest to the laboratory staff was published several years ago, reporting on an in-depth analysis of laboratory HR in Tanzania, Ivory Coast and Rwanda [21].

The authors speak of a crisis in laboratory HR in those countries: shortages in some regions exceed 67% (meaning 2 out of the 3 needed laboratory staff members is not available).

Moreover, according to this report, in Tanzania and Ivory Coast there have been embargoes on hiring laboratory staff, despite shortages of staff, which apparently did not apply to other cadres:

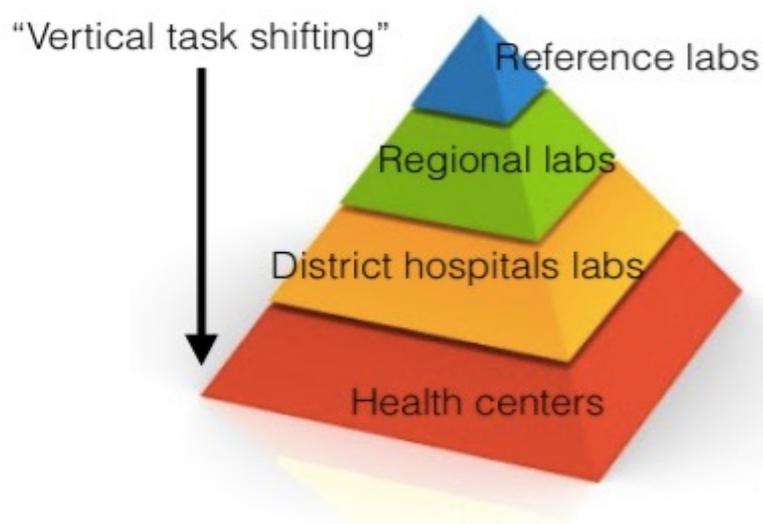
"In United Republic of Tanzania and Côte d'Ivoire, despite national policy guidelines establishing minimum levels of laboratory staffing, there have been embargoes on laboratory staff employment due to economic constraints and structural adjustment programs. During these periods, staff of other cadres, such as nurses, continued to be employed. These decisions have led to an imbalance of health staff cadres, favoring unconfirmed clinical diagnosis."

Apparently, having an adequate number of laboratory staff was deemed of less importance compared to staff of other cadres. Again, the laboratory suffers from a lack of recognition within the health system. Furthermore, based on the last few words of the above statement, we may conclude that HR policies actively contribute to the practice of clinical diagnosis in absence of laboratory confirmation.

## 8. *Interaction between Actors and Content: Task shifting*

Technological advances have allowed staff other than laboratory technicians to perform many of these novel tests. Previously, samples were handled exclusively by laboratory technicians. This “horizontal” task shifting (shifting of tasks among different health cadres that have a similar level of training) has been much debated and is usually the result of shortages in health personnel across different cadres [22].

More importantly perhaps with regard to laboratory testing is vertical task shifting (shifting tasks from higher to lower cadres, or vice versa). Adding to the tendency for vertical task shifting is decentralization of laboratory services as schematically depicted in figure 2: because of the relative ease of operation of a lot of the novel tests, combined with lower infrastructural requirements compared to the traditional tests, they are designed to be placed at peripheral health facilities. At these facilities, less educated and/or experienced may perform these tests.



**Figure 2:** Vertical task shifting in the laboratory system

For instance, HIV-related testing in health centers was usually limited to rapid testing to determine infection: a yes or no answer. Nowadays, staff members at the health center (for instance nurses) may have access to a portable device (such as the PIMA), allowing determination of CD4 count at a decentralized level. This will allow clinicians at lower tiers to assess the immunological status of the patient in order to decide whether treatment should be initiated.

Home testing represents the far end of the decentralization-spectrum, in which patients can test themselves in order to monitor their disease. An obvious example of this type of self-management is diabetes, for which easy to use home-test devices have flooded the market. Many trials are currently ongoing to assess feasibility and ethical aspects of home testing for various diseases, including HIV [23].

The potential benefit for patients of this ongoing decentralization is clear: turn-around-time is expected to decrease and patients (or patient samples) no longer need to travel (or shipped to other laboratories). Although this eliminates the need for shipment of the sample (with concomitant cold-chain and biosafety concerns), these changes will certainly meet with other logistical

challenges. Training and technical support will also have to be decentralized, which poses problems especially in large parts of SSA, due to a lack of road infrastructure or safety concerns.

Another consequence of this development is sometimes overlooked: when non-specialist staff will perform tests, they need to be efficiently supervised by laboratory staff with regard to adequate interpretation of the test and possible trouble-shooting. This requires management and communication skills and will place additional requirements to their training and job description.

## **9. *Interaction between Context, Actors and Content:* Policies regarding laboratory capacity building**

In recent years, there have been several landmark events that have markedly increased awareness concerning the need for efficient laboratory systems. Following the Maputo declaration in 2009 [1], there have been several initiatives aimed at laboratory capacity building.

### 9.1 Trends in Laboratory Quality Assurance

Next to increasing the access to diagnostics, a strong focus has been on increasing overall laboratory quality. The phenomenon of errors in laboratory medicine has been a well-studied topic [24]. Any test involves a multitude of actions by members of various cadres of any health facility, any one of which is prone to error. A central finding is that most errors are made in the pre- and post-analytical phase, i.e. in the stages related to collecting, labeling and transporting the sample to the lab and the collection, communication and dissemination of results. This clearly makes error-reduction by quality management an issue that exceeds beyond the walls of the laboratory.

A suitable starting point for the implementation of quality assurance is an inter-laboratory comparison of performance. One way of accomplishing this is by Proficiency Testing (PT), in which a certain sample is tested by a number of laboratories. The performance of each lab is then determined by comparison to the result by a reference lab (assumed to be the golden standard; alternatively an average of results may be used depending on the test).

This is a form of External Quality Assurance (EQA), as opposed to internal where different lab techs within a lab test the same sample and record their findings anonymously. The main issue of this form of QA is that it does not adequately address issues during pre- and post-analytical phase, which are responsible for most of the errors.

As laboratory quality can be measured, or at least estimated, it may ultimately result in accreditation by an international body such as the International Organization for Standardization (ISO) [25]. For medical laboratories, accreditation according to ISO 15189 is considered the Holy Grail. Unfortunately, in SSA (with the exception of South Africa) only a few accredited labs can be found.

As a response, a consortium of organizations, led by CDC and WHO started SLMTA (Stepwise Laboratory Management Towards Accreditation, pronounced slamta) in 2009, a comprehensive management program that works to improve various aspects of laboratory management, ranging from inventory management to specimen collection and processing [26]. Complementary to SLMTA, the Global Laboratory Initiative (GLI) is very useful tool in the process towards accreditation specifically for TB laboratories [27].

Working as a laboratory manager in a mission hospital Malawi, I've managed to get our laboratory into the program. Although the actual ISO accreditation was clearly not a feasible goal within a decade or so, the attention towards quality issues did wonders to the quality of our results. For instance, the positivity rate for malaria dropped significantly, suggesting many prior false positives. Furthermore, the trainings and PT discussions represented very welcome team-building exercises. The lab received overwhelming support in terms of equipment, training and infrastructure, however the SLMTA project coordinator did make any effort to explain the process to clinicians, who were therefore not at all aware of the steps the laboratory was making. SLMTA was clearly designed to merely improve the quality of the "test menu" from which clinicians could choose, without any attention to their understanding of the menu, or willingness to understand.

As a result, test utilization did not improve notably, at least not in the short term.

## 9.2 National Laboratory Strategic plans

One of the outcomes of the Maputo declaration has been to encourage ministries of health to develop National Laboratory Strategic Plans (NLSPs). Since then, a number of countries in SSA has indeed drafted and adopted such a document, with the help of many funding and implementing partners, such as PEPFAR, Clinton Foundation, CDC, Global Fund.

Glancing over such a document gives a good impression of the complexities of laboratory systems, the amount of agencies and people involved, and the often dilapidated state of laboratory infrastructure (see [28] for an example from Tanzania).

An NLSP usually has many components, including: a situational analysis, policy and regulatory framework, a clarification of the mandate for each tier within the laboratory system, a description of HRH needs and availability, Monitoring and Evaluation framework, quality management, procurement guidelines and infrastructure enhancement [29].

As the Ministry of Health (MoH) is usually the leading agency in both issuing and implementing the policies, political commitment is of the utmost importance. NLSPs are indispensable tools, as they are long-term road maps for laboratory strengthening that identifies priority areas, key partners and guides the distribution of funds.

## **10. Interaction between Actors and Process: Inter-professional collaboration**

Activities conducted in diagnostic laboratories are often regarded as a “black box”. Especially with regard to infectious disease, clinicians often request a yes or no answer with regard to the presence of a particular pathogenic organism or virus. New generation tests often do not allow such an answer, and knowledge regarding the limitations of the tests is often lacking.

Partly due to this lack of knowledge, clinicians both under- and over-request tests which poses a potential threat to adequate clinical management of patients or wasting laboratory resources, respectively [8, 10].

Laboratory staff members, at their end, are often used to work “in the shadows” and are usually not very vocal when it comes to sharing knowledge concerning their work. At morning report, lab techs do normally not join the discussion concerning the clinical management of individual patients, which would make it a truly inter-professional exercise.

The interaction between the two cadres is therefore limited, which makes it hard topic to study. Furthermore, researchers interested in the subject should ideally have knowledge concerning both sides of the work, experience working in similar settings and, importantly, an interest in qualitative research and social and/or psychological factors that co-determine inter-professional collaboration. Therefore, the number of studies reporting on inter-professional involving the laboratory in resource-constrained settings is limited.

Recently, van den Broek et al. established a comprehensive model based on a literature study and in-depth discussion with experts in the field [30]. They’ve taken a pragmatic approach and focused also on when the different cadres meet, i.e. in which phases in the diagnostic process, next to taking into account organizational and personal factors against a dynamic cultural, social, economical and political background.

They tested their model in a pilot study involving several health facilities in Tanzania [31]. From the study, a picture emerges of a lack of collaboration, under-utilization and under-recognition of the laboratory by clinicians, partly caused by a perceived difference in level of education. Interestingly, the way both cadres deal with their grievance towards each other differs: clinicians tend to approach lab staff directly, whereas lab staff complains about clinicians’ attitudes among themselves. This leads to wonder whether there are differences in the way both cadres view their own activities and role in the health system.

### 10.1 Communication between cadres

In a 2005 Clinical Diagnostic Practice Guide, Carter et al. put forward several reasons for the observed lack of communication between laboratory and clinic [32]. A lack of understanding appears to be vital: clinicians may not view interaction with the diagnostic services as their responsibility and “are not aware of the need for, and may fail to add, sufficient information on a patient, which makes it difficult for a diagnostic service to provide clinically relevant results. Clinicians may feel that they do not have the time for such activities, and they may not see that clinical outcomes are in fact tied to the diagnostic processes being followed”.

Similarly, according to them, laboratory staff does not always recognize the clinical importance of laboratory results.

I’ve experienced this to be true: lab staff tends to focus on the task at hand but generally fail to understand the implications of their finding for the patient.

With regard to malaria microscopy, a high number of false positives is a good example: when in doubt whether a certain sample contains malaria parasites, lab staff tend to report positive since they feel a false positive is “less of a mistake” than a false negative.

This can have detrimental consequences: I’ve witnessed a young male arrive in shock, with immeasurably low blood pressure, at the hospital. Basic lab was done within fifteen minutes: 1+ for malaria (*Plasmodium falciparum*), with pronounced leukocytosis.

Following administration of intra-venous fluids, clinicians started the patient on quinine drip, only focusing on the malaria result and suspecting cerebral involvement. A lab tech pointed out that the high number of leukocytes was not indicative of malaria but rather a bacterial infection and offered to re-check the blood for the presence of parasites, which indeed indicated malaria to be absent from the blood. Subsequently, the diagnosis was changed to bacterial sepsis: the patient was started on antibiotics and improved rapidly.

In the wake of this incident, clinicians blamed the lab for the false positive result and did not assume any responsibility for the initial misdiagnosis. The next day, none of the lab workers showed up at morning report to discuss the case, supposedly afraid of being confronted with the situation. This experience is in line with the finding by Tuijn et al. that laboratory staff tend to avoid confrontations with clinicians [31].

Interestingly, Carter et al. also remark that clinicians are not used to work as a team and “may feel uncomfortable working as a member of a team of health workers with different professional training or fewer credentials”.

Misunderstanding appears a re-occurring theme. An experienced laboratory advisor mentioned: “The biggest problem is clinicians don’t understand the lab. To them we’re the geeks in the corner who do strange things. And what they don’t understand they are uncomfortable with”. According to her, part of the reason the role of the laboratory is underestimated is historical: “Before, it was nursing, everything that needed to be done was done by a nurse. Then, the lab came, and all they did was stool and urine. They also got paid less, and still are most of the time.”

Low wages for lab staff is indeed an issue in my opinion: I’ve witnessed well-educated lab staff getting paid less than nursing staff, even in the context of an International NGO-run project. Low wages not only fuel discontent, it may also undermine self-esteem.

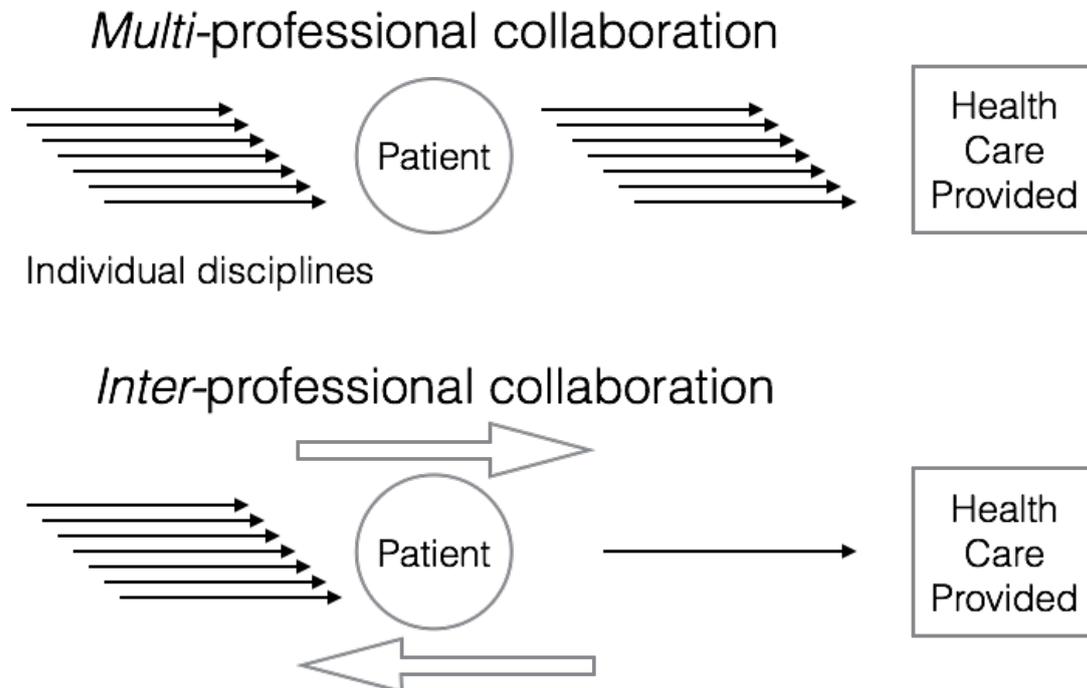
## 10.2 Inter-professional versus multi-professional

The diagnostic process can often be characterized as sequentially multi-professional: a patient visit a clinic, gets seen by a clinician, is referred to the lab for testing, receives the results and shows these to the clinicians who decided on a suitable treatment which may then be administered by nurses or supplied by the pharmacy; many different health workers “exert their expertise” on the patient, with a minimal of inter-professional interaction.

In their book “Inter-professional collaboration in health care” (English translation, unfortunately the book is available in Dutch only, with the original title: *Leren interprofessioneel samenwerken in de gezondheidszorg*), Tsakitzidis and van Royen advocate the implementation of truly inter-professional collaboration [33].

Central to the book is the difference between inter- and multi-professionalism. The difference between the two is graphically depicted in figure 3: in multi-professional collaboration, different professionals interact with and examine the patient, and all provide their separate input towards the

provided health care. In inter-professional collaboration, the same professionals are involved in care, however during inter-professional interaction, they would come up with a single joint plan towards clinical management and provided care.



**Figure 3: Model for Inter-professional versus Multi-professional collaboration in health care**  
Adapted from “Leren interprofessioneel samenwerken in de gezondheidszorg” (Inter-professional collaboration in health care), Giannoula Tsakitzidis & Paul van Royen, 2012, Standaard Uitgeverij.

Following the introduction of the above model, the authors proceed with a number of potential benefits for an inter-professional approach:

1. More frequent and effective communication between cadres, thus improving mutual understanding and trust. With regard to the laboratory, this would include providing sound explanation of the tests performed, including results and limitations of the tests. Vice versa, lab staff may learn about the clinical implications of their work, aiding the development of a sense of urgency and possibly pride in their work.
2. It counters the tendency towards specialization, as it forces professionals to communicate with colleagues in different fields.
3. This approach is better capable of dealing with complex diseases. Especially diseases that require chronic care, such as diabetes and leprosy require a holistic approach, in which professionals from many fields (including for instance physiotherapy) are involved.
4. Inter-professional recognition is generally improved, as the health care workers are witnessing the efforts of colleagues from different fields directly.
5. This would in turn lead to a decrease of competition among cadres.
6. Importantly, the quality of care is likely to improve. Different medical disciplines will become supportive of each other, and errors are more easily discussed and prevented.

7. It would promote a more honest distribution of burden of care. Task shifting (either horizontal or vertical) may now be easily discussed.

Although the authors clearly have written the book to be applied in developed countries, in my opinion aspects of it may also be very useful in more resource-deprived settings, some of which may be implemented based on existing practices. Most clinics in SSA conduct morning reports, at which patients are discussed and which are ideally frequented by members of all cadres. In my experience, however, hospital management does not actively promote participation by non-clinicians and attendance is often viewed as “optional”.

### 10.3 Inter-Professional Education

Stereotypes concerning each other’s roles, which may form barriers for efficient collaboration, apparently are already present during training at undergraduate level, as was shown in a qualitative study in which both biomedical and medical students were asked about their experiences following a series of joint inter-professional group exercises [34]. Biomedical students expressed concerns about being perceived by the medical students as providing a mere supportive role for clinical care, despite the fact that medical students were quite impressed with their scientific competencies.

In order to maximize appreciation of each other’s future professional roles, inter-professional education at an early stage in vocational studies may provide a solution.

With regard to the role of laboratory medicine within the curriculum for medical students, Wilson remarks on the fact that curricula have not changed in decades: “Inertia is a powerful force in health care, no less so in medical education” [35]. He underlines that this lack of adaptiveness is remarkably surprising in light of technological advances in lab science that have been made over the years. Although his remarks are meant to apply to a developed setting (the United States specifically), given the previously discussed lack of knowledge concerning lab testing in SSA, they are most likely also applicable here.

A lack of interest in laboratory medicine in medical school curricula may be one of the reasons for the lack of understanding described in the previous chapter.

As an example of IPE in SSA, clinicians and laboratory staff may learn about malaria together. The course may be followed jointly, however the ultimate learning goal may vary for medical and laboratory science students. For instance, treatment regimens can be considered essential learning for medical students but “nice to know” for future lab staff. The opposite may apply for advanced diagnostic techniques.

To the best of my knowledge, there are currently no efforts to introduce anything resembling IPE involving specifically the lab and clinic in SSA.

An experienced laboratory advisor commented on the phenomenon of inter-professional education in one of the interviews: “They already do it in parts of Africa with dentists and nurses and you see the obvious benefits. It would allow for easier case discussion”.

During an interview, one HR development consultant who is involved in providing cascade-training in order for laboratory capacity building responded very enthusiastically about the potential of IPE. During the courses she provides, she normally asks all the clinicians to perform a test on the GeneXpert themselves, which in her experience helps enormously in raising mutual understanding: “The clinicians become aware that they can actually learn from their laboratory colleagues, which allows for useful discussions on a basis of equality”.

IPE in health care has now been recommended by WHO, based on a multitude of reports, all of which underline its effectiveness. With aging populations, also in SSA, there is a shift towards chronic illnesses that require an inter-professional approach. WHO also claims IPE may be an effective weapon in combatting shortages in health care in developing countries, since students of different faculties can be trained simultaneously.

Although most studies regarding IPE have been performed in a developed setting, Sunguya et al. have conveniently discussed the available evidence with a focus on developing settings [36]. They also comment on the attitude of medical doctors: “they tend to be powerful, as are their medical students relative to students in other professional programs. Medical doctors and students tend to be leaders and others act as team players. This attitude is against the spirit of inter-professional collaboration”.

Again, this argues in favor of a shift in beliefs and behavior of clinicians (medical doctors in this case) in order for IPE to be truly successful, however at the same time paradoxically underlines the need for it.

## 11. Discussion of literature review and analytical framework

### 11.1 Literature search

The literature search resulted in 61 articles, the bulk of which from peer-reviewed journals. Several manuscripts were found in grey literature, including national strategic plans, guides for laboratory quality improvement schemes and documents from international coordinating and advisory bodies such as the WHO. The full list of literature can be found in Appendix II. Please note that not all literature cited in the Appendix actually occurs in the text; this is indicated in the table (under “discussed in thesis”). Conversely, several references appear in the text that do not necessarily relate to laboratory medicine and have therefore not been entered in the table in Appendix II.

Information is abundantly available on the impact of laboratory testing and the threats of obtaining a purely clinically derived diagnosis. In order to avoid a long list of settings and illnesses for which laboratory testing has proven impact in a field-setting, only a few key references were provided, including several reviews.

Contrastingly, literature on Inter-professional collaboration, involving the laboratory, is relatively scarce. As mentioned, the interviews were meant to fill this gap. However, only three interviews could be scheduled and therefore provide anecdotal evidence only.

### 11.2 Analytical framework

The analytical model proved useful in providing guidance to the analyses of the results.

As already mentioned by Walt and Gilson, we should not only describe Content, Context, Actors and Process separately, but also pay attention to the interactions between them, in order to adequately perform a comprehensive analysis.

This thesis is full of examples of such interactions that may be fitted into the model, which, in my opinion, makes it very suitable in providing a theoretical framework for the topics discussed.

In chapter 4 on the utilization of test results, a cost advantage of performing diagnostics over (often needless) treatment with antibiotics (Content) is related to the Process of test utilization. In turn, the reason for the under-utilization of test results is related to the beliefs of the Actors (in this case clinicians).

Chapter 5 deals with a changing Context, which will also have clear consequences on Content. The emergence of drug-resistance to first line treatments, for instance, has prompted novel technologies. This, in turn, will add to the responsibilities of the laboratory staff (Actors), in making sure the technology is well understood by those utilizing the test result (Process).

The issues described in the final three chapters could also be fitted into the model, as can be seen in figure 4. Task shifting (chapter 8) relates both to Actors and Content, as technological advances make it possible it possible for staff members other than laboratory staff to perform certain tests.

Updated policies (chapter 9) are usually a response to shifting needs (Context), aimed at increased laboratory testing and quality (Content) and adapting the work force (Actors) accordingly. They do not, to the best of my knowledge, take into account the Process of final utilization of test results.

Finally, the roles of the main Actors in the Process of end-utilization of test results are discussed in chapter 10 on Inter-professional collaboration.

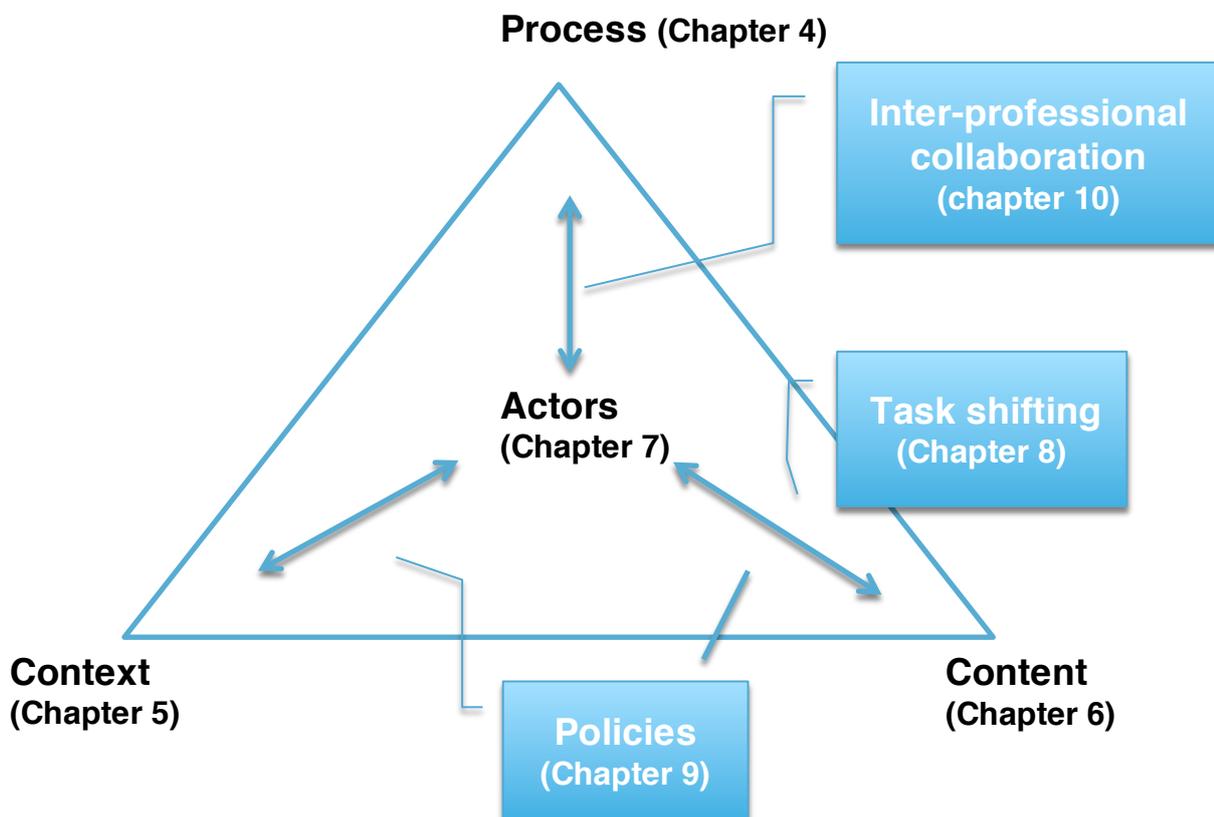
The model employed has proven to be capable of capturing the themes previously identified. Employing such a model may help towards adopting a more holistic approach when implementing novel technologies. Too often, the question is asked: “What can the machine do?”, focusing strictly

on the content, without much regard for whether the health system can support the technology. “How can this technology benefit patients within the context of our health system?” seems a better question to ask, which would take into account the Actors and Context.

For example, the switch from CD4 count to HIV viral load as a primary indicator for monitoring of PLHIV in many countries in SSA was seemingly prompted solely by the diagnostic capability of high-throughput instruments that can only be used in large and well-equipped laboratories. Unfortunately, I’ve seen many such advanced equipment severely underused in reference laboratories, despite a high work load in peripheral labs.

Retrospectively, peripheral staff was not properly trained on sample referral, awareness concerning the testing options was missing with clinicians, and laboratory HR needs were underestimated.

Hopefully, such a model may prove useful for future studies and analyses. For policy makers it may be beneficial to ascertain their efforts will also result in an increased final utilization of laboratory results. Ultimately, it should be realized by all that the impact of any diagnostic is limited by how clinicians act on its results.



**Figure 4: Adapted model including topics discussed in thesis.**

## 12. Recommendations and concluding remarks

Many studies on laboratory utilization have been highlighted in this thesis. However, remarkable little information is available on the process of utilization of the actual test result, i.e. whether a certain result will change diagnosis or treatment when this is indicated.

Scientists at the Amsterdam Institute for Global Health and Development (AIGHD) are currently studying the utilization of HIV-VL results in Uganda, to see whether a measured increase in VL will result in a change in treatment regimen. The results of this study will be of particular interest for anyone working in lab test utilization, in addition to medical doctors who make decisions regarding HIV treatment.

Such studies may have surprising results. An RCT studying final outcomes of increased availability of GeneXpert MTB/RIF testing showed, as expected, more patients starting same-day treatment, more culture-positive patients starting therapy, and a shorter time to treatment [19]. This did, however, not measurably translate into a decrease in morbidity “partly because of high levels of empirical-evidence-based treatment in smear-negative patients.” Empirical treatment may therefore be viewed as a considerable threat to final test utilization; moreover it’s a threat that cannot be eliminated by investing in laboratories alone. More studies relating diagnostics to final outcomes such as morbidity are clearly needed and causal relationships between availability of diagnostics and impact need to be clarified.

Polage and others have found that clinical staff tends to rely on their own judgment [9]. Carter et al [28] suggested that clinicians are not accustomed to teamwork and Tuijn et al. mentioned that lab staff perceives a lack of recognition from clinicians [27]. I would go a step further and put forward that a sense of complacency among physicians with regard to the duties of the lab is one of the key threats to efficient use of laboratory results. A purely qualitative large-scale study on clinicians’ attitudes will hopefully shed more light on the matter from a more sociological viewpoint. The questions I would like to see answered is: In a changing world with regard to context of diseases and rapidly increasing technological possibilities, to what extent are clinicians able to welcome input from specialist laboratory staff, and how would that influence their clinical decision making behavior? As a starting point for such a study, the model developed by van den Broek et al. [26] will prove very valuable.

At the same time, laboratory staff should also acknowledge their increasing role in the health system and assume responsibility accordingly.

Concluding, a “lack of understanding” between lab and clinic is a recurring theme in this thesis, however it is currently hardly being addressed at a local level. Massive investment in improving laboratory infrastructure and quality assurance will ultimately improve access to quality testing, however whether this leads to a concomitant effect on morbidity also depends on clinicians’ receptiveness towards an increased role of the lab.

Better performance will go a long way towards increasing faith in the laboratory, however the assumption that quality will ultimately always result in better test result utilization may prove unfounded.

To the best of my knowledge, efforts towards improving laboratory quality and accreditation schemes put little attention on final test utilization: clinicians are considered “customers” of the laboratory, as if the laboratory were a market in which to shop for suitable results. Regarding the patient as the customer that requires a collaborative effort from all medical staff may be considered a much healthier viewpoint.

In my opinion, implementing inter-professional education in SSA, specifically involving the laboratory staff and clinicians, would be of much value in improving mutual understanding and ultimately lab utilization.

Hopefully, future lab scientists may be viewed more along the line of specialists that orchestrate and coordinate the various efforts related to diagnostics with a shared focus on patient wellbeing, rather than being viewed as “those in charge of urine and stool”. As I hope I have been able to make clear, the changing content and context, in the form of various biological, social, and technological developments, will demand it.

Next to a sustainable effort to increase lab quality, this requires involvement of lab specialists in decision-making processes. The curriculum for laboratory specialist should also emphasize managerial and people skills, and job descriptions should be adapted accordingly. Ultimately, I am convinced that an inter-professional approach on the basis of equality, rather than a multi-professional one should be implemented in health care, also in developing countries.

### **13. Acknowledgements**

I'd like to express my gratitude to the three interviewees, their collaboration strengthened my conviction that this is a topic that is worth to be studied and discussed more.

I'm also grateful to various people from the KIT for their assistance, not only in providing very useful and inspiring comments concerning the topic and content of this thesis, but also relating to the various courses and progress during the course of my studies.

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34. Lewitt, M.S., Ehrenborg, E., Scheja, M. and Brauner. A. (2010) Stereotyping at the undergraduate level revealed during interprofessional learning between future doctors and biomedical scientists. *J. Interprof. Care* **24**(1):53-62.
35. Wilson, M.L. (2010) Educating medical students in laboratory medicine. *Am. J. Clin. Pathol.* **133**:525-528.
36. Sunguya, B.F., Hinthong, W., Jimba, M. and Yasuoka, J. (2014) Interprofessional education for whom? - Challenges and lessons learned from its implementation in developed countries and their application to developing countries: A systematic review. *PLoS One* **9**(5)

## Appendix I: Interview guide

This is for guiding purposes only, additional questions may be asked.

Exact wording will be different, more elaborate.

The questions below will be asked after a general introduction and questions relating to job description, years of experience etc. to ascertain the participant meet the criteria.

### To be asked of **Field staff: Laboratory technicians**

#### *Frequency and nature of interaction with clinicians*

1. Do you talk to colleagues from the clinic on a regular basis? How often, for how long, in what setting (laboratory/ward/social)?
2. What normally is the reason for communicating with the clinicians?
3. How do you generally perceive such an interaction? Please elaborate.
4. Do you feel there is sufficient contact/exchange of information between lab and clinical staff?
5. Is there any animosity sometimes between lab- and clinical-staff? If so, why do you think that happens?

#### *Perception regarding the role of the laboratory in clinical management*

6. How important is the lab for clinical management of the individual patient, in your opinion?
7. Do you think the lab results can be trusted, generally speaking?
8. How do you think the clinicians use the laboratory results?

#### *Perception regarding the performance of clinicians*

9. How many years of training do you think clinicians (focus on clinical officers) have had, prior to assuming service?
10. Do you trust clinicians to do what is best for the patient?
11. How do you think the clinicians perform their job in this hospital? Please elaborate.
12. Are you familiar with the concept of inter-professional education? If so, please elaborate.

### To be asked of **Field staff: Clinical Officer**

#### *Frequency and nature of interaction with laboratory staff*

1. Do you talk to colleagues from the laboratory on a regular basis? How often, for how long, in what setting (laboratory/ward/social)?
2. What normally is the reason for communicating with the lab staff?
3. How do you generally perceive such an interaction? Please elaborate.
4. Do you feel there is sufficient contact/exchange of information between lab and clinical staff?
5. Is there any animosity sometimes between lab- and clinical-staff? If so, why do you think that happens?

#### *Perception regarding the role of the laboratory in clinical management*

6. How important is the lab for clinical management of the individual patient, in your opinion?
7. Do you think the lab results can be trusted, generally speaking?
8. Do you normally have more faith in your own clinical judgment over the laboratory results? Please elaborate and/or give examples.

#### *Perception regarding the performance of laboratory staff*

9. How many years of training do you think laboratory technicians have had prior to assuming service?
10. Do you think laboratory technicians generally are concerned about individual patients?
11. How do you think the laboratory staff, in general, performs their job in this hospital? Please elaborate.
12. Are you familiar with the concept of inter-professional education? If so, please elaborate.

Questions asked of **key informants** will be highly similar, however phrased differently. For example, I will ask: "do you think laboratory technicians generally trust clinicians will use the laboratory results?", etc.

## Appendix II: Literature list

Please note not all literature cited in the list below actually occurs in the text; this is indicated in the table (under “discussed in thesis”. Conversely, several references appear in the text that do not necessarily relate to laboratory medicine and have therefore not been entered in the table below.

Nr.	Authors	Title	Year	Citation/Location	Topic	Type	Cited in thesis?
1	Alonso-Cerezo MC, Martín JS, García Montes MA, de la Iglesia VM.	Appropriate utilization of clinical laboratory tests.	2009	Clin. Chem. Lab. Med. 2009;47(12):1461-5. doi:10.1515/CCLM.2009.335.	Review highlighting the need for Clinical Practice Guidelines for efficient use of laboratories	Review	y
2	Amexo M, Tolhurst R, Barnish G, Bates I.	Malaria misdiagnosis: Effects on the poor and vulnerable.	2004	<i>Lancet</i> 2004;364(9448):1896-1898. doi:10.1016/S0140-6736(04)17446-1.	Diagnosis and treatment of malaria	Review	y
3	Bates I, Maitland K.	Are Laboratory Services Coming of Age in Sub-Saharan Africa ?	2006	Clin. Infect Dis. 2006 Feb 1;42(3):383-4.	Editorial comment on Petti et al. (#40)	Editorial	n
4	Berger D.	A brief history of medical diagnosis and the birth of the clinical laboratory.	1999	Med. Lab. Obs. 1999;31:28-30, 32, 34-40.	Historical perspective of medical diagnostics	Review	y
5	Birx D, de Souza M, Nkengasong JN.	Laboratory challenges in the scaling up of HIV, TB, and malaria programs: The interaction of health and laboratory systems, clinical research, and service delivery.	2009	Am. J. Clin. Pathol. 2009;131(6):849-51. doi:10.1309/AJCPGH89QDSWFONS.	Lab strengthening general	Review/Opinion	n
6	Bor J, Abraham J Herbst, Marie-Louise Newell, and Till Bärnighausen	Increases in adult life expectancy in rural South Africa: valuing the scale-up of HIV treatment	2012	Science. 2013 February 22; 339(6122): . doi:10.1126/science.1230413	Article studying the impact of ART coverage on life expectancy	Quant. study	y
7	Bridges DR, Davidson R a, Odegard PS, Maki I V, Tomkowiak J.	Interprofessional collaboration: three best practice models of	2011	Med. Educ. Online 2011;16:1-10.	Inter-professional	Review	n

		interprofessional education.		doi:10.3402/meo.v16i0.6035.	education		
8	van den Broek A, Tuijn CJ	“Boosting laboratory workers’ contribution to providing quality patient care” in Low Income Countries	2008	Concept note, Royal Tropical Institute. 2011;31(December).	Barriers to lab medicine in developing countries	Concept note	n
9	van den Broek A, Tuijn CJ, Van't Klooster L, et al.	Understanding the interface between clinical and laboratory staff.	2014	Afr. J. Lab. Med. 2014;3(1):1-6. doi:10.4102/ajlm.v3i1.127.	Inter-professional communication	Literature review	y
10	Carter J, Irmela Müller-Stöver, Harald Östensen, Claus Chr. Heuck	Good Clinical Diagnostic Practice (WHO regional publication)	2005	<a href="http://applications.emro.who.int/dsaf/dsa236.pdf?ua=1">http://applications.emro.who.int/dsaf/dsa236.pdf?ua=1</a>	Efficient use of diagnostics by clinicians	WHO guide	y
11	Carter JY, Lema OE, Wangai MW, Munafu CG, Rees PH, Nyamongo JA	Laboratory testing improves diagnosis and treatment outcomes in primary health care facilities.	2011	Afr. J. Lab. Med. 2011;1(1):6-11. doi:10.4102/ajlm.v1i1.8.	Impact and cost-effectiveness of lab tests	Quant. study	y
12	Cohen GM.	Access to diagnostics in support of HIV/AIDS and tuberculosis treatment in developing countries.	2007	AIDS 2007;21 Suppl 4:S81-7. doi:10.1097/01.aids.0000279710.47298.5c.	Access to diagnostics relating to HIV/AIDS	Review	n
13	Dacombe RJ, Squire SB, Ramsay a R, Banda HT, Bates I.	Essential medical laboratory services: their role in delivering equitable health care in Malawi.	2007	Malawi Med. J. 2007;18(2). doi:10.4314/mmj.v18i2.10914.	Impact laboratory services	Report	n
14	Datema TAM, Oskam L, Engelberts MFM, et al.	Global laboratory initiative tool for a stepwise process towards tuberculosis laboratory accreditation.	2012	Int. J. Tuberc. Lung Dis. 2012;16(5):704-5. doi:10.5588/ijtld.11.0701.	Introduction GLI	Short communication	y
15	Datema TAM, Oskam L, van Beers SM, Klatser PR.	Critical review of the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA): suggestions for harmonization, implementation and improvement.	2012	Trop. Med. Int. Health 2012;17(3):361-7. doi:10.1111/j.1365-3156.2011.02917.x.	Assessment of accreditation scheme	Report	n
16	Fonjungo PN, Kebede Y, Arneson W, et al.	Preservice laboratory education strengthening enhances sustainable laboratory workforce in Ethiopia.	2013	Hum. Resour. Health 2013;11(1):56. doi:10.1186/1478-4491-11-56.	Training of lab scientists	Report	n
17	Gersh-Damet G-M, Rotz P, Cross D, et al.	The World Health Organization African region laboratory accreditation process: improving the quality of laboratory systems in the African region.	2010	Am. J. Clin. Pathol. 2010;134(3):393-400. doi:10.1309/AJCPTUUC2V1WJQBM.	Lab Quality Assurance /accreditation	Review/Opinion	n

18	Ghebremichael M.	The Syndromic versus Laboratory Diagnosis of Sexually Transmitted Infections in Resource-Limited Settings.	2014	Isrn Aids 2014;2014:103452. doi:10.1155/2014/103452.	Diagnosis of STI's	Quant. study	n
19	Girosi F, Olmsted SS, Keeler E, et al.	Developing and interpreting models to improve diagnostics in developing countries.	2006	Nature 2006;444 Suppl :3-8. doi:10.1038/nature05441.	Theoretical study to estimate effect of novel diagnostics	Modeling study	n
20	Gotlib Conn L, Reeves S, Dainty K, Kenaszchuk C, Zwarenstein M.	Interprofessional communication with hospitalist and consultant physicians in general internal medicine: a qualitative study.	2012	BMC Health Serv. Res. 2012;12(1):437. doi:10.1186/1472-6963-12-437.	Inter-professional communication	Qualitative research	n
21	Guindo MA, Shott JP, Saye R, et al.	Promoting Good Clinical Laboratory Practices and Laboratory Accreditation to Support Clinical Trials in Sub-Saharan Africa.	2012	Am. J. Trop. Med. Hyg. 2012;86(4):573-579. doi:10.4269/ajtmh.2012.11-0691.	Lab QA in light of clinical trial requirements	Mixed-methods research	n
22	Haddara W, Lingard L.	Are we all on the same page? A discourse analysis of interprofessional collaboration.	2013	Acad. Med. 2013;88(10):1509-15. doi:10.1097/ACM.0b013e3182a31893.	Inter-professional communication	Qualitative research	n
23	Jani I V., Peter TF.	How Point-of-Care Testing Could Drive Innovation in Global Health.	2013	N. Engl. J. Med. 2013;368:2319-2324.	Development of diagnostics	Review	n
24	Lara AM, Kandulu J, Chisuwu L, Kashoti A, Mundy C, Bates I.	Laboratory costs of a hospital-based blood transfusion service in Malawi.	2007	J. Clin. Pathol. 2007;60(10):1117-20. doi:10.1136/jcp.2006.042309.	Blood transfusion systems	Quant. study	n
25	Leshabari M.T., Eustace P.Y. Muhondwa, M.A. Mwangu, Naboth A.A. Mbembati	Motivation of health care workers in Tanzania: a case study of Muhimbili national hospital	2008	East African Journal of Public Health 2008;5(1):32-37.	Motivation among health care workers	Mixed-methods research	n
26	Lewitt MS, Ehrenborg E, Scheja M, Brauner A.	Stereotyping at the undergraduate level revealed during interprofessional learning between future doctors and biomedical scientists.	2010	J. Interprof. Care 2010;24(1):53-62. doi:10.3109/13561820902921704.	Inter-professional education	Program evaluation/Mixed-methods	y
27	Manongi RN, Marchant TC, Bygbjerg IC.	Improving motivation among primary health care workers in Tanzania: a health worker perspective.	2006	Hum. Resour. Health 2006;4:6. doi:10.1186/1478-4491-4-6.	Motivation among health care workers	Qualitative research	n

28	Marshall MN.	How well do general practitioners and hospital consultants work together? A qualitative study of cooperation and conflict within the medical profession	1998	British Journal of General Practice, 1998, 48, 1379-1382	Inter-professional communication	Qualitative research	n
29	Masanza MM, Nqobile N, Mukanga D, Gitta SN.	Laboratory capacity building for the International Health Regulations (IHR [2005]) in resource-poor countries: the experience of the African Field Epidemiology Network (AFENET).	2010	BMC Public Health 2010, 10(Suppl 1):S8	Laboratory strengthening in general	Report	n
30	Mbah H, Negedu-momoh OR, Adedokun O, Anibbe P.	Implementing and measuring the level of laboratory service integration in a program setting in Nigeria.	2014	PLoS One 2014;9(9):e107277. doi:10.1371/journal.pone.0107277.	Study highlighting the lack of integration of vertical programs	Quant. study	n
31	Mephram SO, Squire SB, Chisuwo L, Kandulu J, Bates I.	Utilisation of laboratory services by health workers in a district hospital in Malawi.	2009	J. Clin. Pathol. 2009;62(10):935-8. doi:10.1136/jcp.2009.069062	Utilization of laboratory	Quant. observational study	n
32	Mundy, C. J. F., I. Bates, W. Nkhoma, K. Floyd, G. Kadeweile, M. Ngwxra, A. Khuwi, S. B. Squire and C. F. Gilks	The operation, quality and costs of a district hospital laboratory service in Malawi.	2003	Trans. Royal Soc. Trop. Med. Hyg. (2003) 97, 403-408	Cost and quality of lab utilization in Malawi	Quant. study	y
33	Njelesani J, Dacombe R, Palmer T, et al.	A systematic approach to capacity strengthening of laboratory systems for control of neglected tropical diseases in Ghana, Kenya, Malawi and Sri Lanka.	2014	PLoS Negl. Trop. Dis. 2014;8(3):e2736. doi:10.1371/journal.pntd.0002736.	Neglected Tropical Diseases	Mixed-methods research	n
34	Nkengasong JN, Birx, D	Quality matters in strengthening global laboratory medicine.	2014	Afr. J. Lab. Med. 2014;3(2):2-5. doi:10.4102/ajlm.v3i2.239.	Quality Assurance	Review	n
35	Nkengasong JN, Mesele T, Orloff S, et al.	Critical role of developing national strategic plans as a guide to strengthen laboratory health systems in resource-poor settings.	2009	Am. J. Clin. Pathol. 2009;131:852-857. doi:10.1309/AJCPC51BLOBBPAKC.	Underlines the need for national strategic lab plan	Review	y
36	Nkengasong JN, Nsubuga P, Nwanyanwu O, et al.	Laboratory systems and services are critical in global health: time to end the neglect?	2010	Am. J. Clin. Pathol. 2010;134(3):368-73. doi:10.1309/AJCPMPSINQ9BRMU6.	Laboratory strengthening in general	Review/Opinion	y
37	Nkengasong JN.	A shifting paradigm in strengthening laboratory health systems for global health: acting now, acting collectively, but acting differently.	2010	Am. J. Clin. Pathol. 2010;134(3):359-60. doi:10.1309/AJCPY5ASUEJYQ5RK.	Lab strengthening general	Editorial	y

38	Olmsted SS, Moore M, Meili RC, et al.	Strengthening laboratory systems in resource-limited settings.	2010	Am. J. Clin. Pathol. 2010;134(3):374-80. doi:10.1309/AJCPDQOSB7QR5GLR.	Barriers to lab medicine in developing countries	Qualitative research	n
39	Palchadhuri S, Tweya H, Hosseinipour M.	Assessment of Laboratory Test Utilization for HIV / AIDS care in ART clinics of Malawi.	2014	Malawi Medical Journal; 26 (2) 42-44 June 2014	Lab utilization by clinicians for HIV/AIDS	Quant. study	y
40	Peter TF, Rotz PD, Blair DH, Khine AA, Freeman RR, Murtagh MM.	Impact of laboratory accreditation on patient care and the health system.	2010	Am. J. Clin. Pathol. 2010;134(4):550-555. doi:10.1309/AJCPH1SKQ1HNWGHF.	Effect accreditation on clinical decision making	Review/Opinion	y
41	Petti CA, Polage CR, Quinn TC, Ronald AR, Sande M.A.	Laboratory medicine in Africa: a barrier to effective health care.	2006	Clin. Infect. Dis. 2006;42(3):377-82. doi:10.1086/499363.	Barriers to lab medicine in Africa	Review	Y
42	Pillay T, Turzyniecka M, Naidoo S.	Cost-effective utilisation of basic biochemical laboratory investigations in primary care.	2012	Contin. Med. Educ. 2012;30(7):249-251.	Overview of lab tests	Review	n
43	Plebani M.	Exploring the iceberg of errors in laboratory medicine.	2009	Clin. Chim. Acta. 2009;404(1):16-23. doi:10.1016/j.cca.2009.03.022.	Errors in laboratory practice	Literature review	p
44	Polage CR, Bedu-addo G, Owusu-ofori A, et al.	Laboratory use in Ghana: Physician perception and practice.	2006	Am. J. Trop. Med. Hyg., 75(3), 2006, pp. 526–531.	Utilization of laboratory	Quant. study	y
45	Prinsloo EAM, Dimpe MW, Maphakisa M V, Shabalala S, Joubert G.	Doctors' use of laboratory tests in the diagnosis and treatment of patients.	2010	South Afr J Epidemiol Infect 2010;25(3):16-20	Use of diagnostics by clinicians	Quant. study	n
46	Regional director WHO	Strengthening public health laboratories in the WHO African region: a critical need for disease control	2008	AFR/RC58/6	Resolution for laboratory strengthening	WHO Concept note	n
47	RJ Dacombe, SB Squire, ARC Ramsay, HT Banda, I Bates	Essential medical laboratory services: their role in delivering equitable health care in Malawi	2006	Malawi Med. J. 2006;18(2):77-79.	Lab strengthening general	Short review	n
48	Shared effort from WHO, CDC and other organizations	Guidance for Development of National Laboratory Strategic Plans	2010	<a href="http://www.aphl.org/aphlprograms/global/Documents/GH_2010Aug13_GuidanceNLStrategicPlans.pdf">http://www.aphl.org/aphlprograms/global/Documents/GH_2010Aug13_GuidanceNLStrategicPlans.pdf</a>	Guidance for development laboratory plans at national level	Guide	y

49	Sunguya BF, Hinthong W, Jimba M, Yasuoka J.	Interprofessional education for whom? - Challenges and lessons learned from its implementation in developed countries and their application to developing countries: A systematic review.	2014	PLoS One 2014;9(5). doi:10.1371/journal.pone.0096724.	Barriers for efficient interprofessional education	Systematic review	y
50	Theron G, Zijenah L, Chanda D, et al.	Feasibility, accuracy, and clinical effect of point-of-care Xpert MTB/RIF testing for tuberculosis in primary-care settings in Africa: a multicentre, randomised, controlled trial.	2014	Lancet 2014;383(9915):424-35. doi:10.1016/S0140-6736(13)62073-5.	Impact novel Tuberculosis diagnostic tool	RCT	y
51	Tuijn CJ, Msoka E, Mushi DL, Sumari-de Boer M, Chilongola J, Van den Broek A.	The interface between clinicians and laboratory staff: A field study in northern Tanzania.	2014	Afr J Lab Med. 2014;3(1), Art. #126, 7 pages. <a href="http://dx.doi.org/10.4102/ajlm.v3i1.126">http://dx.doi.org/10.4102/ajlm.v3i1.126</a>	Inter-professional communication	Mixed-methods research	y
52	UNITAID	Hiv/aids - Diagnostics Technology Landscape.	2014	<a href="http://www.unitaid.eu/images/marketdynamics/publications/UNITAID-HIV_Diagnostic_Landscape-4th_edition.pdf">http://www.unitaid.eu/images/marketdynamics/publications/UNITAID-HIV_Diagnostic_Landscape-4th_edition.pdf</a>	Review of diagnostics on market and in pipeline	Report	y
53	Unknown	The Maputo Declaration The Maputo Declaration on Strengthening of Laboratory Systems.		2 <a href="http://www.who.int/hiv/amds/amds_maputo_dec_lab_sys.pdf?ua=1">http://www.who.int/hiv/amds/amds_maputo_dec_lab_sys.pdf?ua=1</a>	Expresses intent to invest in laboratory infrastructure	Declaration	y
54	Urdea M, Penny L a, Olmsted SS, et al.	Requirements for high impact diagnostics in the developing world.	2006	Nature 2006;444 Suppl :73-79. doi:10.1038/nature05448.	Development of diagnostics	Review	n
55	WHO	WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region.	2011	<a href="http://www.afro.who.int/en/clusters-a-programmes/hss/blood-safety-laboratories-a-health-technology/blt-highlights/3859-who-guide-for-the-stepwise-laboratory-improvement-process-towards-accreditation-in-the-african-region-with-checklist.html">http://www.afro.who.int/en/clusters-a-programmes/hss/blood-safety-laboratories-a-health-technology/blt-highlights/3859-who-guide-for-the-stepwise-laboratory-improvement-process-towards-accreditation-in-the-african-region-with-checklist.html</a>	Lab Quality Assurance	WHO Guide	n
56	Wilson ML.	Educating medical students in laboratory medicine.	2010	Am. J. Clin. Pathol. 2010;133:525-528. doi:10.1309/AJCPQIA4FUGMVHT8.	Inter-professional education	Editorial	y
57	World Health Organization	Integrated Laboratory Strengthening for High Burden Diseases (Tuberculosis, HIV, Malaria and Neglected Tropical Diseases).	2010	<a href="http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/prevalence_survey/lab_strength.pdf">http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/prevalence_survey/lab_strength.pdf</a>	Lab strengthening general	WHO publication	n

58	Yao K, Luman ET & Collaborating Authors.	Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems.	2014	Afr. J. Lab. Med. 2014;3(2). doi:10.4102/ajlm.v3i2.262.	Lab Quality Assurance	Audit report	n
59	Yao K, McKinney B, Murphy A, et al.	Improving quality management systems of laboratories in developing countries: an innovative training approach to accelerate laboratory accreditation.	2010	Am. J. Clin. Pathol. 2010;134(3):401-9. doi:10.1309/AJCPNBBL53FWUIQJ.	Lab Quality Assurance	Qualitative research	n
60	Yao, K., Talkmore Maruta, Elizabeth T. Luman, John N. Nkengasong	The SLMTA programme: Transforming the laboratory landscape in developing countries.	2014	Afr J Lab Med. 2014;3(1), Art. #194, 8 pages. <a href="http://dx.doi.org/10.4102/ajlm.v3i1.194">http://dx.doi.org/10.4102/ajlm.v3i1.194</a>	Experiences from Accreditation program	Report	y
61	Zhi M, Ding EL, Theisen-Toupal J, Whelan J, Amaout R.	The landscape of inappropriate laboratory testing: a 15-year meta-analysis.	2013	PLoS One 2013;8(11):e78962. doi:10.1371/journal.pone.0078962.	Lab utilization by clinicians	Meta-analysis	y