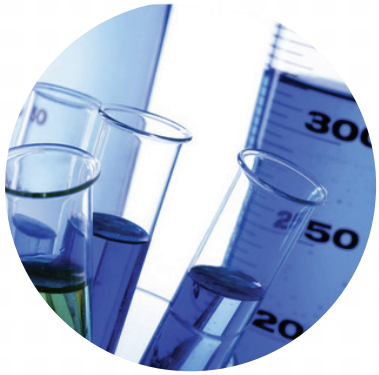
Approved November 2009



Assessment Report on Reference Laboratories in the SADC Region

ORIGINAL IN
ENGLISH

Acknowledgements

This work was made possible through the collaboration of the Southern African Development Community (SADC) Secretariat with Member States and various stakeholders. The Secretariat would like to acknowledge all the contributions. Firstly, Member States of SADC, through their Laboratory Coordinators and other focal points for National Reference Laboratories, provided information about Member States programmes, and coordinated discussions with other stakeholders during the field assessments. Additionally, laboratory coordinators reviewed drafts and provided valuable technical input and guidance to the report.

Senior government officials in the Communicable Diseases Project Steering Committee, National AIDS Authorities and Members of the HIV and AIDS Technical Advisory Committee reviewed final drafts and made recommendations to facilitate finalisation. This work also benefitted from collaborating partners including the United Nations Organisations, namely WHO. The SADC Secretariat would like to thank them for their technical inputs in reviewing various drafts of the document as well as participating in technical meetings to discuss the work.

The consultant for this work was Prof Elopy Nimele Sibanda who collected data from the Member States and produced a situation and response analysis report. Additionally, the consultant provided valuable technical inputs and drafted various drafts of the report based on feedback provided.

Lastly, this Assessment would not have been possible if it were not for the financial support provided by the African Development Bank for funding this work through their grant to the SADC Secretariat on Communicable Diseases (HIV and AIDS, TB and Malaria). Furthermore, the Secretariat would like to acknowledge financial assistance by the Joint Financing and Technical Collaboration for co-funding of the Consensus building workshop.

ISBN: 978-99968-0-127-3

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired immunodeficiency virus
ART	Antiretroviral therapy
EIA	Enzyme immunoassay (synonym ELISA)
ELISA	Enzyme-linked immunosorbent assay (synonym EIA)
HIV	Human immunodeficiency virus
IATA	International Airline Transport Association
MDR	Multidrug-resistant
MDG	Millennium Development Goals
MTCT	Mother-to-child transmission (of HIV)
PCR	Polymerase chain reaction
RDT	Rapid diagnostic test
SADC	Southern African Development Community
SNRL	Supranational reference laboratory
TB	Tuberculosis
VCT	Voluntary counselling and testing
WHO	World Health Organization
XDR	Extensively drug-resistant

EXECUTIVE SUMMARY

The purpose of the assessment of national reference laboratories in the Southern African Development Community (SADC) region was to obtain objective and independently verifiable data on their status and capacity to support the primary diagnosis and management of communicable diseases, with special reference to HIV & AIDS, tuberculosis (TB) and Malaria. The findings should guide SADC Member States in their efforts to strengthen laboratory capacity. The assessment process involved a review of relevant literature and documentation sourced from SADC and international cooperation partners, including the WHO. This was followed by assessment visits to Member States. Informants identified by Member States were interviewed. Information was verified during guided site visits. An ad hoc technical review meeting was convened in Windhoek, Namibia, in May 2009, to review the results of the assessment. The meeting comprised representatives of selected Member States, as well as technical cooperation partners. Written contributions were received from the World Health Organization (WHO). Recommendations from the meeting were incorporated, and a revised document was presented to a consensus-building meeting held in Gaborone, Botswana, in August 2009, where 13 Member States were represented.

The assessment recognised that laboratories exist as a result of policy guidelines, and that the purpose, mission, equipment and the staff complement are guided by strategies adopted by the respective Member States to support their HIV & AIDS, TB, Malaria, and other programmes. The first area of assessment sought an understanding of policy guidelines, the structure and organisation of the laboratories, and their coordination, scope of services delivery and financing logistics. The subsequent areas of assessment sought an appreciation of how the policies were translated into practice. This included the physical infrastructure that had been built, the availability of human resources deployed and the availability and appropriateness of equipment procured. Finally, the assessment looked into the operations of the personnel, as reflected in the performance of laboratory tests, quality management, information management, as well as the safety of the work environment.

The basic repertoire of tests used in the diagnosis and treatment monitoring of the respective conditions was based on WHO recommendations. A key observation was that policies were only available in half the SADC Member States. The process of laboratory policy compilation was at different stages of advancement. Some Member States were yet to draft policy documents, while others had Acts of Parliament guiding laboratory activities.

In others, laboratory services were guided by respective HIV & AIDS, TB and Malaria programmes. The interface of national reference laboratories, Ministries of Health and the programmes was therefore studied on the basis of available documentation and experiences in their implementation, as observed during site visits. The laboratory services were coordinated from Laboratory Services Departments (where these existed), or from programmes. Laboratory structures were vertical programme-led and programme-specific in seven Member States, and horizontally coordinated in eight. The general profiles of the laboratories were diagnostic or public health. Laboratories were operated as parastatals in two Member States. Laboratories, other than the parastatals, were predominantly funded from national budget allocations. These experienced perennial funding shortfalls suggesting inadequate budgetary support. The scope of services delivery and capabilities varied. Many national reference laboratories had limited capacities to provide urgently needed diagnostic services, particularly in the areas of HIV drug resistance diagnosis, drug sensitivity testing for second-line TB drugs, provision of quality assurance services, nationwide surveillance of disease hotspots, and attending to the training needs for the personnel. Quantitative and qualitative human resources challenges were observed across the Member States. The quality assurance practices, information management systems, health and safety practices and the infection control measures varied considerably and generally left room for improvement.

National reference laboratories in Member States have inadequacies that are likely to compromise service provision in support of communicable disease control efforts. Areas of weakness include the lack of policy guidelines, inadequate coordination mechanisms and inadequate allocation of resources. The existing laboratories provide either diagnostic or public health services, whereas both are required. There is an urgent need to strengthen the laboratories in order to enhance diagnostic and public health capabilities. Capacity strengthening should be guided by laboratory policies and strategic implementation plans. This intervention would be assisted by a common definition of the roles, functions, staffing complements and desirable capabilities of national reference laboratories. Human resource deficits should be addressed with the development of laboratory human resource policies and strategic implementation plans. This should be complemented by the strengthening of training facilities and proactive efforts at staff retention within SADC Member States. Most of the shortcomings of the laboratories could be addressed if adequate financial resources were available.

The consensus-building workshop recommended that 7-10% of national health budgets be allocated to laboratory services. It was noted with concern that only three Member State national laboratories had the capacity to diagnose HIV drug resistance and only two were capable of diagnosing extensively multidrug-resistant (XDR) TB. The diagnosis of resistance to anti-malarial was only conducted at research levels. It is recommended that this gap should be filled in the short-term by the establishment of one or more supranational reference laboratories. Some gaps, however, cannot readily be filled by national reference laboratories. They include the augmentation of quality management systems, and the development of human resource bases and information management systems. Ideally, those should be addressed by regional centres of excellence with a focussed mandate on the development of these areas. The strengthening of these systems at national reference laboratories should be prioritised and cascaded to lower-level laboratories.

1. INTRODUCTION

The 15 Member States of the SADC collectively account for a high percentage of people with HIV & AIDS, TB, Malaria and a host of neglected diseases, including schistosomiasis, onchocercosis, and trypanosomiasis. The challenges facing Member States include the increasing incidence of communicable diseases, and the emergence of multidrug-resistant (MDR) and XDR-TB, as well as drug-resistant HIV. With respect to Malaria, there is increasing resistance to erstwhile first-line medicines. Addressing these challenges requires laboratory support. However the capacity of laboratories has hitherto been perceived as generally weak, hindering provision of care and support.

Whereas SADC Member States account for a mere 5% of the world population, the region accounts for 36% of the global HIV & AIDS burden. The same disparities apply to TB. In 2007 in the SADC region, almost 750 000 people were diagnosed with TB – an average notification rate of 516 per 100 000 population, which is almost almost four times higher than the world average of 139 per 100 000 for the same year. SADC Member States also have the highest Malaria prevalence and morbidity in the world.

These diseases occur against a background of limited human and financial resources, and related inadequacies in infrastructure. The diseases are depleting human resources and diverting scant financial resources from developmental efforts. Control of the three major communicable diseases depends on the existence of interdependent capacities to gather epidemiological surveillance data and diagnose persons presenting with infections. Concerns about the mitigation and control of these diseases have exercised the SADC Member States since the inception of the regional grouping. The morbidity and mortality due to these diseases has prompted Member States and international developmental partners, working with the technical assistance of WHO and other UN agencies, to put in place strategies for mitigation. In 1998, SADC Member States, in collaboration with their WHO-African Regional Office (AFRO) counterparts, called for the development of well-staffed and -equipped laboratory services as a first step in the management of communicable diseases.

SADC in 2004 ratified its *Protocol on Health*, which among things calls upon Member States to cooperate, harmonise and, where appropriate, standardise policies for the case definition for diseases, notification systems, and treatment and management of major communicable diseases, and to cooperate in the establishment of regional reference laboratories and in sharing technical expertise. (1)

Several policy framework and disease specific implementation plans have been developed and ratified since, among them:

- The Regional Indicative Strategic Development Framework, (2)
- The Strategic Framework for TB Control, including MDR/XDR, in SADC Region, 2007-2015, (3)
- The Emergency Response Plan, (4)
- The Malaria Elimination Framework, (5) and
- The SADC Malaria Strategic Plan. (6)

Ministers of Health from SADC Member States, meeting in Maputo in September 2006, also addressed the issue of communicable diseases (including MDR-TB and XDR-TB) and agreed on steps to tackle the problems in the region. Concerned about the effects of AIDS on populations, Member States declared AIDS an emergency during their Maseru Meeting *(the Maseru Declaration)*. In January 2008, the *Maputo Declaration* on strengthening laboratory systems was issued. (7) This was followed by a call for the development of laboratory policies, strategic planning, laboratory leadership, the development of public health capacity and quality assurance made during the 58th Session of WHO-AFRO held in Yaoundé, Cameroon, in 2008 with the participation of SADC Member States. The SADC agenda on communicable diseases complements regional African Union Abuja Targets (8) and the global Millennium Development Goals of the United Nations. (9)

All these initiatives recognise the centrality of laboratories in strategies to mitigate communicable diseases, which require information on the prevalence of the conditions, geographic distribution, routes of spread and populations at risk. The information which is gathered through public health surveillance by laboratories guides the establishment and spatial distribution of diagnostic services.

The management of these communicable diseases starts with a laboratory diagnosis, and the success of such strategies rests on the availability of accurate and quality assured diagnosis in adequately staffed and appropriately resourced laboratories that provide a safe working environment for the workers. Laboratory services are also central to the monitoring of treatment adherence, identifying the side-effects of otherwise useful medicines and validating the continued clinical usefulness of the medicines, and diagnostic and therapeutic innovations.

The laboratory services should be buttressed by an enabling policy framework and well-structured strategic implementation plans that allow access to competent national reference-level facilities. There is a virtuous interdependence between the capacity of laboratories to provide diagnostic data, policy formulation and resource allocation. They rely on the availability of disease incidence data. Despite their central importance, laboratory services appear to have lagged behind, however. Whereas every SADC Member State, for an example, for several decades has been training nurses, only a few are now beginning to set up laboratory technologist training facilities. This hampers the provision of diagnostic, care and support services for the Member States communities.

1.1 HIV & AIDS

All the pillars of HIV treatment, disease control and prevention rest on reliable laboratory derived data, yet this service is largely overlooked, poorly staffed and inadequately resourced.

Laboratory services play a central role in diagnosis and treatment monitoring of patients with HIV & AIDS. All the activities aimed at mitigating the condition rely primarily on laboratory confirmation of seropositivity. The early diagnosis of HIV infection is a key strategy for limiting further spread of the virus. It provides infected mothers with the option of seeking medication that can prevent transmission of HIV infection to their infants. For their children, dry blood spot diagnosis of infection in infancy can trigger early, life-prolonging treatment.

Adults can appropriately time the commencement of their treatment on the basis of laboratory data. The criteria for commencing antiretroviral therapy (ART) rely on evidence of CD4+ T lymphocyte attrition to gauge disease progression. Responses to treatment and detection of treatment failures are detected by evidence of decreasing CD4+ T lymphocyte numbers and increasing viral loads. The adverse side effects of drugs are diagnosed by measuring laboratory parameters. Laboratory services are essential for verifying the emergence of HIV drug resistance. The reduction of AIDS-related mortality among persons on ART requires the availability, accessibility and vigilant use of quality assured laboratory services to diagnose infection, monitor treatment and detect the emergence of drug resistance. This information guides policy and impacts on counselling services, prescribing practices, drug procurement policies, resource mobilisation and budgetary allocations. The totality of HIV & AIDS management therefore depends heavily on laboratory services.

1.2 Tuberculosis

Laboratories are critical in the diagnosis of tuberculosis. The laboratory services range from sputum smear examination in pulmonary TB, to the histological examination of solid tissues and lymph nodes in extra-pulmonary disease. A laboratory confirmation of TB infection triggers treatment and follow-up of the patient, case detection among immediate contacts and in the community. At population level, public health surveillance and case hospitalisation may reduce the risk of disease spreading locally and across borders. The success of TB treatment is judged by the conversion from smear or culture positivity to negativity. The pressing challenge in TB diagnosis is to detect and treat multidrug-resistant (MDR) or extensively multidrug-resistant (XDR) disease. XDR-TB (defined as multidrug-resistant TB that is also resistant to more than three of six major classes of second-line drugs) is a major threat to TB control programmes and a diagnostic challenge. XDR-TB cases now constitute around 2% of all MDR-TB cases.

MDR- and XDR-TB are detected with drug sensitivity testing in suitably equipped laboratories. The prompt and accurate diagnosis MDR- or XDR-TB allows for appropriate treatment, which can reduce morbidity and mortality, and which is cost-effective. The capacity of national reference laboratories to provide such services has been inadequately appraised. The readiness of Member States to address the challenges of these communicable therefore remained to be ascertained.

1.3 Malaria

The techniques used in the diagnosis of Malaria have not evolved as rapidly as for HIV and TB diagnosis. The mainstay of diagnosis remains blood film examination on appropriately prepared slides viewed by a trained technician. Clinical diagnoses are frequently used to prompt treatment, sometimes pending laboratory confirmation.

In line with the SADC Malaria Elimination Framework (6) and the SADC Malaria Strategic Plan (2007-2015) (7), and complemented by global initiatives such as the WHO Malaria Elimination Manual and the Global Malaria Programme (10), some Member States are now moving from control to pre-elimination phases of the Malaria elimination continuum. Others (Lesotho, Mauritius and Seychelles) are at the stage of prevention of re-introduction. Both phases require the verification of every diagnosis of Malaria, using laboratory tests. The tests should be conducted according to specific guidelines and in observance of acceptable quality assurance processes. Laboratory support is required for the confirmation of diagnosis monitoring of Malaria induced anaemia (haemoglobin).

A combination of disease surveillance supported by laboratory services has allowed for the documentation of chloroquine resistance, and informed a life-saving strategic shift from mono- to combination therapy in some Member States. The capacity of other Member States, faced with the same challenges, to utilise their national reference laboratories to support strategic disease management is hampered by the lack of appreciation of the capacities, strengths and weaknesses of the laboratory services.

One common denominator of the "big three" diseases – HIV & AIDS, TB and Malaria – afflicting SADC Member States is that they all require functional, adequately resourced, well-equipped and suitably staffed laboratories that are guided by coherent policies. This assessment sought to determine the capacity of Member States' national reference laboratories to provide those essential services.

2. PURPOSE OF THE REPORT

The purpose of the report is to provide a regional picture of the capacities of national reference laboratories to provide primary diagnosis and case management of the "big three" communicable diseases in the SADC Member States.

The report provides a detailed analysis of the range of services, the policy framework that guides the services, and the infrastructure, human resources, equipment and tests used in the detection, diagnosis and management of HIV & AIDS, TB and Malaria.

The report further assesses the capacity of national reference laboratories to provide disease surveillance and epidemiological information gathering, and highlights key challenges. It also provides guidance on ways to strengthen national reference laboratories. In addition, it explores options for regional collaboration to strengthen laboratory networks.

3. METHODOLOGY

The assessment was carried out using a combination of methodologies. These included a literature review, a site assessment visit during which competent officials assigned by Ministries of Health were interviewed and the laboratory sites inspected. Data was collected using assessment tools designed by the SADC (for TB) and by the South African Standards Association for the HIV & AIDS and Malaria laboratories.

The findings of the assessment were critiqued by a technical review panel consisting of representatives of Member States and technical cooperation partners. The revised draft was discussed at a consensus-building workshop comprising 13 participating Member States. Their inputs were incorporated in the report.

3.1 Site selection and visits

The report is based on field visits carried out in Member States between December 2008 and March 2009. The visits targeted national reference laboratories for HIV & AIDS, TB and Malaria, respectively. National reference laboratories were defined as the diagnostic facilities at the pinnacle of diagnostic pyramid within the Member States. Member States selected the facilities. Ministries of Health reported that they had no national reference laboratories for HIV & AIDS in three Member States and no relevant Malaria laboratories in five Member States. It was not possible to visit facilities in one Member State (Seychelles). A list of the facilities visited is attached as an Appendix.

3.2 Site visit protocol

On arrival in a Member State, the consultant reported to the Offices of the Permanent Secretary or to an earlier identified hosting official. The Ministry of Health was appraised of the terms of reference and purpose of the visit. A local schedule of the visits was prepared, officers were assigned to facilitate the mission and laboratories to be visited were identified. At the end of the visit a debriefing session was scheduled. The schedule of visits is attached as an Appendix.

3.3 Data collection methods and report review

The process of data collection and report review had four components: a background literature search, site assessment visits within Member States, a technical review by an ad hoc SADC technical committee and a review at a consultative consensus-building meeting attended by 13 Member States.

Background data was obtained through a desk review of relevant literature, SADC documents, and documents from international (WHO, STOP-TB, Roll Back Malaria) multilateral partners (CDC) and academic references.

National authorities in Member States identified national reference laboratories, which were then visited to gather information. Within Member States, data was obtained by using a combination of:

- Review of documents submitted by Member States;
- Key informant interviews. Key informants were identified by Member States and included officials of the Ministries of Health, representatives of HIV & AIDS, TB and

Malaria programmes, and cooperation partners. Laboratory personnel were consulted in all cases (see interviewees listed in Appendix 2);

- Laboratory site assessment visits and interviews with national reference laboratory managers and staff in 14 Member States;
- The completion of standard assessment tools using the SADC assessment tool for TB and the SANAS assessment tool for HIV and general laboratory management.

An *ad hoc* technical review meeting comprising representatives of three Member States and technical cooperation partners (with CDC and WHO input) was convened to review the report. The input of the review meeting was incorporated. The report was reviewed at a consensus-building workshop, where 13 Member States were represented. The meeting provided useful information that verified the assessment mission findings and provided supplementary information which otherwise may not have been available.

3.4 Limitations of the assessment

The assessment encountered some limitations. The first was that one Member State could not be visited due to factors beyond the control of the consultancy. Secondly, site assessment was restricted to facilities defined by Member States as national reference laboratories. The information obtained and reported depended on the knowledge base of the informants delegated by the Member States to chaperone the consultants. Policy documents were not readily available and the familiarity of some interviewees with the content of those documents was limited. Relevant laboratories in some Member States were not visited due to in-country logistics. Any gaps resulting from these limitations were filled based on information provided by participants at the consensus-building meeting.

4. GENERAL ASSESSMENT FINDINGS

The assessment of the national reference laboratories was guided by the identification of certain key component factors that contribute to effective service delivery. These were systematically observed in each of the facilities visited. National HIV reference laboratory facilities were visited in 11 Member States, national TB reference laboratories were visited in 14 Member States, and Malaria diagnostic facilities were assessed in eight Member States. Not all Member States had facilities designated as Malaria national reference laboratories. Ministry of Health officials selected the sites. The key areas of assessment included generic issues that would affect laboratories regardless of their specialties (such as policy), as well as issues that specifically affected the capacity to provide diagnosis and treatment monitoring for HIV & AIDS, TB and Malaria.

The following areas of assessment were assessed in all Member States visited:

- Policies regulating laboratory operations in the country,
- Human resource capacity (personnel numbers, qualifications),
- Models of existing laboratories,
- Structure, operations and management of laboratories,
- The financing status of the laboratories,
- State of the physical infrastructure,
- Equipment, reagents and consumables,
- Quality assurance,
- Laboratory information management,
- Continuing professional education, operational research and training, capacity,
- Health and safety including infection control,
- Disease-specific tests.

4.1 Policies regulating laboratory operations in the Member States

An appraisal of the programmes of action adopted by Member States to ensure the delivery of laboratory services as contained in policy documents were the starting point for the assessment process within Member States. The assessment of policies regulating laboratory operations paid attention to the availability and scope of the policies, the allocation of responsibilities for the administration of laboratories, and the existence of strategic implementation mechanisms.

4.1.1 Existence of policies

Six Member States had written laboratory policy documents, while the policy was in draft form in one Member State. There were no written policy documents in five Member States.

The operations of laboratories were defined and guided by the operations of parastatal organisations in two Member States (Namibia and South Africa).

The documents made available for the appreciation of the intentions of Member States in establishing national reference laboratories included Acts of Parliament (Democratic Republic of Congo and Namibia), laboratory sections of general staffing norms and, in a limited number of cases, laboratory policy documents and laboratory strategic operational or business plans. In one Member State (Zimbabwe), quality systems and information management policies were also made available.

4.1.2 Administration and coordination of laboratories

The coordination of laboratory services was reviewed. In five of the Member States Directorates of Laboratory Services represented laboratories at the Ministries of Health.

There was no formal representation of laboratory at Ministry of Health level in five Member States, while in five others representation was nominal or functionally ineffective.

Directorates of laboratory services, when available, were ready custodians of pertinent documentation and were involved in the development or review of laboratory policies, strategic implementation plans and business plans.

The scope of the policy documents included recommendations of human resource requirements at various levels of the laboratory pyramid, from health centres to national reference laboratories and mechanisms for the coordination, forecasting and procurement of laboratory equipment, reagents and consumables.

In Member States where national-level laboratory representation was weak, inadequate or absent, the availability and access to laboratory-related documentation was a challenge.

With one exception, it was difficult to gain access to such documentation in Member States without functional national-level laboratory representation. Generally, these documents tended to be outdated and infrequently reflected the observations made during site visits.

Where there was no effective national-level laboratory representation, policies tended to be guided by the specialised communicable diseases programmes (HIV & AIDS, TB or Malaria). In this setting, disease- or programme-specific laboratories had been set up.

The mechanisms for national-level oversight were poorly defined, weak or absent. Strategic and operational plans were devised or implemented with a Programme specific bias.

Table 4.1: Availability of laboratory policy documents in Member States

Member State	Does a laboratory policy exist?
Angola	Policy in place
Botswana	National health policy in place; general laboratory policy drafted; laboratory standard in place; Laboratory Act soon to be drafted.
DRC	Policy in place and available.
Lesotho	Laboratory policy in place
Madagascar	No written policy document
Malawi	Laboratory policy in place
Mauritius	No written policy document
Mozambique	No written policy document
Namibia	Laboratory services provided by a parastatal institution (National Institute of Pathology) established through an Act of Parliament.
Seychelles	No written policy document; guided by public health policy statement.
South Africa	National Policy is to operate laboratory services as a parastatal
Swaziland	Draft policy in place: five-year strategic plan in place.
Tanzania	No specific laboratory policy; national health policy with disease- specific guidelines used; standards for laboratories in place (2003); strategic plan (2009-2012) in place.
Zambia	Policy available; programme-specific implementation plan guidelines under review.
Zimbabwe	National laboratory policy in place; national strategic plan in place; quality management plan in place

Note: Information verified by participants in the consensus-building workshop, Gaborone, Botswana, August 4-6, 2009.

Non-programme aspects of laboratory services (particularly histopathology, clinical chemistry and haematology) were relatively neglected. Besides South Africa, fewer than ten histopathologists were working in national reference laboratory service. Three Member States did not have a single histopathologist in the public sector.

General or disease-specific strategic implementation plans were available in five Member States. Business plans were operational in Member States that had opted to run laboratories as parastatals. The absence of policy and strategic plans limits the capacity of laboratories to support communicable diseases control measures. Two interrelated factors contribute to this situation: the coordination of laboratory services, and policy formulation and implementation.

Member States where laboratories were coordinated through identifiable structures (such as the Directorates of Laboratory Services) tended to have comprehensive guiding policy documents and strategic implementation plans. In the absence of such coordination, policies were absent or fragmented along disease- or programme-specific faultlines. It is important that mechanisms for the coordination of laboratory services be implemented. Laboratory coordinating structures should establish policy guidelines and provide mechanisms for policy implementation through time-limited strategic implementation plans.

4.2 Human resources of laboratories

The availability of human resources is the key determinant of laboratory capacity. The numbers and skills base of the personnel define the scope of operations and determine the composition and complexity of laboratory equipment.

The numbers of laboratory personnel vary with the size and purpose of the facility. The human resources assessment therefore considered adequacy within the context of the fulfilment of existing staffing norms. The staffing norms, in turn, were reviewed in the context of existing workloads. In the case of national reference laboratories for TB, WHO recommendations that technicians or technologists should process some 30 sputum samples per day were used as a basis for ascertaining human resource adequacy. The qualitative assessment of human resources focused on the

adequacy of the formal training, skills and experience of laboratory personnel to provide routine services, and the potential to undertake the more sophisticated functions expected of national reference laboratories.

Only three Member States were satisfied with technical personnel staffing levels in their national reference laboratories (Angola, Democratic Republic of Congo and Mauritius) (Table 4.2). However, those Member States reported inadequate staffing in peripheral laboratories. The remaining Member States reported quantitative inadequacies in laboratory human resources. Most Member States had unfilled vacancies.

The number of people working in laboratories does not match the workload, which is high in most Member States. In the case of TB, where standard norms exist, twice to thrice the recommended number of sputum samples is processed by personnel due to staff shortages. Increasing workloads have not been matched with upward reviews of staffing norms or increased recruitment.

Several factors contribute to this state of affairs, including inadequate training capacity, an inability to retain staff, and rigid or outdated staffing norms that have not been adapted to increasing workload (particularly in HIV and TB diagnosis). Retention challenges were associated with unfavourable remuneration. The latter factors, along with absent or poorly defined career progression pathways, encouraged "brain drains". Staff often depart to nongovernmental organisations (NGOs) and the private sector, or seek employment abroad in countries were remuneration packages are attractive. Botswana, Lesotho, Namibia, South Africa and Swaziland also benefited from such migration.

In summary, the following factors contribute to quantitative human resource limitations:

- Inadequate and outdated staffing norms,
- Inadequate estimation of staff requirements and non-recruitment,
- Absense of human resource policy or audit to anticipate laboratory human resources requirements,
- Unavailability of candidates for available positions,
- Poorly-defined career development pathways negatively affecting staff retention,
- Non-inclusion of critical support staff such as data capture clerks, stores management, information technology system operators, and instrument technicians in the staffing norms, and
- Lack of a training pipeline due to the absence of local training facilities.

There are widespread qualitative deficits, as well.

The majority of the laboratories were staffed by technician-level personnel. There were few structured pathways for skills enhancement through training in new diagnostic techniques (for example, liquid culture and polymerase chain reaction). Very few laboratory staff held university-level degrees, although all the staff in one Member State (Zimbabwe) national reference laboratory for HIV were university degree holders. Only four Member States' national reference laboratories had PhD level scientists (Democratic Republic of Congo, Lesotho, Madagascar and South Africa) involved in routine laboratory service provision. The numbers of non-technical laboratory staff (including administrative staff, logisticians, information technology, surveillance officers and training officers) were limited to laboratories that had a public health profile. Those staff members were not included in the staffing norms of Member States with diagnostic profile laboratories.

The major challenges associated with laboratory service delivery were recruitment and retention, inadequate staffing norms and limited access to post basic training. Efforts to address these challenges were hampered by the absence of human resource policies and limited numbers of training facilities (with low intakes and generally devoid of post-basic training capabilities).

The implications of qualitative human resource deficits were not always fully appreciated and therefore infrequently addressed. With the exception of the Democratic Republic of Congo, Madagascar, Mauritius and South Africa, there was no indication that the human resources available in Member States' academic or private sectors were being harnessed to augment the services of the public sector laboratories. Government and academic laboratory services ran parallel to one other. When synergistic activity and academic input was present, however, the quality of services and operational research improved. Ways must be found to to harmonise these relationships and leverage complementarities and synergies.

4.2.1 Training of laboratory personnel

Facilities for training technicians or technologists existed in 12 of 14 Member States. Basic training of laboratory scientists (BSc.-level) was well-established in three of them and recently began in another three. Post-basic training was offered in three Member States

(Democratic Republic of Congo, South Africa and Zimbabwe). Small numbers of laboratory personnel were being trained outside their countries (in the region or overseas). Despite these efforts the numbers of trainees still do not adequately cater for current laboratory needs.

4.2.2 Continuing professional education

Continuing professional education is the cornerstone of staff development within the laboratory systems. This enables strengthening of the knowledge base and skills of personnel who are required to use increasingly complex instruments and diagnostic methods.

Organised continuing professional education within the Member States laboratories was limited. Policies were absent, and motivation was limited. The registration requirements for laboratory technicians, technologists and scientists only stipulated the need for continuing professional education in one Member State (Zimbabwe). Facilities conducive for continuing professional education including seminar rooms, libraries were adequate in four Member States (Angola, Botswana, Democratic Republic of Congo, and United Republic of Tanzania). However, the range of reference books available was limited and the texts were old. There was minimum computerisation, making even basic e-mail access a challenge. Access to web-based internet sites was limited or non-existent. Organised mentorship of staff, including in-house training, was infrequent.

The absence of continuing professional education in a setting where diagnostic techniques are rapidly evolving and human resources are continually depleted for various reasons is not optimal and should be addressed. Policies supporting continuing professional education should be considered.

Table 4.2: Staffing levels and challenges in Member States' national reference laboratories

Member State	Staffing Level	Training Capability	Major Challenges
Angola	Adequate	Local diploma and university programmes	Recruitment and retention
Botswana	Inadequate	Diploma and new university programme	Recruitment and retention
DRC	Inadequate in regional labs	Local diploma and degree training programmes	Post-basic training
Lesotho	Inadequate	Diploma-level programme	Retention
Madagascar	Inadequate	Local training	Recruitment and retention
Malawi	Inadequate	Diploma and university programmes	Retention
Mauritius	Inadequate	No local training programme	Recruitment and retention
Mozambique	Inadequate	No local training programme	Recruitment and retention
Namibia	Inadequate	New degree programme	Recruitment and retention
Seychelles	Inadequate	One 3-year Diploma in Medical Laboratory Technology course	Recruitment and retention
South Africa	Services run as parastatal	No specific national lab training programme, in-service training for technikon graduates	Recruitment and retention
Tanzania	Inadequate (less than 20% staffing)	Lab training schools for laboratory assistants, diploma (5), university degree (2)	Recruitment and retention
Swaziland	Inadequate	No training schools	Inadequate establishment, recruitment and retention
Zambia	Inadequate staffing levels	Four training institutions	Retention challenges
Zimbabwe	Inadequate	University training, programme lab technician training resumed	Retention

4.3 Models of existing laboratories

The delivery of laboratory services is influenced by the type of model followed in a Member State. The purpose, ownership, financing models and testing profiles were assessed on the basis of founding documents and observations of laboratory operations.

A review of the documentation (when available) and observation of the work profile showed that laboratories were founded to fulfil two broad objectives: diagnostic and public health.

Diagnostic-oriented national reference laboratories were geared to support clinical units and hospitals. Public health-oriented ones were geared to support Ministries of Health with epidemiological and surveillance data. A hybrid of the two functions was observed in some Member States. Laboratories with a diagnostic profile tended to be located adjacent to or within national reference hospitals.

These performed a wide range of mainly routine tests. Typically, there were high sample volumes. The laboratories were staffed mainly by technical personnel (technicians or technologists), in line with the expectations and work profile.

Table 4.3: Staffing levels in TB national reference laboratories in SADC Member States

	Angola	*Botswana*	*DR Congo*	*Lesotho*	*Madagascar*	*Malawi*	*Mauritius*	*Mozambique*	*Namibia*	*Seychelles*	*South Africa NHLS*	*South Africa MRC*	*Swaziland*	*Tanzania*	*Zambia*	*Zimbabwe*
MD			*1*		*2*						+				*1*	
PhD				*1*	*1*						+	*1*				
BSc/.Msc. scientists	*1*	*4*	*6*	*1*	*1*			*1*			+	*4*	*1*		*3*	
Msc.							*1*				+				*1*	
Senior Technologists	*5*	*6*	*4*	*2*	*4*	*3*	*3*	*2*			+	*5*	*1*			*1*
Technologists				*3*	*2*	*3*	*2*		*2*		+	*1*		*8*	*4*	*2*
Technicians								*2*	*3*		+	*4*	*2*	*5*		
Laboratory Assistants									*2*		+					
Microscopists				*2*				*2*	*0*		+					
Data manager/IT											+	*1*				
Data capture clerk											+	*1*				*1*
Finance officer											+	*1*				
Stores man			*1*								+	*1*				
Safety officer						*1*					+	*2*				
Admin supports staff								*1*			+	*2*				*2*
Nursing staff			*2*								+					
Other (driver etc)				*2*							+	*3*	*1*		*5*	
TOTAL	**6**	**13**	**13**	**10**	**12**	**6**	**6**	**8**	**8**		**+**	**28**	**5**	**13**	**14**	**6**

Laboratories with a preponderantly public health profile tended to be self-contained structures with reduced and specialised test repertoires. They were geared to conduct additional activities, including surveillance, data collection and participated in national disease surveys. The staff included more scientists (BSc. or MSc.), as well as personnel reflecting the additional activities of the laboratory (logisticians, Information technologists, surveillance officers and training officers). The laboratories at the National Institute for Public Health (Angola), the National Institute for Biomedical Research (Democratic Republic of Congo), the Pasteur Institute (Madagascar), the College of Health Sciences Unit (Malawi), the Medical Research Council laboratories (South Africa), and the National Microbiology Reference Laboratory (Zimbabwe) fell in the latter category. A public health laboratory was being established in Botswana. The expectations and resulting operational profile of the two laboratory categories differed, as did the staffing complement.

In the majority of Members States, national laboratory facilities were state-owned and state-run. In two Member States (Namibia and South Africa), previously state-owned laboratory networks were run as parastatals. State-owned and -run laboratories were encumbered with the general challenges facing Government institutions.

These included staff shortages, inadequate budgets, poorly structured financial accounting systems and cumbersome information management methods. The parastatal laboratories had apparently robust financial management and had the latitude to generate and allocate financial resources autonomously, thus obviating the bureaucratic delays that characterise larger institutions. Their business models ensured increased accountability and the upgrading of information management. Staff shortages were minimised through flexible remuneration policies, making them attractive for inward personnel migration.

The two broad laboratory profiles (diagnostic and public health) serve different but complementary functions. The capacity to provide basic functions was variable and was to a large extent influenced by the financial resources available.

The operational models were state-owned and state-run, and state-owned but run as a parastatal. Each of the approaches has advantages and disadvantages, a careful appraisal of which would be useful for formulating policy guidelines to strengthen laboratory services.

4.4 Laboratory organisation and structure

The structure of laboratories affects their capacity to render services in HIV & AIDS, TB and Malaria programmes.

There are two broad laboratory models: vertical, disease-centred ones, and horizontally-integrated versions. Vertically-structured laboratories are disease-specific (HIV, TB or Malaria laboratories). Horizontally-integrated laboratories cover the spectrum of laboratory services, including communicable disease functions. Each approach has advantages and disadvantages. In SADC Member States, laboratory services for communicable diseases are structured along either of those lines (Table 4.4). Non-programme specific laboratory disciplines, on the other hand, are integrated.

Seven Member States have vertical structures, while the remainder have horizontally-integrated ones. But the distinctions are not rigid. The merits and demerits of the two systems were debated during the consensus-building workshop, with the vertical model considered to be more likely to attract programmeme-specific resources and provide sustainable services. But it was also associated with potential inequities in funding, a potential duplication of scant human and financial resources and a neglect of non-programmeme specific laboratory disciplines. The model poses challenges in coordination and supervision, and is associated with duplication of management tasks and resources.

The integrated model, on the other hand, was seen to maximise resources and allow for cost-sharing among different programmes through pooling of donor funding for laboratory services. The model allowed integrated surveillance, monitoring and evaluation and joint planning, and was more likely to benefit non-programme disciplines through “spillover” effects. One of the disadvantages cited was that integration was akin to putting all one’s eggs in one basket, with the possible collapse of a laboratory simultaneously affecting all programmes.

A model that capitalises on the advantages of the vertical approach linked to disease-specific strategic plans and then subsequently integrated in line with the availability of funding was also discussed. This would allow for harmonisation and alignment in line with the Maputo Declaration. (7) Overall, the consensus-building workshop favoured an integrated approach led by a department for laboratories within the Ministries of Health.

Table 4.4: Organisation of laboratories for communicable diseases in Member States

Member State	*Laboratory organisation*
Angola	Integrated
Botswana	Vertical
Democratic Republic of Congo	Vertical
Lesotho	Vertical
Madagascar	Vertical
Malawi	Vertical
Mauritius	Centralised and integrated
Mozambique	Vertical
Namibia	Integrated
Seychelles	Centralised HIV and TB laboratory
South Africa	Integrated
Swaziland	Integrated
Tanzania	Vertical
Zambia	Vertical
Zimbabwe	Integrated

4.5 State of physical infrastructure

The assessment of the laboratory physical infrastructure and working environment included the integrity of the laboratory building, the material from which the building had been constructed (concrete, semi-concrete, wood, prefabricated, old, renovated or new structure), the adequacy of ventilation and lighting, the availability of water, electricity and relevant back-up services. Additional observations were made of the procedures for pathological waste disposal services, fire safety precautions, the controlled access to designated laboratory areas, the designation of eating areas, and the availability of sanitary facilities for staff and patients (Tables 4.5 & 4.6).

In many cases, HIV and Malaria diagnosis was carried out within the same structures, therefore the infrastructure of the laboratories was assessed together. TB laboratories were self-contained and were assessed separately.

With few exceptions, laboratory buildings were architecturally sound, allowing for adequate ventilation and natural light. There were new laboratory buildings in four Member States, durable older buildings in five, three Member States had buildings undergoing renovation, and in four Member States TB laboratories were found to be inadequate in size, structural integrity and architectural design respectively. Those require replacement. There were variable country-specific inadequacies in water and electricity supply. Three Member States laboratories had controlled access security features. The provision of eating areas for staff was absent in two Member State laboratories.

Floor plans and working surface locations were variable, but broadly functional. Laboratory benches were, with one exception, made of satisfactory impervious material. One laboratory had significant cluttering which posed a health hazard.

Air conditioning was not functioning in half the laboratories and the resulting overheating caused the malfunction of temperature-sensitive pieces of equipment. Fire safety was neglected in most of the laboratories, with emergency fire exits and appropriate extinguishers limited. The servicing arrangements for fire fighting equipment were weak.

Table 4.5: The state of TB laboratory physical infrastructure in 14 Member States

New buildings	South Africa (NHLS), Botswana, Democratic Republic of Congo, Swaziland
Refurbished	Madagascar, Namibia
Need minor renovation	Angola, Tanzania, Zimbabwe
Inadequate	Lesotho, Malawi, Mauritius, Mozambique, Zambia
Old, adequate	South Africa (MRC)

Table 4.6: HIV laboratory physical infrastructure in 12 Member States

New Buildings	Botswana, Swaziland, Tanzania
Refurbished	Madagascar, Malawi, Namibia,
Need minor renovation	Angola, Democratic Republic of Congo, Mauritius, Zambia,
Inadequate	
Old adequate	South Africa, Zimbabwe

Figure 4.1: New laboratory complex, Mbabane, Swaziland

Figure 4.2: New laboratory complex, Dar es Salaam, Tanzania

4.6 Equipment used in national reference laboratories

The availability and state of servicing of laboratory equipment is essential for the provision of laboratory services.

The methods of equipment acquisition affect servicing, maintenance and replacement arrangements. This assessment examined the modalities of equipment acquisition in order to determine whether these influenced the sustained capacity to provide basic diagnostic services.

The routes of equipment acquisition in Member States included purchases secured with the support of Global Fund support, the US President's Emergency Plan for AIDS Relief (PEPFAR), The Clinton Foundation, the CDC and other bilateral partners, including the Foundation for Innovative New Diagnostics (FIND). Some of the equipment was donated. In all cases, Member States were responsible for servicing, maintenance, disposal and replacement, in addition to sourcing reagents and consumables.

The useful life of most pieces of laboratory equipment is approximately 10 years. The costs of keeping the equipment operational, replacing or disposing is high, leading to the cluttering of laboratories with equipment that may be obsolete or out of production due to costly or unavailable spare parts and reagents.

The donation of equipment is usually intended to fill an identified void. Equipment may be donated by research projects that are winding up their operations. Equipment donation is emotive: often a well-wisher mobilises the home community to purchase equipment, and transport them to the recipient country.

The recipient is obliged to gratefully accept, but may be unable to use the machinery because of incompatibilities (for example, electricity voltage) insufficient expertise, lack of local availability of reagents or the absence of equipment engineering expertise.

4.6.1 HIV laboratory equipment

Equipment for the diagnosis of HIV and monitoring of AIDS treatment was available in all Member States national reference laboratories.

Consumables for rapid HIV testing were available and predominantly donor supported. Enzyme-linked immunosorbent assay (ELISA) equipment was available in a majority of Member States, but was not routinely used due to local testing algorithm preferences.

Five Member States had functional Western blot equipment, which was routinely used in two Member States, both with low HIV prevalence.

Only one national reference laboratory did not have equipment for lymphocyte subset enumeration (CD4). The instruments used are listed in Table 4.7.

Occasionally, available equipment was not routinely used due to the prohibitive costs of consumables, equipment servicing and maintenance. Polymerase chain reaction equipment used for viral load measurement was available in 11 Member State national reference laboratories.

Classical and real-time polymerase chain reaction equipment was available in four Member States' national reference laboratories.

The rationale for such dual acquisitions was unclear and the expertise in use was limited. There was evidence of expensive duplication of equipment acquisition, following programme or donor dictates rather than laboratory needs.

Equipment for HIV-DNA sequencing was available in five Member States and was routinely used in two others, with use impending in another Member State. The equipment was being used mainly for surveillance with diagnostics being a smaller component.

This equipment for HIV diagnosis and treatment monitoring was generally new and in good working condition; in some Member States, the equipment was still boxed. The modalities for longer-term servicing and maintenance were inadequately addressed and posed potential risks for service interruptions.

Figure 4.3: HIV Laboratory equipment in Lilongwe, Malawi

Figure 4.4: Equipment in the general laboratory where HIV work is conducted in Mbabane, Swazilanda

Figure 4.5: HIV Genotyping: A 3130 Genetic Analyser at the National Microbiology Reference Laboratory, Harare, Zimbabwe

Table 4.7: Equipment used for the enumeration of CD4+ T lymphocyte numbers in Member States

	Angola	*Botswana*	*Democratic Republic of Congo*	*Lesotho*	*Madagascar*	*Mauritius*	*Malawi*	*Mozambique*	*Namibia*	*South Africa*	*Swaziland*	*Tanzania*	*Zambia*	*Zimbabwe*
BD-FACS Cali bur	*1*	*3*	*1*	*-*	*1*		*0*	*-*		*2*	*1*	*3*	*1*	*1*
BD FACScan														
BD-FACScount			*1*		*1*	*1*	*1*	*1*			*1*	*2*	*1*	*1*
Beckman-Coulter EPICS							*0*		*4*	*4*	*2*			
Partec Cyflow	*1*						*1*							

4.6.2 TB laboratory equipment

The availability, functional status and servicing procedures of TB laboratory equipment were assessed. The types and quantities of pieces of equipment are listed in Table 4.8.

Microscopy remains the mainstay of tuberculosis diagnosis. However, microscopes were inadequate in number, with 30-70% of microscopes in Member States inventories not functional. Microscope service engineers were nationally available in three Member States (Botswana, Zambia and Zimbabwe). Member States lacking national servicing capacity had to rely on external technicians for microscope servicing, which brought increased costs and delays that disrupted service delivery.

TB culture was predominantly the solid media. Each of the laboratories had basic, sometimes dated essential equipment. Equipment for liquid media culture and drug-sensitivity testing (Mycobacteria Growth Indicator Tube, or MGIT) was available in seven Member States and operational in four. Challenges with liquid media systems included lack of personnel training and the high costs of consumables. Where line probe assays were performed, the requisite equipment was available, and generally was in good working condition (probably due to the relative novelty of the technique). Biological safety cabinets (predominantly Class II) were widely available. Some were fitted with germicidal ultraviolet (UV) lights. Half the Member States outsourced the servicing of biosafety cabins to a specialised company which provided comprehensive servicing in six monthly cycles. There was inconsistent use of available biosafety cabins in some laboratories.

The availability of reagents and consumables including sample containers, stains, inoculation sundries and media posed challenges in six of the Member States.

Shortages were due to a variety of factors, including the exhaustion of allocated budgets, high cost, the unavailability of a supplier within the country, delayed ordering and the age of the equipment (too old, or the manufacturer had stopped producing reagents).

Table 4.8: Functional pieces of equipment in national TB reference laboratories, by Member State

	Autoclaves	Biological safety cabinets	Germicidal UV lights	Centrifuges	Inspissators	Incubators,	Light microscopes,	Fluorescent Microscopes	LED microscopes	Refrigerators 2-8°C,	Freezers -20	Freezers 0 to -80°C,	MGIT manual	MIGT 960	BACTEC	PCR gene probe assay	Weighting scales	pH meters	Water baths	liquid nitrogen	pH indicator strips
Angola	1	5	+	4	1	2	2	-	-	5	1	1		-	-		1	1	2		
Botswana	4	3	+	4	-2	6	4	2	-	+	+	+		4	-	+	1	+	+	+	?
Namibia	+	3		3	0	+	3	2		+		1		4	+	+	+	0	+		+
South Africa (MRC)	+	4	+	+		+	+	+		+	+	+		2		+		+	+	+	
South Africa (NHLS)	+	+	+	+	+	+	+	+		+	+	+		28		+	+	+	+	+	
DRC		+				+	+	-	-	+	+		-	-	-	+/-	+		+	-	-
Tanzania	2	3	-	2	1	1	2	-	-	3	3		-	-	-	-	2	-	1	-	-
Lesotho	+	5		2		2	3	1	1	+				1		+					
Madagascar	3	3	5	1	1	3	4	4	-	+	1	1	-	-	-		3	1			
Mozambique	2	2	-	2	1	2	2	1	-	2	1	-	-	-	-	-	1	1	2	-	1
Swaziland	1	2	+	2	-	1	2	-	-	+	+		-	1	-	+	-	-	-	-	-
Zambia	3	2	-	2	2	2	6	+	-	3		1	1	1	-	-	1	2	2		
Malawi	4	3	+	2	1	2	2	1		3	1	1	-	-	-	-	1	1	1	-	-
Mauritius	1	(1)	-	(1)	1	(1)	2	(1)	-	1	-	-	-	-	-	-	-	1	1	-	1
Zimbabwe	2	3	-	2	1	1	1	-	-	2	1	-	-	-	-	-	2	2	2	-	-

Note: The figures in brackets indicate equipment that was in use but needed attention. The [+] indicates adequate quantities. The best-equipped TB laboratory was the NHLS laboratory South Africa.

4.6.3 Malaria diagnostic equipment

The equipment required for the diagnosis of Malaria remains basic. Microscope slides and appropriate stains (usually Giemsa, but also Field A and Field B stains) are used. Basic light microscopes are used and there has been little variation in these. Recently, acrydine orange microscopes were introduced, but they have not found widespread use.

Other requirements are a staining trough, a drying rack, a timer, hand tally counters and slide driers. Molecular techniques hold a potential in the diagnosis of drug-resistant strains of Malaria, but are still largely limited to experimental settings. The location of Malaria microscopy services within larger laboratory complexes means that pre-testing (reception, recording and logging) and some post-testing logistics (result dispatching) are shared. Improvement in these services will need to be holistic and not Malaria-specific.

4.6.4 Servicing and maintenance of laboratory equipment

Laboratories depend on the availability and use of functional and serviced pieces of equipment. The predominant practice in Member States laboratories is that equipment-servicing is carried out by biomedical engineers who also service hospital equipment. The expertise of these teams is limited by the complexity of modern laboratory equipment. Their availability is limited by the low staff numbers and the high work loads that usually covers the whole country.

Additionally, the provision of servicing and maintenance of equipment is hamstrung by warranties that dictate servicing by appropriately qualified employed service engineers (usually employed by the manufacturer or supplier). The use of non-designated service engineers invalidates warranties. Current servicing modalities are inadequate. Institutions that train biomedical engineers were reported in one Member State (Malawi), though there may be more. The competencies imparted are general and not instrument-specific, which rules out the employment of these graduates in the servicing of newer and more complicated equipment in laboratory inventories.

The logistics of instrument acquisition do not always incorporate service contracts. The funding for servicing machines outside service contracts is high and often unsustainable. Consequently, when there equipment malfunctions, services are paralysed. A private sector company offered the servicing of pipettes in Zimbabwe, but the servicing of microscopes was unavailable in a majority of Member States.

Biosafety cabins were serviced by a South African-based company that visited participating laboratories bi-annually to offer pre-emptive maintenance servicing and repairs. The company visited some 10 Member States.

4.7 Financing of laboratory services

Information regarding the financing of laboratory services was not readily available. This was partly because the laboratory budget is controlled externally and informants were not well- versed in the details.

The laboratory assessment found that the exhaustion of allocated budgets was a common experience and that funding for routine laboratory operations did not last the financial year. This affected the availability of reagents and consumables, and resulted in the halting of testing until the next financial year and budget. This indicates that the budgets are inadequate. The two Member States that did not report such concerns each ran laboratories as parastatal businesses.

Laboratory services are the costliest component of HIV and AIDS, TB and (to a lesser extent) Malaria management. The costs are not always recognised, partly because of limited representation of laboratory expertise in decision-making fora. Some general, testing and non-testing costs are summarised in Table 4.9. There seems to be little appreciation and strategic analysis of the overall costs of providing quality laboratory services. This is evident in the avoidable shortages and suboptimal service provision. Several factors contribute to this state of affairs, including:

- The budget was underestimated for various reasons,
- Allocated budgets were inadequate for the needs of the laboratories,
- The services increased beyond anticipated levels,
- Inflationary pressures eroded an otherwise adequate budget, and
- Inadvertent wastage or deliberate leakage of consumables may have contributed.

Table 4.9: Some costs associated with the provision of laboratory services

Laboratory costs
General
Human resources (administrative, technical, non-professional)
Computers, printers, toners, paper
Internet, telephone, water and electricity bills
Transport
Insurance
Testing costs
Procurement of tests, consumables and reagents for HIV, TB and Malaria diagnosis
Monitoring (CD4 count, viral loads, clinical chemistry, haematology)
Exclusion of co-morbid and opportunistic infections
Drug resistance surveillance and case monitoring
Logistics of test referral nationally or internationally
Non-testing costs
Maintenance of infrastructure (buildings, furniture, lighting, air-conditioning, electricity, water, security)
Procurement and laundry of personal protective clothing
Provision and maintenance of back-up generators and water storage
Employment of requisite highly qualified personnel,
Servicing and maintenance of equipment,
Logistics for delivery and storage of consumables
Pre-analysis and post analysis logistics (staff, equipment, stationary)
Quality assurance costs, national and external
Staff welfare

4.8 Information management in national reference laboratories

The systems for data collection, management and use were generally not guided by policy. The usefulness of any data relies on the tools available for collection.

Request forms are the key tools in laboratory setting, but these were not standardised in and between Member States laboratories, and request forms were rarely completed entirely. In the case of TB, the ages of patients, their locations and clinical data indicating whether a sputum sample was from a newly-presenting, currently-treated or recrudescent patient were omitted. The completion of Standardised WHO TB Registers was thereby compromised and the opportunity to centrally collect data was lost.

Systems of pre-analysis information management were variable and broadly inadequate. With few exceptions, there were no functional information management systems, electronic hospital information systems were used in three Member States, and one was piloting a home-grown laboratory information management tool. Generally, there were no procedures or personnel to ensure data adequacy. The equipment including computers were inadequate.

In Member States with a computerised, bar-coded aided MEDITEC information collection tool and relatively complete data, the information was disease- or diagnosis-linked, with no unique patient identifiers – making it impossible to identify which, as opposed to how many, patients had TB. Consequently, there was limited usefulness of data for informing programmes and the Ministry of Health.

Pre-analysis documentation procedures were poorly standardised, barely resourced (personnel, equipment, telephony, messengers) and scarcely prioritised. Post-analysis procedures were also poorly standardised and variable within laboratories. There were no standard operating procedures for result disposal. The transfer of information to programmes or Ministries of Health was slow, compromising the ability of programmes and Ministries of Health to react timeously.

The opportunity for using the laboratory systems as a focal information nexus is lost due to a lack of policies, lack of strategy and the absence of budgetary support.

The main obstacles are the absence of policies, the lack of adherence to existing practices, and a lack of dedicated trained personnel to receive samples and ensure that all required data is completed. The lack of basic stationery, computers and toners also impairs data collection and availability.

The availability of laboratory pre- and post-testing procedures mirrored the economic means of Member States and the state of health sector financing in general, and appears to be an overlooked budget item.

Figure 4.6: Specimen containers and request forms in a national reference laboratory. Containers and request forms were not standardised in most Member States

Figure 4.2: New laboratory complex, Dar es Salaam, Tanzania

4.9 Operational research for health

The burden of communicable diseases is high in SADC Member States. Evolving disease patterns call for modifications of the approaches to diagnosis and treatment. The evidence base for any such modification should be based on systematic data generated in part by laboratories conducting operational research for health. Results of the research do influence policy decisions and can help save lives. For example, the discovery of clusterings of MDR- and XDR-TB cases in South Africa led to the current state of heightened vigilance in Member States. Likewise, the finding of a high prevalence of chloroquine resistance in Angola and Madagascar led to the cessation of the use of chloroquine and its replacement with artesunate and amiodiaquine as first-line drugs. Operational research activities were rarely conducted in Member States national reference laboratories. This was either because they were not envisaged during conceptualisation, or because staffing numbers were inadequate. The few exceptions in this regard were the Botswana Harvard HIV Laboratory, the National Institute for Biomedical Research (INRB) in the Democratic Republic of Congo, the Pasteur Institute in Madagascar, and the Medical Research Council laboratories in South Africa.

Laboratories with personnel holding higher degrees were more often involved in operational and, in some cases, basic research. The research bias was influenced by the disease profile within the respective Member States. There is ongoing Malaria operational research in Angola, Demoratic Republic of Congo and Madagascar, while HIV research predominates in Botswana, as does TB research in South Africa.

The capacity of national reference laboratories to undertake operational research for health was influenced by the overall laboratory profile, operational policies, human resource availability and funding opportunities. The capacity to undertake operational research for health should be strengthened with enabling policies that are coupled with adequate human resources and increased funding.

4.10 Quality management

Quality management includes quality planning, quality control, quality assurance, and quality improvement, as outlined in quality manuals. These manuals were complete in only two Member States. Generally, quality management practices were variable in Member States. The implication of internal quality control and positive and negative predictive values was generally well understood and implemented. There were challenges in the appreciation of the broader concepts of quality management, though. The distinction between quality control and training and follow-up was blurred. Component elements of quality management were often construed as the totality – thus quality management meant different things in different Member States' national reference laboratories. With few exceptions, standard operating procedures, when available, were infrequently updated. In some Member States, quality assurance was perceived as donor-driven with little relevance to day-to-day practices. At laboratory level, the concepts of quality assurance and proficiency testing were used interchangeably and were frequently confused with training and follow-up.

Other challenges in implementation included human and financial resources to facilitate training, supervision and quality assurance roll out. Quality assurance coverage was generally patchy and restricted to programmeswith earmarked funding support (HIV serology, CD4 counts, TB microscopy and culture). A majority of Member States did not have a budget for quality assurance. National quality assurance schemes were at nascent stages of evolution with only two accredited schemes (in South Africa and Zimbabwe). The uptake of funded external quality assurance schemes was good, but the utilisation of the tests for corrective measures revealed some fundamental misunderstandings of its role and usefulness. Laboratories refer their samples to different quality control schemes for CD4 count external quality assurance.

The most commonly cited were AFREQUAS, QASI and Thistle. Schemes as far afield as Canada and Australia were used by some Member States (Table 4.10). Funding for CD4 quality assurance is supported by the WHO in most countries. Other sources of funding were the US government (through the Centres for Disease Control) and the Japanese International Cooperation Agency.

4.10.1 Quality assurance for HIV serological and virological tests

Although no longer recommended by the WHO, a majority of the Member States had a policy of retesting 10% of the samples tested. ELISA assays were performed infrequently. Evidence of participation in external quality assurance schemes was not always available. External quality assurance for HIV serology was provided by the National Institute for Communicable Diseases (South Africa) and the African Quality Assurance Scheme (AFREQUAS). WHO supports both schemes.

The only Member State with in-country RNA-viral load quality control was South Africa. The remainder used different schemes (especially those of the Centres for Disease Control in the USA).

4.10.2 Quality assurance for TB sputum microscopy

The National Health Laboratory Service group of laboratories, in conjunction with the National Institute for Communicable Diseases in South Africa, offers a WHO-supported microscopy external quality assurance scheme. However, the turn-around time was reportedly lengthy. Meanwhile, national laboratories provide quality assurance services for peripheral laboratories, with an average of 10% of samples re-examined by personnel at the national laboratory. However, this practice was not uniformly enforced, due to problems that included a lack of transport to conduct field visits and overall shortages of personnel to conduct routine testing. Quality assurance was therefore compromised. External quality assurance services for TB culture are predominantly provided by the Medical Research Council in Pretoria, South Africa. Member State national reference laboratories receive 20 samples in six-monthly cycles. The turn-around of reports was reported as satisfactory.

4.10.3 Quality assurance for Malaria diagnosis

The primary testing method for Malaria is microscopy. The reproducibility of a test result depends on the assay procedure, the instrument and the operator. Quality control of these components is co-ordinated by national reference laboratory technologists supported by the Malaria programmes. Blind retesting of 10% of slides examined, and follow-up training appear to be the main methods for ensuring quality. External quality assurance is provided by the WHO/National Institute for Communicable Diseases scheme for participating Member States. In one Member State (Democratic Republic of Congo), quality testing of reagents and ICT rapid tests was conducted by the national reference laboratory in support of the Malaria programme.

Table 4.10: Quality assurance schemes used by national laboratories

Member States	Quality assurance scheme used
Angola	WHO/Portugal
Botswana	WHO/NCID
Democratic Republic of Congo	WHO, CDC
Lesotho	WHO/NICD
Madagascar	WHO
Malawi	AFREQUAS, UK-NEQUAS
Mauritius	WHO/NICD
Mozambique	WHO/NICD, Italy
Namibia	QASI and Thistle
South Africa	National
Swaziland	NICD
Tanzania	QASI, Canada
Zambia	REQUAS
Zimbabwe	ZINQUAP, AFREQUAS, WHO/NICD

4.11 Health and safety

Laboratory services include work with hazardous infectious diseases. It is incumbent on the laboratories to ensure that the working environment is kept safe. In this assessment, special attention was paid to health and safety considerations and to the presence and observance of health and safety practices.

Member States have national health and safety policies, but their implementation was inadequate in all but three (Botswana, Namibia and South Africa) Member States. Designated health and safety officers were often not in place, earmarked financial resources for this service were often unavailable, servicing of biological safety cabins was poor, the architectural design of some laboratory buildings was inappropriate, and there was inadequate provision of personal protective equipment.

There was a limited appreciation of health and safety implications for workers employed to process samples infected with dangerous pathogens such HIV and MDR- or XDR-TB. In some Member States, available safety equipment was used inappropriately or inconsistently. The modalities for ensuring the observance of health and safety precautions were wanting.

There is an urgent need for strengthening the observance of health and safety guidelines in Member States laboratories. An urgent, first step should be the appointment and training of health and safety officers in every national reference laboratory.

4.12 Sample transport logistics across international borders

The capacity of laboratories to provide specialised diagnostic services in-country is limited. It is often necessary to transport samples to regional and international centres for the purposes of diagnosis or quality control.

This assessment noted that, in general, there were no standard protocols for the packaging and transportation of TB samples within countries and across international borders. Regulations for the export and import of potentially infectious materials varied between Member States, and were not standardised.

While the UN has approved packaging, and WHO and CDC have designed containers for the transportation of samples, there are no specialised and accredited courier companies in the majority of Member States. In South Africa, a local company packages, imports and exports infectious materials, and has been used to transport TB samples for drug sensitivity testing. The transportation of samples is hampered by different national requirements for the importation and exportation of biological samples and infectious materials, in general. There is an urgent need to harmonise regulations governing the transportation of infectious biological samples between Member States, and these should be in line with international regulations.

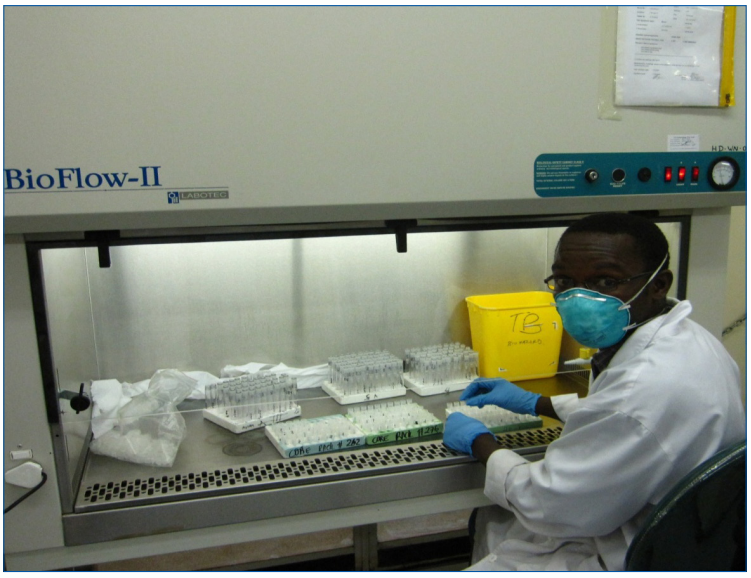

Figure 4.8: The observance of health and safety precautions at the National Institute of Pathology, Windhoek, Namibia

5. DISEASE-SPECIFIC FINDINGS ON LABORATORIES

The generic considerations create an environment within which routine laboratory testing can be conducted. These involve the policies and strategic implementation plans, as well as infrastructure, management and financing. The capacity of national reference laboratories to provide disease surveillance and epidemiological information gathering hinges on both the general factors and the procedures carried out within the laboratories. The capacity to provide primary diagnosis and case management of the "big three" communicable diseases is defined by specific, in addition to the general requirements.

This section examines the actual conduct of testing and the factors that affect the comprehensiveness and quality of the services delivered. It details testing procedures, the indications for testing, the protocols that are followed, the methods used, the quality control of the procedures employed, and the personnel involved. It also details the types of equipment and reagents that are used, as well as assessing the adequacy of systems of documentation and recordkeeping.

5.1 Diagnosis of HIV infection

The HIV & AIDS department of WHO has published recommendations on laboratory investigations for clinical care (Appendix III). These recommendations were used in the assessment of the scope of services provided in the national reference laboratories. The list includes serological diagnostic tests employing rapid or ELISA techniques, the tests used for the staging and monitoring of HIV & AIDS, as well as molecular methods used for determining viral copy numbers and resistance to antiretroviral medicines.

5.1.1 Rapid tests

All the Member States laboratories have the capacity to carry out rapid diagnostic tests for HIV infection, but these were not always done routinely. Rapid diagnostic tests were used in varying combinations and in serial and parallel testing algorithms. There was a judicious choice of highly-sensitive, followed by a highly-specific, tests. The most commonly used diagnostic kits were the Abbott Determine, UniGold, and SD-Bioline. The testing algorithm was predominantly serial, starting with Determine as a screening test, followed by UniGold as a confirmatory test. SD-Bioline was the preferred tie-breaker test.

Rapid diagnostic tests were used in national reference laboratories for the confirmation of infection or to aid in the training of personnel from peripheral testing facilities.

Although no longer recommended by the WHO, the predominant rapid diagnostic tests quality assurance procedure was the random sampling of 10% of all tests carried out at voluntary counselling and testing sites, and retesting using either rapid tests or ELISA.

5.1.2 ELISA and Western Blot

Indications for ELISA assays were:

- Quality control of rapid tests,
- Primary diagnosis of HIV infection (four Member States)
- To resolve discrepant results from referring laboratories,
- Confirmation of discordant results, and
- In the conduct of research and surveys.

ELISA testing was conducted in both serial and parallel testing algorithms. All the national reference laboratories visited had the technical capacity to perform ELISA assays. This was a routine procedure in 90% of those laboratories and it was conducted when required in the rest. A variety of ELISA kits were in use.

The most widely used was the Vironostika HIV Uniform II Ag/Ab (bioMerieux b.v. Boseind, Netherlands). The Genscreen HIV 1/2, Enzygnost, Murex HIV Ag/Ab-combination (GE 41/42) Axsym HIV Ag/Ab Combo were the other kits used in parallel or serial testing algorithms. The number of laboratories routinely performing the Western blot was small, and indications were to confirm discordant ELISA results.

The ultrasensitive p24 antigen diagnostic method was used in a research setting in one Member State (Swaziland).

Figure 5.1: HIV serological testing using the ELISA technique at the INRB, Kinshasa, Democratic Republic of Congo

Figure 5.2: CD4 workload at the National Institute of Pathology in Namibia, with Coulter EPICS flow Cytometer in the background

5.1.3 CD4+ T lymphocyte counts

Indications for the enumeration of CD4+ T lymphocyte numbers were to stage HIV disease and determine the optimum time of treatment commencement, as well as the monitoring of immunological responses to antiretroviral therapy. All national treatment programmes rely on the numbers of CD4+ T lymphocytes to guide the initiation of antiretroviral therapy and to monitor progress on therapy.

The methods used for CD4 testing was flow cytometry. Testing protocols required the determination of CD4 T lymphocyte numbers at the time of diagnosis and at varying (usually quarterly, four-monthly and bi-annual) intervals thereafter. Certain predetermined levels of CD4+ T cell numbers triggered the initiation of antiretroviral therapy.

The capacity to determine CD4 percentages that are critical in paediatric care was available in all but two Member States national reference laboratories. Quality control of the procedures was conducted with the support of the WHO, and was coordinated by AFREQUAS in the majority of Member States. The numbers of personnel involved in CD4 testing were limited, however.

A range of flow cytometry instruments were used in the laboratories, including those manufactured by Becton Dickinson and Beckman Coulter. A limited number of national reference laboratories had Cyflow instruments.

5.1.4 Molecular diagnostic tests

RNA polymerase chain reaction assays are used to confirm the diagnosis and stage HIV disease prior to commencement of treatment, to monitor the progress of therapy, and to determine the possible emergence of resistance.

The RNA polymerase chain reaction (viral load) determination is in wide, but not universal use. The instruments used are the Roche Amplicor and the bioMerieux systems. The diagnostic capabilities of the two platforms are comparable.

Common challenges related to human resources and financing. Training in the operation of the polymerase chain reaction equipment was provided by the equipment suppliers. Interruptions in the provision of that service were commonly associated with the costs and logistics of acquiring test kits. DNA polymerase chain reaction viral antigen determination was used in paediatric diagnosis of HIV infection under the auspices of relevant programmesand with partner support.

The p24 viral antigen test was used in only one Member States, in a research setting. The provision of external quality assurance was inhibited by the absence of a relevant quality assurance scheme. Most Member States national reference laboratories utilised the quality assurance scheme, run by the CDC (USA).

5.1.5 Tests for monitoring adverse effects of antiretroviral therapy

The medicines used for the treatment of AIDS have known toxicities and should be regularly monitored. The most widely used first-line drug combinations are Zidovudine, Lamivudine, Stavudine, Nevirapine and Effavirenz. The toxicities associated with the use of these drugs affect the haematopoietic system, the liver kidneys and pancreas. Some increase serum lactate, which can lead to death. Side effects should be monitored when patients take these medications.

All the national-level laboratory facilities reportedly had access to full blood counts, and clinical chemistry analyses including the liver and kidney function tests and glucose levels. Lactate analyses were less frequently performed, with only three Member States laboratories offering the assay. The availability of these services was readily verified in multi-discipline laboratories. Disease-specific, vertical laboratories relied on other laboratories for the services or established duplicate facilities within the laboratories.
Although testing capacity was available, there were no standard testing algorithms and no uniform schedule for the frequency of testing. This consideration is best addressed in conjunction with the clinical departments.

Quality assurance of the tests was inconsistent, and was available in a handful of Member States. The major challenge was the lack of resources for external quality assurance.

5.1.6 HIV drug resistance testing

Antiretroviral medicines have been used in SADC Member States since the early 1980s and have been rolled out widely from the late 1990s. The widespread use of any medicine is associated with organism resistance to the medicine. In the case of HIV & AIDS this manifests as treatment failure despite drug adherence. Recent studies show that this increases morbidity and mortality of patients on treatment.

Resistance to ART is diagnosed with genotypic assays. Despite the central importance of the assays, there was no routine HIV drug resistance testing occurring outside South Africa (where the assay was offered by the National Institute for Communicable Diseases). Three other Member States had the facilities to offer HIV drug resistance assays, but had limited the service to drug resistance surveys and not routine testing.

Figure 5.3: FACS Calibur Flow Cytometer at the new National Health Laboratory, Quality Assurance and Training Centre in Tanzania

Figure 5.4: Modern equipment in an open plan HIV serology laboratory in Windhoek, Namibia

Challenges include the costs of the equipment and reagents required to perform the assay, the technical complexity of its performance and the human resource capacity that is required. Additional challenges arise from the lack of accreditation of the majority of national reference laboratories. The WHO Global HIV Drug Resistance Network (HIV ResNet), which was established to provide quality-assured laboratory results for HIV drug resistance surveillance and monitoring, has recommended that laboratories will need to fulfil certain accreditation requirements (including a capacity to perform viral sequencing) before it can receive WHO accreditation for HIV genotyping. A small number of Member States laboratories have met those requirements.

Access to HIV drug resistance testing is urgent, but availability is limited. The capacity to perform viral sequencing is available in Botswana, South Africa and pending in Zimbabwe. There was no quality assurance scheme for HIV drug resistance in the region. There is a need to establish modalities that enable Member States laboratories to provide HIV drug resistance testing for their populations so that the spread of drug-resistant HIV in the SADC region can be reduced.

5.2 Tuberculosis

Pulmonary TB is diagnosed on the basis of a suggestive clinical history, supportive radiological investigations and laboratory confirmed by sputum smear positivity. Sputum smear microscopy remains the most accessible and reliable of all the primary diagnostic methods, and is meant to prompt treatment initiation. Increasing rates of drug resistance require laboratory services to determine the sensitivity profiles. The aerosol transmission of TB makes it a major public health concern and the early diagnosis and prompt treatment has important implications for individual patients and their communities.

This assessment examined the indications, procedures, equipment and personnel involved and quality assurance practices in TB diagnosis in order to determine the capacity of national reference laboratories to offer comprehensive primary, and first- and second-line drug sensitivity testing.

5.2.1 Diagnosis of M. tuberculosis

Sputum smear microscopy was indicated when there was clinical suspicion of TB. This procedure remains the gold standard. The procedure is standardised throughout the region.

The principal method for the diagnosis of TB in the SADC is sputum smear microscopy of Ziehl-Nielsen stained smears. Smears were examined directly, with or without decontamination. Fluorescence microscopes were available in five Member States. The number of smears examined per patient varied from one to three. A majority of Member States were examining three separate sputum smear samples, in line with previous guidelines. Recently the WHO recommendations on the numbers of sputum samples tested have been revised from three to two under specified circumstances. (11) The implementation of the new recommendations varied between Member States. LED microscopes (supported by FIND and piloted in South Africa) were operational in one Member State (South Africa) and awaited commissioning in another (Lesotho).

The personnel conducting TB microscopy were experienced and competent. Major challenges were high sample volumes in the context of limited personnel numbers. In addition, Member States experienced a shortage of microscopes, partly due to inadequate equipment servicing logistics. Occasionally, testing had to be halted due to shortages of reagents. Since the cost of TB microscopy reagents is not high, the shortages were probably caused by inadequacies in the supply chain.

Quality assurance for TB microscopy was supported by the WHO and coordinated by the National Health Laboratory Service network of TB laboratories in South Africa. Participation in TB external quality assurance was high. There was no routine use of rapid diagnostic and point of care assays in TB diagnosis. The standard diagnostic whole blood test, which detects the presence of antibodies to TB, has not found use in this endemic region. The detection of extra-pulmonary infections, which requires the examination of histology tissue sections, was hindered by the limited availability of histopathologists in the region. Cases of extra-pulmonary TB are expected to increase significantly in the wake of HIV-induced immunosuppression, and contingency plans are required to facilitate diagnosis.

5.2.2 Culture and drug sensitivity testing

The general indications for taking culture and drug sensitivity testing samples from patients were:

- Treatment defaulters,
- Treatment failures or non-converters after two to three months of treatment,
- Disease relapse after a course of treatment,
- Chronic infections,
- New cases,
- Close contact with MDR patients.

While there was general consensus on the indications, there was variable implementation. Variations resulted from the challenges encountered in patient follow-up, partly due to weak practices of patient documentation and recording, as well as patient mobility.

Testing algorithms were not rigorously followed and there was limited enforcement of scheduled re-testing of patients on treatment to detect non-converters and treatment failures. Laboratory personnel had little influence on the clinical decisions to refer patients for testing, however the existence of testing policies would have addressed some of the shortcomings. The definitions of the indications for TB microscopy were not standardised.

The recommended testing algorithm was carefully adhered to in five Member States. These laboratories retested all patients after two months on treatment; if positive, they were retested again after three months. First-line drug sensitivity testing is carried out on samples that remained positive after three months of treatment.

Culture methods (solid and liquid media)

Cultures are conducted in liquid and solid media. Five Member States exclusively use solid media for culture and drug sensitivity testing. Both solid and liquid media cultures and drug sensitivity testing was used in three Member States.

Liquid media cultures were used in five, but there was no TB culture testing in two Member States. The advantages cited for the use of solid media included extensive, hands-on experience, lower cost of consumables associated with in-house capacity to produce media, and lower rates of contamination.

Operational research comparisons in Lesotho show a four-fold higher (7.8%) contamination rate with liquid MGIT versus L-J solid media (1.9%). National reference laboratories also continued solid media to meet the training needs of laboratory technologists from peripheral sites, recognising that it was easier to decentralise this method than the MGIT system. In a majority of Member States, cultures were read at weekly intervals from the second week.

The maximum culture time for L-J media cultures is 42 days. Liquid cultures were read weekly and when flagged by instrument indicators.

5.2.3 Drug sensitivity testing (MDR- and XDR-TB)

First-line drug sensitivity testing was conducted in 13 Member States. Methods used were LJ slopes and the MGIT system. The drugs used were Rifampicin, Isoniazid, Ethambutol, Streptomycin, and Pyrazinamide. First-line Thiacetazole testing was conducted in one Member State. Drug concentrations used were standard.

Second-line drug sensitivity testing was offered in one Member State (South Africa), while the Medical Research Council in Pretoria provided second-line drug sensitivity testing services for other Member States. The turnaround time of results was satisfactory. In Angola, second-line drug sensitivity testing was preferentially referred to Portugal.

The capacity to diagnose XDR-TB through second-line drug sensitivity testing is only available in the Democratic Republic of Congo and South Africa. Although over 500 XDR-TB cases had been notified in six countries (Botswana, DRC, Mozambique Namibia, South Africa, and Swaziland) by May 2008, the rates in other SADC Member States remain unknown because of a lack of access to second-line drug sensitivity testing.

It is noteworthy that Member States reporting XDR-TB had the required logistics to refer samples for second-line testing and may not be the only ones with the XDR-TB. The Medical Research Council laboratories in Pretoria provided quality assurance for first-line drug sensitivity testing; it is the only WHO-recognised supranational TB reference laboratory in the SADC region.

5.2.4 Molecular methods of TB diagnosis

Molecular methods of TB diagnosis were routinely available at the Medical Research Council and the National Health Laboratory Service in South Africa and Madagascar. These rely on the amplification of specific gene sequences.

The results can be available within two days. The technical expertise required, laboratory infrastructure, the cost of reagents and consumables make this diagnostic method inaccessible to a large number of countries.

Table 5.1: MDR- and XDR-TB prevalence in some SADC countries

	Population	MDR	XDR
Botswana	1.6 million	142	3
Namibia	2 million	359	27
Lesotho	1.9 million	246	1
South Africa	48 million	1.6%	9%
Swaziland	1.2 million	153	4

Figure 5.5: The MGIT liquid culture medium equipment used for drug sensitivity testing in Mbabane, Swaziland

5.2.5 TB culture and drug sensitivity testing

TB culture and drug sensitivity testing services remain limited to national and tertiary reference facilities or are not operational. The current TB burden is higher than was anticipated when the laboratories were designed. It is noteworthy that drug-resistant TB is reported in countries with a capacity to diagnose (the majority of XDR-TB cases notified are in South Africa) or with resources and logistics enabling test referral. Second-line drug sensivity testing is currently restricted to laboratories in one Member State (South Africa).

Several steps need to be taken:

- Strengthen the capacity of current drug sensivity testing services in Member States by addressing policy frameworks, human resource, quality assurance, and health and safety;
- Increase and roll-out the capacity for culture and drug sensivity testing in Member States as a matter of urgency;
- Provide the routes and logistics to enable Member States that lack national capacity to access first- and second-line drug sensivity testing, by establishing a supranational TB diagnostic service;
- In light of the very high rates of HIV and TB co-infection in the SADC region, explore ways for addressing the challenges posed by sputum smear-negative HIV+ patients who are likely to harbour MDR-TB;
- Strengthen monitoring and evaluation and the methods of tracking all contacts of known MDR-TB cases;
- Address the underlying causes of deficiencies, including the limited numbers of personnel, inadequate strategic planning, weak information systems and inadequate funding.

5.2.6 Line probe assays

Molecular diagnostic techniques (line probe assays) are recommended for phased adoption by countries within the context of national plans for the management of MDR-TB patients and local screening algorithms. The techniques require specialised human resources expertise in molecular biology techniques, increased laboratory space, stringent biosafety and contamination controls all of which were wanting in the laboratories.

The following steps are recommended:

- In line with WHO recommendations, Member States laboratories should devise plans to enable the introduction of line probe assay capability at national reference laboratory level to expedite MDR- and XDR-TB diagnosis;
- In implementing the WHO recommendations, Member States should take stock of and address existing challenges, chief among them human resource capacity and quality assurance;
- Molecular tests should be introduced in phases:
  - In the short-term, utilise available facilities (for example, in South Africa) to acquire hands-on training for their personnel;
  - Establish a supranational diagnostic facility and provide it with capacity for diagnosis and training;
  - Personnel training should be a budgeted line item. Participants and centres of excellence should be supported to provide training;
  - Liaise with academic and training institutions to train technologists in molecular biology techniques;
  - Ensure the sustainability of service by creatively retaining key personnel and by structuring and funding a back-up human resource plan, including the involvement of academics and expatriates, if possible;
  - Refurbish laboratories to create space for the molecular biology testing;
  - Acquire equipment and ensure the sustained availability of reagents and technical back-up;
  - Design the required standard operating procedures and in line with these and with the support of mentoring laboratories, commence molecular diagnostics;
  - Establish a quality assurance system from the start.

5.2.7 Limitations of diagnostic tests and the need for operational research

The diagnostic methods that are currently available are not ideal. Sputum smear microscopy has limited sensitivity in paediatric and HIV-positive populations, and is irrelevant in extra-pulmonary TB. The results are delayed due to logistical reasons. The rapid turnover of diagnostic personnel leaves relatively inexperienced

people in charge, microscopes are poorly maintained and quality assurance is weak. Improvements, such as fluorescence microscopy are hamstrung by the same constraints. Solid culture methods are notorious for delaying treatment for up to eight weeks.

The balance between giving treatment for suspected, rather than confirmed, disease and the relative impact of this on the development of MDR-TB should be considered and addressed. Newer methods that have become standard practice elsewhere (including liquid cultures and molecular diagnostics) are unlikely to become universally accessible in the SADC due to costs, infrastructural and personnel deficiencies and the erratic availability of electricity.

Consequently, there is a need for an adequately resourced effort to establish regional operational research facilities to improve and contextualise currently available diagnostic procedures and to improve diagnostic methods.

5.2.8 Monitoring of treatment response

The monitoring algorithms were variable but not always designed in a manner that allowed for the early diagnosis of TB treatment failure (which often suggests MDR-TB).

Several steps therefore need to be taken:

- Design suitable, standardised data capture tools that uniquely identify patients;
- Improve the capture and accessibility of demographic data to allow for patient recall and thus assist clinical and surveillance departments in identifying treatment failure and initiating MDR treatment timeously;
- On the basis of operational research data and with the participation of partners (including WHO) standardise testing algorithms to allow testing at time points that are most likely to yield drug resistance data without compromising patient convenience. The most widely used testing algorithm is baseline, two or three months, five or six months, treatment completion, and 12 months after completion. This schedule could be recommended until operational research suggests otherwise;
- Ensure consistent use of any chosen testing algorithm within Member States;
- Recognising its central or unique role in diagnosing MDR-TB, designate and capacitate (though human resource provision, funding and logistics) the national reference laboratory to serve as the central source of TB diagnostic information to support the TB programme.

5.2.9 Health and safety in TB laboratories

The availability of a safe working environment in a TB laboratory requires policies that define safety risks and provide minimum required standards for their mitigation. This should include the safety conscious design of facilities and the availability of safety equipment and personal protective gear. The policies should also address the safety of individual laboratory workers through safety training, supervision and provision of risk-level tailored safety gear. The routine use of appropriate protective gear is a cardinal safety consideration in the era of MDR-and XDR-TB. Within the laboratory, institutional support for health and safety, including the designation and empowering of safety officer, should be provided. Sample collection jars should be safely designed, and spillage management standard operating procedures should be implemented.

5.3 Malaria

The diagnosis of Malaria is conducted in laboratories that should be adequately staffed and equipped. The operations should be guided by policies and strategic implementation plans that define management, financing and infrastructure requirements.

The capacity of national Malaria reference laboratories to provide diagnostic services, disease surveillance and epidemiological information gathering hinges on those general factors, as well as on the procedures that are carried out within the laboratories. The general operating environment and the specific test performance define the capacity to provide primary diagnosis and case management Malaria.

This section addresses the actual conduct of testing and the factors that affect the comprehensiveness and quality of the services that are delivered. It details testing procedures, the indications for testing, the protocols that are followed, the methods used, the quality control of the procedures employed and the personnel who are involved. It also details the types of equipment and reagents being used, as well as the adequacy of information management systems.

5.3.1 Role of laboratories in phases of Malaria elimination

The role of Malaria laboratories varies with the phases of the Malaria elimination continuum.

Laboratory services are central to the pre-elimination phase, when case detection is required to be accurate, comprehensively documented (including the genotyping of parasites) and rapidly reported through efficient information systems. During the elimination phase the genotyping of parasites becomes a routine requirement in addition to the services provided in other phases of the elimination programme. The downstream success of the programmes will depend on the capabilities of their national and regional laboratories.

5.3.2 Laboratory diagnosis of Malaria infection

WHO recommended laboratory investigations for the diagnosis of Malaria at national level reference facilities are blood film microscopy and rapid diagnostic tests. Additional methods are clinical diagnosis and molecular tests.

The microscopic examination of blood smears remains the cornerstone of Malaria diagnosis in SADC Member States. All the national reference laboratories visited routinely offered Malaria microscopy services. There were no dedicated Malaria diagnostic technicians at national reference laboratory level, due to the widespread familiarity with the technique. Standard stains were being used throughout. The use of special microscopes for acridyne orange stained slides have been abandoned due to lack of servicing and cost of reagents.

Malaria microscopy services were plagued by limitations in the numbers and technical conditions of the microscopes, shortages of microscopists and stock-out of reagents. Dedicated microscope service technicians were not available in a majority of Member States. Those available were servicing all hospital equipment, including laboratory equipment and were generally short-staffed.

The capacity to provide rapid diagnostic testing using immunochromatographic tests existed in all the centres visited. The practice was limited, however, by the higher costs of the immunochromatographic tests, and the existence of robust more familiar microscopy techniques. The range of immunochromatographic tests that was available, along with conflicting messages regarding their reliability, led to them being sidelined.

There was no routine Malaria external quality assurance service in the majority of Member States' national reference laboratories. The quality management provisions were directed at proficiency testing and training of personnel in more peripheral sites, rather than at the national reference laboratory. It was recognised that microscopy detects the presence of parasites and that the presence of parasites did not always mean that the parasites were the cause of any presenting complaints. Healthy adults in endemic areas can be asymptomatically parasitised. The majority of patients are diagnosed and treated for presumed Malaria on clinical grounds. Useful tests for monitoring disease and treatment include the determination of haemoglobin levels to detect anaemia, which is a common complication. These tests were available in all Member States.

5.3.3 Clinical diagnosis of Malaria

Clinical diagnosis of Malaria relies on the recognition clinical symptoms in exposed persons who reside in or have travelled to areas where the risk of infection exists.

In Member States with high Malaria prevalence, it was reported that the majority of Malaria episodes were treated on the basis of clinical suspicion. Hospitalised patients were more likely to have blood films sent for laboratory testing. The practice is in line with certain WHO guidelines, particularly in paediatric populations. The laboratory services currently do not have the human resource and infrastructural capacity to confirm all cases. Clinical diagnosis of Malaria is consistent with the WHO recommendations that all febrile children in endemic areas should be offered anti-malarials. (12)

While clinical diagnosis is advocated as part of the WHO Integrated management of Childhood Illnesses (IMCI), it also speeds up the development of drug resistance, thus increasing morbidity. It is important that all people who are suspected to have Malaria are offered definitive diagnostic tests, film smear examination or ICT. The necessary reliance on clinical suspicion must be accompanied by operational research to evaluate possible emergence of resistance. Molecular diagnostic capacity should be developed.

5.3.4 Microscopy

Malaria microscopy services are plagued by limitations in the numbers and technical conditions of the microscopes, shortages of microscopists, and stock-out of reagents. The use of special microscopes for acridine orange stained slides have been abandoned due to lack of servicing and a shortage of reagents.

5.3.5 Immunochromatographic point-of-care tests

A number of immunochromatographic points of care diagnostic tests have recently become available in the market, including ParaSight, ParaCheck (Pf), and SD Malaria Ag Pf/Pan.

The positioning of these tests in diagnostic algorithms for Malaria is not fully established. There were few policies that stipulated the indications for the use of these tests. Immunochromatographic point-of-care tests provided diagnosis in places without microscopes or microscopists. In Mauritius, which is in the prevention of re-introduction phase of Malaria elimination, immunochromatographic point-of-care tests are used to differentiate between P. Falciparum (Pf hrp-2) and P. Vivax (Pv Specific pLDH). The disadvantage to immunochromatographic point-of-care tests remains the cost, as well as variations in test kit quality in settings that lack the human and financial resources to undertake kit validation.

5.3.6 Molecular methods in Malaria investigations

While clinical diagnosis is advocated as part of the WHO Integrated management of Childhood Illnesses (IMCI), it also speeds up the development of drug resistance, thus increasing morbidity. It is important that all people who are suspected to have Malaria are offered definitive diagnostic tests, film smear examination or ICT. The necessary reliance on clinical suspicion must be accompanied by operational research to evaluate possible emergence of resistance. Molecular diagnostic capacity should be developed.

6. RECOMMENDATIONS

Laboratory services are at the forefront of responses to the major communicable diseases (including HIV & AIDS, TB and Malaria) and emerging diseases (such as ebola and Marburg fever) that afflict the SADC region. There is a recognition that these services play an important role but that their development has lagged behind other aspects of health care delivery. The deficiencies in laboratory services are now seen as obstacles hindering efforts to control communicable diseases.

The provision of effective laboratory services cannot be achieved quickly. Long-term planning is required to ensure that certain milestones can be achieved within a specified timeframe. Those would vary between Member States, since some already have policies and strategic plans in place, while others still have to develop them.

The recommendations below are therefore wide in scope and are intended to accommodate different levels of laboratory service development. The detail included may not be useful to all Member States, but should serve as a useful guide. The recommendations of Member States representatives attending the consensus-building workshop in August 2009 have been incorporated in these recommendations.

The areas focused on are policy, human resources, information management, health and safety, as well as the logistics of transporting test samples across international borders.

6.1 Strengthening the policy and legal environment for national reference laboratories in Member States

Member States should have policies guiding the operations of national reference laboratories.

- The policies should address both diagnostic and public health aspects of service provision, and should guide the processes of data gathering and surveillance, monitoring and evaluation, health and safety and quality assurance;
- Policies should be responsive and relevant to the specific needs of Member States, and must address existing and projected disease patterns;
- The process of policy formulation should involve all relevant stakeholders and consider the population to be served, and the sustainable availability of resources. Human resource availability, retention and development should be specifically addressed in policy infrastructure availability, human resource availability and human resource development;
- Member states should provide the logistics necessary for the optimum functioning of the national reference laboratories;
- Policy implementation should be guided by strategic implementation plans, which should realistically estimate the human and financial resources and planning that are needed to fill identified gaps in all laboratory disciplines (including HIV & AIDS, TB, Malaria, parasitology, haematology, clinicalchemistry, immunology, bacteriology histopathology and virology).

The SADC Secretariat, in collaboration with relevant partners, should develop minimum standards to guide the development of laboratory and strategic implementation plans.

6.2 Strengthening human resources, staff retention and training

Member States should have human resource policies and strategies that:

- Address staffing norms, levels and levels of training and areas of responsibility and staff retention;
- Address the training of human resources for the laboratories and promote career development pathways for those working in the laboratory;
- Explore innovative methods for boosting personnel numbers, including public-private partnerships in laboratory service delivery;
- Explore private-public artnerships in the provision of laboratory services.

Member States should also:

- Carefully analyse the reasons for staff departures and accelerate efforts aimed at staff retention;
- Establish career development pathways for laboratory personnel;
- Craft creative incentives to retain laboratory personnel.

The SADC Secretariat must:

- Explore best practice models for boosting manpower in the region and facilitate the exchange of experiences and expertise;
- Coordinate the mobilisation of gap-funding resources for staff retention (without staff there is no laboratory to strengthen), and create a coordinating mechanism to facilitate this;
- Develop minimum standards for the human resource needs of Member States' national reference laboratories. In relation to the training of laboratory personnel, Member States should:
- Establish training capacity where it does not currently exist;
- Encourage existing training institutions to consider increasing their intake in line with current and projected national needs;
- Ensure that new and established training schools for laboratory staff incorporate health and safety, quality assurance, laboratory information systems in their training syllabi;
- Facilitate the involvement of private and academic laboratory practitioners in laboratory services offer laboratory personnel regular continuing professional education opportunities;
- Consider structured exchange visits to centres with better facilities within SADC Member States (in

collaboration with SADC, WHO and other partners) to support the exchange of best practices.

The SADC Secretariat should:

- Establish a mechanism to enable candidates from institutions without training facilities to access them in other Member States;
- Maintain a register of expert resource persons and facilities, coordinate knowledge transfer and augment key aspects of laboratory services;
- Cooperate with WHO and others in coordinating the adaptation and harmonisation of training manuals in line with evolving diagnostic needs;
- Explore the feasibility of establishing regional post-graduate laboratory training facilities;
- Facilitate structured exchange visits to centres of excellence with the support of Member States and partners (including WHO);
- Explore ways to encourage and coordinate staff recirculation between different facilities, for example through twinning, partnering or mentorship arrangements.

6.3 Reviewing of the organisation and structure of laboratory services

The assessment confirmed that national reference laboratory services are best co-ordinated from Ministries of Health. Hence it is recommended that Member States:

- Consider establishing laboratory services representation at the level of the Ministry of Health in order to provide a unified interface and to facilitate the coordination of laboratory activities, resource mobilisation and allocation, as well as surveillance functions;
- In view of the presence of vertical laboratory structures, consider establishing inter-programme laboratory management teams under the leadership of the Ministry of Health or laboratory director, and incorporating stakeholders and partners (international, multilateral, academic and others);
- Ensure that all disciplines offering laboratory services (including essential but non-programme associated disciplines such as clinical biochemistry, clinical immunology, haematology, histopathology, microbiology and virology) are provided with the requisite resources;
- Examine the merits of integrated laboratory services and move towards their realisation.

6.4 Enhancing quality management

Member States should integrate quality management practices in their activities. This can be achieved by:

- Appointing quality managers for each national reference laboratory as a way of strengthening quality assurance;
- Training laboratory managers on quality management;
- Participating in accredited external quality assurance schemes;
- Providing a recurrent budget for quality management as an integral component of laboratory budgets;
- Engaging partners in mobilising resources for quality assurance funding.

The SADC Secretariat should:

- Strengthen quality management practices within the SADC region by establishing regional centres of excellence;
- Harmonise regulations relating to transportation of samples;
- Establish intellectual property guidelines in the handling of biological materials exchanged between laboratories.

6.5 Ensuring health and safety practices

The steps required of Member States include:

- Ensuring that the design of laboratory facilities takes account of health and safety concerns;
- Creating the posts and appointing a designated, appropriately trained and frequently refresher-trained health safety officer in larger laboratories;
- Incorporating health and safety training in laboratory training curricula and continuing professional education programmemes;
- In view of MDR- and XDR-TB, placing greater emphasis on the funding of personal protective clothing;
- Expeditiously supporting the upgrading of P3/P4 containment facilities in countries prone to outbreaks of highly infectious pathogens Ebola and Marburg (such as the Democratic Republic of Congo), where staff face mortal risks in the execution of their duties;
- Ensuring the availability and consistent use of personal protective equipment (gloves, NP95 masks, appropriate laboratory coats for all staff);
- Providing structured, routine monitoring of laboratories staff (chest X-rays for TB staff);
- Taking all appropriate measures to mitigate the occupational risks associated with working in clinical laboratories (vaccination of other laboratory staff against hepatitis B, access to post-HIV exposure prophylaxis kits to all laboratory staff).

The SADC Secretariat should:

- Develop minimum standards for health and safety to assist Member States in establishing their own minimum health and safety standards for laboratories;
- Facilitate the logistics for the establishment of regional repository to promote quick and unfettered access to important essential personal protective equipment (gloves, masks, laboratory coats).

6.6 Ensuring the adequacy and sustainability of diagnostic services

The key function of national reference laboratories is to provide diagnostic services. Member States should therefore:

- Provide adequate capacity to diagnosis of communicable diseases (including HIV & AIDS, TB and Malaria), specifically, the capacity to do HIV drug resistance testing, TB drug sensitivity testing and the diagnosis of resistance to medicines used for the treatment of Malaria and incecticides;
- Provide the neccesary complement of human resources;
- Provide adequate financial support to national reference laboratories.

6.7 Ensuring the provision of operational research for health

Laboratory services are driven by innovation, the ability to uncover the disease patterns in the country and the implementation of interventions that are effective. Operational research should therefore extend to optimising current and establishing novel diagnostic methods. Member States should strengthen the capacity to conduct operational research for health by:

- Establishing guidelines that identify operational research as a core mandate of national reference laboratories;
- Providing appropriate human resource capabilities;
- Allocating adequate financial resources for operational research;
- Providing the research logistics;
- Promulgating the institutional mechanisms that promote collaboration between local and regional research institutions;
- Providing access to electronic communication to expedite research and facilitate the timely sharing of information through teleconference calls, internet and webcasts.

6.8 Strengthening laboratory information systems

Laboratory information systems are central to the utilisation of the data collected by the laboratory services to inform policy direction. Member States should therefore ensure:

- That there are policy guidelines that define the scope and utility of laboratory information;
- The standardisation of test request forms (a primary tool for laboratory data collection);
- The implementation of electronic laboratory information systems in order to expedite information management;
- Provision of the logistics necessary for data collection and dissemination (including dedicated human resources, and equipment);
- That relevant personnel are trained in information management;
- That the data being collected enables patient tracking.

6.9 Ensuring the adequate financing of national reference laboratories

Laboratory services are the costliest component of HIV and tuberculosis care. The costs include testing and no-testing expenditure. There seems to be little strategic analysis of the overall costs of providing quality laboratory services and this is reflected in suboptimal service provision.

In order to provide cost-effective and sustainable laboratory services, Member States should:

- Provide adequate financial support to the laboratories;
- Strengthen the administrative and financial management of laboratories (laboratory managers and finance officers);
- Adequately estimate the total costs of laboratory service provision (including human resources, equipment, consumables, quality assurance, infrastructure, water, electricity, etc.);
- Establish a costed testing policy framework in the context of national capacity;
- Cost-effectively streamline and standardise the testing menu and prioritise the range of tests performed.

The SADC Secretariat should:

- Assist in identifying resources especially personnel that can be seconded to the national laboratories to assist in the strengthening of financial management and other relevant laboratory protocols;
- Mobilise gap funding from partners and the donor community.

WHO, UN agencies and partners should:

- Provide technical support;
- Assist in resource financial mobilisation.

6.10 Ensuring the adequacy of laboratory physical infrastructure

- Laboratory buildings should be built on the basis of standard laboratory guidelines;
- The building should meet minimum design and safety standards;
- Elevate containment levels of national reference laboratories to a minimum of P3.

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APPENDICES

Appendix I: Schedule of visits during the assignment

Country	Date visited
Botswana	December 2008
Mozambique	December 2008
Madagascar	December 2008
Tanzania	January 2009
Lesotho	January 2009
Swaziland	January 2009
Zambia	January 2009
Malawi	January 2009
Zimbabwe	February 2009
Namibia	February 2009
South Africa	February 2009
Democratic Republic of Congo	February 2009
Angola	March 2009
Mauritius	March 2009
Seychelles	Not visited

Appendix II: Officials, laboratory personnel and partners who assisted in the assessment

Member State	Organisation	Name of person	Designation
Angola	National Institute of Public Health (INSP)	Filomena Gomes Da Silva filomenasilva5@yahoo.com.br	Director General
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Angola	INSP	Dr. Maria Antonia Sanazenge: sanazenge@hotmail.com	Chefe de Divisao de High. Alimentar
Angola	Ministry of Health	Maria Palma mariapalma58@yahoo.com.br	
Angola	Ministerio du Saud	Nilton Saraiza G S Francisco: niltonsar@yahoo.com.br pnodeangola@gmail.com	Medico, Epidemiologista Programmea de Malaria
Botswana	National Health Laboratory	Dr. Isaac M Mtoni imtoni@gov.bw	Consultant Microbiologist and Head of Laboratory
Botswana	Botswana Harvard HIV-RL	Dr. Madisa Mine mmine@bhp.org.bw	Senior Scientist in Charge, Diagnostic Services
Botswana	Botswana Harvard (BHHRL)	Bright Kifi Sakyi bsakyi@bhp.org.bw	
Botswana	National TB Laboratory	Kobiditse Radisowa kradisowa@yahoo.com	Head, National TB Reference Laboratory
Botswana	National TB Ref Laboratory	Obert Kachuwaire kachuwaire@gmail.com	
Botswana	CDC/BOTUSA	Ebi Bile bile@bhp.org.bw	
Botswana	Safe Blood for Africa Found	Sarah M. Gaolekwe Email: sarah@safebooldforafrica.org	PEPFAR Project Manager & Country Coordinator Botswana
Botswana	National TB Programme	Mr. Maolosi	Ministry of Health, TB Control programme
Botswana	Nyangabgwe Hospital	Dr. N T Gokhale Email: ngokhale@gov.bw or ntg@botsnet.bw	Consultant Microbiologist
Botswana	Botswana-Harvard Lab	Dr. Rosemary M Musonda Email: musonda@bhp.org.bw	Research Associate/ Lab. Director Botswana Harvard Lab.
Botswana	Botswana-Harvard Lab.	Mr. Dube	Head, Diagnostic Services
Botswana	Nyangabgwe HIV Ref. lab.	Saliwe Nfila saliwenfila@yahoo.co.uk	APHL Consultant
Botswana	Nyangagbwe HIV Ref Lab	Godfrey Nawa gsnawa@gmail.com	QA Officer, Head lab Accreditation Task Force
Botswana	Nyangagbwe HIV Ref Lab	M Chinme muschinme@yahoo.co.uk	Laboratory Scientist
Botswana	Nyangagbwe HIV Ref Lab	Chrispen Dandavare cdandavare@yahoo.co.uk	Laboratory Scientist
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DRC	Min. de la Sante Publique	Prof. J J Muyembe-Tamfum, MD, PhD	Director INRB
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DRC	Ministere Sante Publique	Cleophas If Malaba Munyanji Email: malabac@yahoo.fr	Medical Biologist, Head, Directorate of Laboratory Services
DRC	Centre Provincial De Transfusion Sanguine	Suzy Kapinda Mulamba Email: kapingasuzy2002@yahoo.fr	Biologist Medicine
DRC	Ministry of Public Health	George Kabuya	PNT Chief, Laboratories
DRC	Ministry of Public Health	F. Baleka	Biologist: Microbiology, Chief of Division
DRC	Ministry of Public Health	Dr. Kaswa, MD	Operational Research, NTB programme
DRC			
Lesotho	National TB Ref Laboratory	Mathabo Mareka mmareka2000@yahoo.com	Principal Laboratory Technologist

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Lesotho	National TB Ref. Lab.	Lebohang Marai maraipatrick@yahoo.co.uk	Senior Laboratory Technologist
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Madagascar	SLTL	Dr. Gabriel M RANJALAHY ranjagalym@yahoo.com	Chief Executive Officer
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Appendix III: WHO recommendations of tests to be performed at national-level HIV laboratories (excerpt)

	Angola	Botswana	Democratic Republic of Congo	Lesotho	Madagascar	Malawi	Mauritius	Mozambique	Namibia	Seychelles	South Africa	Swaziland	Tanzania	Zambia	Zimbabwe
HIV ANTIBODY TESTING															
RDT 1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RDT2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ELISA	X	X	X	X	X		X		X	X	X	X	X	X	X
Western blotting							X			X	X			X	X
VIRAL DIAGNOSTICS															
RNA viral load	X	X	X	X	X	X	X	X			X	X	X		X
DNA viral load		X				X					X				X
Ultrasensitive p24												X			
Viral sequencing		X									X				X
HAEMOGLOBIN	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
FBC and DIFF	X	X	X	X	X	X	X	X	X		X	X	X	X	X
CD4 LYMPHOCYTES															
Absolute count CD4	X	X	X	X	X	X	X	X	X		X	X	X		X
PecentageCD4 lymphocytes	X	X	X	X	X			X	X		X	X	X	X	X
HIV RESISTANCE TEST		X									X				
Pregnancy test															
Urine pregnancy test	X	X	X	X	X	X	X	X	X		X	X	X		X
GLUCOSE	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Blood dipstick															
Urine dipstick	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Blood glucose															
SERUM ELECTROLYTES	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
LACTATE		X							X		X				

Note: These are divided into diagnostic tests used in the initiation of treatment and tests used in the monitoring of antiretroviral therapy. The national reference laboratories had the capacity to perform a majority of the diagnostic tests and had access to the treatment initiation and monitoring tests from other departments within the laboratory complexes.

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ISBN: 978-99968-0-127-3