NATIONAL HEALTH
LABORATORY SERVICE

Strategic Plan

Fiscal years

2018 – 2020

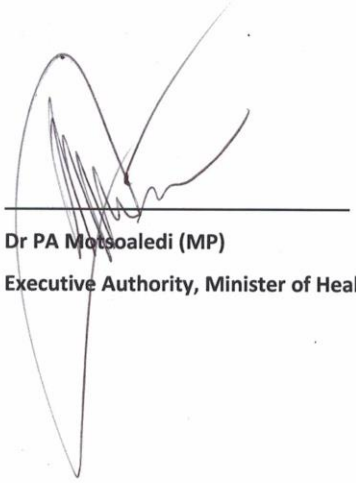
Tabling Date: March 2018

MINISTER'S FOREWORD

It is with great pleasure to present the National Health Laboratory Service's (NHLS's) revised Strategic Plan for the 2018/19 – 2019/20 financial years, which outlines what the entity intends to achieve during the last two years of the five-year strategic plan term of 2015/16 – 2019/20 period. The NHLS's Strategic Plan and APP are aligned to the South Africa health policies and mandates, for the Sustainable Development Goals (SDGs), the National Development Plan (NDP): Vision 2030 and the Medium Term Strategic Framework (MTSF) (2014 – 2019); as well as the National Department of Health (NDoH) strategy.

I am encouraged by the NHLS's commitment to ensure that the entity continues to provide quality, affordable and sustainable health laboratory and related public health services to all public healthcare providers, other government institutions and any private healthcare provider in need of service through its Strategic Plan period.

For this reason I would like to wish the NHLS success and all the best in achieving its strategy and mandate. My sincere gratitude goes to the Board for their strategic support and counsel, to the Executive team for their leadership and employees for being the real implementers of this strategy.



Dr PA Motsoaledi (MP)

Executive Authority, Minister of Health

STATEMENT – By the Chairperson of NHLS

This medium term NHLS Strategic Plan builds on the foundations of quality laboratory services consistently provided to the public health sector at low cost by its skilled staff focussed on the NHLS triple mandate of service, education and research. Progress has been made in a number of areas, such as professional staff retention, maintenance backlogs and supplier debt, but complex challenges face the NHLS going forward. These include financial and leadership stability and meeting increased demand for services at lowered real costs. This Strategic Plan provides a path forward for the NHLS to:

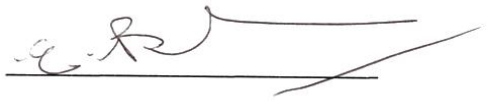
- Ensure an accessible pathology service, which subscribes to international standards, aligned to the national goal of modernised and accessible laboratory service
- Academic excellence as the foundation for meetings its training and research mandates.
- Sound Governance and improved stakeholder relations to ensure sound corporate governance and to ensure that regular payments are by users of the NHLS services.
- Effective, efficient and ethical organisation for improved service delivery and implementation of NHI. This will be realised through efficient of resources, integrated systems and improved monitoring and evaluation.
- Efficient financial practices to ensure efficient financial management, policy and practice and strengthen the management of financial resources and procurement processes.
- Skilled, competent and motivated workforce, which is the foundation of any successful organisation.

The NHLS enters this Strategic Period with a below inflation annual increase in tariffs, historic debt, and backlogs in payment by some Provincial Health Authorities. It needs to cover its improved salary packages and increased demand in the face of constrained government budgets. While financial performance has improved, more needs to be done. This Plan sets the path to be followed.

The electronic gate keeping has been implemented in all nine provinces to reduce the inappropriate ordering and repeat of laboratory tests in order to curb laboratory expenditure and promote the rational use of the laboratory service.

The NHLS shall develop and implement an effective contract management plan, which will ensure that there are active supplier contracts at all times, appropriate and functional equipment, and supplies to support uninterrupted service delivery.

Information Technology (IT), is integral in enabling the effective and efficient patient centred service delivery. It is for this reason that NHLS shall invest in modernised, innovative and efficient IT systems.



Professor Eric Buch

Chairperson of the Board (NHLS)

OFFICIAL SIGN OFF

It is hereby certified that this second draft Strategic Plan:

- Was developed by the management of the National Health Laboratory Service (Herein under referred to as the NHLS) under the guidance and support of the Board.
- Takes into account all the relevant policies, legislation and other mandates for which the NHLS is responsible.
- Accurately reflects the strategic goals and objectives which the NHLS will endeavour to achieve over the period 2018/19 – 2020/21.

Gabashane — 31 Jan 2018

Ms Violet Gabashane
SENIOR MANAGER: MONITORING AND EVALUATION **DATE:**

TDoki — 31/01/2018

Mr Tashen Dokie
ACTING CHIEF FINANCIAL OFFICER **DATE:**

KChetty — 31/01/2018

Dr Karmani Chetty
ACTING CHIEF EXECUTIVE OFFICER **DATE:**

31/1/2018

Professor Eric Buch
NHLS BOARD CHAIRPERSON **DATE:**

Approved by:

1/3/2018

Dr PA Motsoaledi (MP)
EXECUTIVE AUTHORITY, MINISTER OF HEALTH **DATE:**

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LIST OF ABBREVIATIONS

AARQA	Academic Affairs, Research and Quality Assurance
AIDS	Acquired Immune Deficiency Syndrome
AG	Auditor-General
CCMT	Comprehensive Care, Management and Treatment
CD4	Immune level indicator
CDC	Centres for Disease Control
CEO	Chief Executive Officer
DCST's	District Clinical Support Teams
HCT	HIV and AIDS Counselling and Testing
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
HTA	Health Technology Assessment
ICT	Information and Communication Technology
ISO	Organisation of International Standards
LIS	Laboratory Information System
MTSF	Medium Term Strategic Framework
NAPHISA	National Public Health Institutes of South Africa
NCR	National Cancer Registry
NDP	National Development Plan
NDoH	National Department of Health
NHA	National Health Act
NHI	National Health Insurance
NHLS	National Health Laboratory Services
NICD	National Institute for Communicable Diseases
NIOH	National Institute for Occupational Health
NPP	National Priority Programme
NPPU	National Priority Programme Unit
NSF	National Stakeholder Forum
OHSACT	Occupational Health and Safety Act

PAIA	Promotion of Access to Information Act
PDPs	Personal Development Plans
PMTCT	Prevention of Mother to Child Transmission
POCT	Point-of-Care-Testing
POPI	Protection of Personal Information Act
QMS	Quality Management System
SANAS	South African National Accreditation System
SOP's	Standard Operation Procedures
TAT	Turn Around Times
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights

PART A: STRATEGIC OVERVIEW

1. Vision

Efficient Patient Centred Services and Global Centre of Excellence for Innovative Laboratory Medicine.

2. Mission

To provide quality, affordable and sustainable health laboratory services through an integrated network of laboratories, the provision of training for health science education and the execution of innovative and relevant research with focus on patient care.

3. Introduction

In our vision as National Health Laboratory Service (NHLS), we put the patients first by providing services which are clinically excellent, responsive, cost effective, equitable and integrated with other elements of the Department of Health's strategy.

4. Values

The NHLS has identified the following values as the principles that will govern behaviour of all employees within the organisation:

#	Value	Description
3.1	Care	*The primary goal of the NHLS is to ensure the overall care and well-being of patients by supporting a strong and effective public healthcare system. In addition, we also care about the environment and society*: This involves consideration of our impact on the environment and local communities, acting with concern and sensitivity. We are committed to behave ethically and contribute to the economic development of the workforce, community and society at large. It's about giving back to the society and the environment as well as capacity building for a sustainable future.
3.2	Unity of Purpose	*All Working together towards a common goal*: All employees should be united by a common vision and support each other in contributing to a beneficial and safe working environment. Teamwork and cohesion are

#	Value	Description
		key and collaboration should include pooling resources and communicating about each other's roles. We foster trust and honesty in interactions with colleagues and behave professionally. We value all contributions, treat everyone consistently and fairly and capitalise on diverse viewpoints. We will address and resolve conflicts effectively. We will listen to others to fully understand and give clear, concise information when communicating expectations and accountabilities and providing feedback during coaching. We will make the NHLS' goals a priority, use NHLS' resources wisely and effectively and take responsibility for our work.
3.3	Service Excellence	V*aluing good work ethics and striving towards service excellence for customers*: This represents being committed to working with customers and building good relationships with them by understanding their needs, responding quickly and providing appropriate solutions. We will treat them with respect at all times; we are helpful, courteous, accessible, responsible and knowledgeable in our interactions. We understand that we have internal and external customers that we provide services and information to. This information should be presented in a clear and concise form, where the message is adapted to the audience.
3.4	Transformation	*Looking forward to the future and growing together*: We will encompass investing in professional growth of staff by sharing knowledge and experience, peer networking, education through training and seeking opportunities to develop. We will enable equitable representation of Race, Gender and People with Disabilities across all occupational levels within the organisation. This covers creative problem solving, informed risk-taking, learning from our mistakes and experiences and behaving professionally. We should adapt to change timeously and positively, address setbacks and ambiguity and adapt our thinking/approach as the situation changes to ensure long-term sustainability of transformation. Our ideas will be shared and implemented effectively. Leaders should develop innovative

#	Value	Description
		approaches and drive continuous improvement as well as effective and smooth change initiatives.
3.5	Innovation	*Pioneering relevant research to address health challenges:* We are committed to fostering an environment that supports research, with particular emphasis on innovative approaches to diagnostics, surveillance and health systems strengthening to support national programs. We will work on identifying needs for priority health challenges in South Africa within the laboratory and at the clinical-laboratory interface. We will encourage operational research with an emphasis on measuring the impact of diagnostic interventions on patient care, ensuring these are cost effective, affordable, accessible and evidence-based. We will support the investment in the analysis of "big data' for surveillance of public health needs but also for addressing individual and community based healthcare needs. We will encourage social entrepreneurship and support innovative ideas and individuals to enable translation of new products and processes into clinical practice. We will encourage pioneering personalities to operate outside the classic research paradigm and generate intellectual property for which they are rewarded and adequately acknowledged. Partnerships with various universities, donors, NGOs and relevant government departments are critical to creating the needed space, funds and sustainability. Mentoring and communication with senior managers to change the way they view laboratory services will be a necessity. Novel approaches to training will be considered in the face of scarce skills, a large laboratory footprint and the ever-changing economic pressure on traditional learning structures.
3.6	Integrity	*Working with integrity, ethics and responsibility:* We will set and achieve goals, consistently delivering business results while complying with standards and meeting deadlines. We will display commitment to organisational success and ethical behaviour; proactively identifying ways to contribute and taking initiative to address

#	Value	Description
		problems/opportunities. We will build efficiencies in the best use of public resources. We will ensure integrity of financial information, and annual financial statements.

5. Legislative and other mandates

The NHLS[1] is the largest diagnostic pathology service in South Africa with the responsibility of supporting the national and provincial health departments in the delivery of healthcare. The NHLS provides laboratory and related public health services to over 80% of the population through a national network of laboratories. Its specialised divisions include the National Institute for Communicable Diseases, National Institute for Occupational Health, National Cancer Registry, Diagnostic Media Products and South African Vaccine Producers. The legislative mandate of the NHLS is broadly derived from the Constitution, the National Health Act, 2003 (Act No. 61 of 2003), the National Health Laboratory Service Act, 2000 (Act No. 37 of 2000) (hereinafter referred to as the "NHLS Act"), and several pieces of legislation, regulations and policies passed by Parliament. The primary legislative mandate is from the NHLS Act.

5.1 Constitutional Mandate

In terms of the Constitutional provisions, the NHLS is, amongst others, guided by the following sections and schedules and its role is to contribute towards:

1) The Constitution of the Republic of South Africa, 1996, places obligations on the state to progressively realise socio-economic rights, including access to health care.
2) Section 27 of the Constitution states as follows: with regards to Health care, food, water, and social security:

   (1) Everyone has the right to have access to –

   (a) health care services, including reproductive health care;

   (b) sufficient food and water; and

   (c) social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.

   (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights; and

   (3) No one may be refused emergency medical treatment.

[1] www.nhls.ac.za

5.2. National Development Plan 2030 vision

The National Development Plan (NDP) sets out nine (9) long-term health goals for South Africa. Five of these goals relate to improving the health and well-being of the population, and the other four deals with aspects of health systems strengthening. NHLS' role is to contribute and align its services to the National Development Plan vision 2030.

By 2030, South Africa should have:

1. Raised the life expectancy of South Africans to at least 70 years;
2. Progressively improve TB prevention and cure;
3. Reduce maternal, infant and child mortality;
4. Significantly reduce prevalence of non-communicable diseases;
5. Reduce injury, accidents and violence by 50 % from 2010 levels;
6. Complete Health system reforms;
7. Primary healthcare teams providing care to families and communities;
8. Universal health care coverage; and
9. Filled posts with skilled, committed and competent individuals.

The NDP 2030 states explicitly that there are no quick fixes for achieving the nine goals outlined above. The NDP also identifies a set of nine (9) priorities that highlight the key interventions required to achieve a more effective health system, which will contribute to the achievement of the desired outcomes. The priorities are as follows:

a. Address the social determinants that affect health and diseases;
b. Strengthen the health system;
c. Improve health information systems;
d. Prevent and reduce the disease burden and promote health;
e. Financing universal healthcare coverage;
f. Improve human resources in the health sector;
g. Review management positions and appointments;
h. Strengthen accountability mechanisms;
i. Improve quality by using evidence; and
j. Meaningful public-private partnerships.

5.3. Sustainable Development Goals 2030

The Sustainable Development Goals (SDG) 2030 built on Millennium Development Goals 2015 were adopted as the Global Goals by world leaders on 25 September 2015. There are 17 Sustainable Development Goals (SDGs) to end poverty, fight for equality and tackle climate change by 2030. The following targets have been adopted for Goal 3 "Ensure healthy lives and promote well-being for all at all ages:

1. By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births;

2. By 2030, end preventable deaths of new-borns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortalities to at least as low as 25 per 1,000 live births;

3. By 2030, end the epidemics of AIDS, Tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases;

4. By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being;

5. Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol;

6. By 2020, half the number of global deaths and injuries from road traffic accidents;

7. By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes;

8. Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all;

9. By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination;

10. Strengthen the implementation of the World Health Organisation Framework Convention on Tobacco Control in all countries, as appropriate;

11. Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all;

12. Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and Small Island developing States; and

13. Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.

5.4 The National Department of Health Strategic Plan 2015-2020

The overall laboratory strategy and annual performance plans are aligned to the National Department of Health's (NDoH) Strategic Plan for the same period (Department of Health Strategic plan, 2015-2020)

The Department of Health's five year strategic goals are:

- Prevent diseases and reduce their burden, and promote health;

- Make progress towards universal health coverage through the development of the National Health Insurance scheme' and improve the readiness of Health facilities for its implementation;

- Re-engineering primary healthcare by: increasing the number of ward based outreach teams, contracting general practitioners, and district specialist teams, and expanding school health services;

- Improve health facility planning by implementing norms and standards;

- Improve financial management by improving capacity, contract management, revenue collection and supply chain management reforms;

- Develop an efficient health management information system for improved decision making;

- Improve the quality of care by setting and monitoring national norms and standards, improving systems for user feedback, increasing safety in health care, and by improving clinical governance;

- Improve human resources for health by ensuring appropriate appointments, adequate training and accountability measures

5.5. The National Health Act, 61 of 2003

The above mentioned Act provides a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services. The objects of the National Health Act (NHA) are to:

- unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation;
- promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans; and
- create the foundations of the health care system, and must be understood alongside other laws and policies which relate to health.

5.6. The National Health Laboratory Service Act, 37 of 2000

This Act mandates the NHLS to provide cost-effective and efficient health laboratory services to all public sector health care providers; any other government institution inside and outside of the Republic that may require such services; and any private health care provider that requests such services. The Act also mandates the NHLS to support health research; and provide training for health science education.

The National Health Laboratory Service Amendment Bill was submitted to parliament to amend the NHLS Act so as to define certain expressions and to delete a definition, to make Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000) applicable to the NHLS to adjust the objects and duties of the service and to strengthen the governance and funding mechanism of the Service and to provide for matters connected therewith.

5.7 Other planned legislative and policy initiatives

The NHLS will also support the following policy initiatives:

5.7.1. National Public Health Institute of South Africa (NAPHISA)

The envisaged establishment of the National Public Health Institutes of South Africa (NAPHISA), comprising divisions dealing with the following:

(a) Communicable Diseases;

(b) Non-Communicable Diseases including Cancer Surveillance

(c) Injury and Violence Prevention; and

(d) Occupational Health and Safety

The establishment of NAPHISA as a single national public entity is intended to provide a high level of coordination across functions for surveillance. The entity will provide evidence, expertise and advice the government to achieve improvements in the health of the population; it will provide coordinated disease and injury surveillance, research, training and workforce development, monitoring and evaluation of services and interventions directed towards the major health problems affecting the population; provide training, conduct operational research and support interventions aimed at reducing the burden of communicable; non-communicable diseases; injuries and violence and occupational health and safety.

The NAPHISA Bill has been tabled in Parliament and the anticipated implementation date is currently not known.

5.7.2. National Health Insurance

The phased implementation of National Health Insurance (NHI) is intended to ensure integrated health financing mechanisms that draw on the capacity of the public and private sectors to the benefit of all South Africans. The policy objective of NHI is to ensure that everyone has access to appropriate, efficient, affordable and quality health services.

To achieve universal health coverage, institutional and organisational reforms are required to address structural inefficiencies; ensure accountability for the quality of the health services rendered and

ultimately to improve patient centred health outcomes particularly focusing on the poor, vulnerable and disadvantaged groups.

The NHLS together with the Department of Health are working on means to reduce laboratory diagnostic test costs through rational laboratory usage and electronic gate keeping projects. The NHLS is optimising its strategic position as a partner to the Department of Health through collaboration at various levels, i.e. from Health Facilities, District, Region, Provincial Tertiary and National Central to National Department of Health.

The public pathology services in South Africa constitute less than 3% of the total health spend in the public sector and yet the benefit of pathology to health is established in both developed and developing countries, from training of undergraduate and postgraduate health professionals to clinical consultation, surveillance, infection control and prevention, diagnosis and monitoring of disease. Data from developed countries show that pathology services are important in 70-80% of critical medical decisions.

Health promotion, strongly emphasised in the NHI policy, requires a thorough understanding of the epidemiology of disease in South Africa. National laboratory surveillance is crucial to providing detailed information on the national and local level to inform policy and drive appropriate interventions. The NHLS has significant surveillance capacity with a data powerhouse supported by a seamless Laboratory Information System (LIS). In this regard, the NHLS is a national asset.

6. Situational Analysis

6.1 Performance Environment

6.1.1. Introduction

This document reflects a mid-term strategic review of the National Health Laboratory Service (NHLS) Strategic Plan (2015-2020). The overall laboratory strategy and Strategic Plan are aligned to the NDoH's Strategic Plan for the same period (Department of Health Strategic plan, 2015-2020). The NHLS has aligned its strategic goals to the NDoH's five (5) year strategic goals. According to the Framework for Strategic Plans and Annual Performance Plans ("the Framework"), issued by the National Treasury, a Strategic Plan should extend over at least five years; however, a review is allowed during this process. This deviation must be limited to revisions related to significant policy shift or changes in the service-delivery environment. Several Organisational changes as well as a change in national programs and priorities have necessitated this review. Provision of Laboratory Services is a dynamic process and thus there is a constant

evolution of needs as clinical treatment changes occur and new technology becomes available for laboratories and systems in the digital economy.

The Board reviewed and updated the five (5) year strategic plan, and aligned it to address the governance issues raised in the 2016/17 Auditor General's audit opinion.

6.1.2. The Landscape in South Africa

Medical testing laboratories are distributed across the public and private health sector in South Africa. The NHLS was established in 2000 by an Act of Parliament to provide pathology services for the public health sector, servicing over 80% of the population across all 9 provinces. The population of South Africa is growing rapidly with recent figures suggesting 56,52 million individuals (STATS SA, July 2017, mid-year population estimates) who require healthcare compared to the 53,7 million estimated in 2014, just prior to the development of the current 5-year strategic plans. The demographics, geographic distribution and prevalence of disease contributes greatly to the type and capacity of laboratory services required.

Gauteng (14,3 million) is the most highly populated province, followed by Kwa Zulu Natal (11,1 million), both provinces are characterised by migration and significant population influxes. South Africa has a young population with at least 29.6% less than 15 years of age and only 8% greater than 60 years. Life-expectancy varies across gender and age groups, with males significantly lower than females at 61,2 years versus 66,7 years, respectively. Nearly 1 million births occur per annum with most occurring to mothers in the 20-24-year age group (31%) and an alarming number in the 10-19 year (13.9%) category (STATS SA, 2016: recorded live births).

The priority diseases in South Africa remain the HIV and TB epidemics which require significant volumes of testing to support their management, the sheer burden of which is unparalleled globally. With the increased pressure of the HIV 90:90:90 targets and END TB strategies, this is likely to remain an important mandate of the NHLS. The prevalence of HIV is estimated at 12,6% for the general population and rises to 18% in the 15-49-year age group. Over 7 million South Africans are HIV infected with approximately 4,3 million individuals on antiretroviral therapy. The recent WHO report confirms the unique nature of these epidemics in South Africa where high rates of co-infection occur, further challenging diagnostic assay algorithms and needs (WHO, Global Tuberculosis Report, 2017). At least 69% of TB cases are co-infected with HIV. Tuberculosis has showed signs of decline in South Africa, but a prevalence of 380/100 000 (210-590) and incidence of 450/100 000 (400-510) confirm that there is still much to be done. As treatment progress has been made, an inevitable consequence has been the development of both HIV drug resistance and multi/extremely drug-resistant (MDR/XDR) TB, requiring new technologic approaches to diagnosis and monitoring. The rapid acceleration plans for HIV and TB treatment access will have a knock-

on effect on the NHLS that will require significant program review with the automation, modernization, consolidation and integration of laboratory platforms and services to ensure affordability. The accelerated HIV treatment initiation plan alone will impact heavily on the investment requirements of the NHLS, if the targets of 6 million on treatment by 2019/2020 are to be realised.

The most recent mortality reports reflect that tuberculosis remains the leading cause of natural deaths, followed closely by diabetes and cardiovascular disease. Non-communicable diseases now contribute to 60% of the top ten causes of death (STATS SA, Mortality and causes of death 2015, released February 2017). This will require significant strategic planning for supportive laboratory services.

A wave of non-communicable diseases is likely to add further requirements to laboratory services with Cancer predicted to increase by at least 30% by 2030 with annual figures reaching an estimated 10 million cases (Lancet,2017). In a recent survey in rural South Africa, high rates of stroke, cardiovascular disease, hypertension and dyslipidemia was noted in addition to HIV, with at least 56% of individuals having 2 or more of these diseases (Hofman,2014: SAMJ). By 2030 it is predicted that non-communicable diseases (NCDs) will account for over 6-fold more morbidity than Communicable Diseases. Due to the high burden of communicable diseases, non- communicable diseases have not been the priority of the National Department of Health and have not received enough attention. This is changing as demonstrated by national public health policies released recently to facilitate national access to diagnosis and care for Cervical and Breast Cancers (NDoH Breast cancer, Prevention and control policy; Cervical cancer policy, August 2017). In addition, occupational, environmental and safety risk factors, including workplace exposures and injuries, are significant contributors to the global burden of diseases and to morbidity and mortality (The Lancet 2016 Vol 388, Issue 10053, p1659-1724). These examples clearly demonstrate the increasing need and greater investment in precision laboratory medicine to facilitate greater prevention in public health. Much needs to be done on the laboratory front where there are only 230 pathologists serving the public sector and only 75 anatomical pathologists [1 per 750 000 of the population (NHLS, 2017)].

This occurs in the backdrop of a decline in economic growth, budget deficits and rising health care costs. There is thus a huge role for embedding innovation into the culture of the organisation.

7. Organisational environment

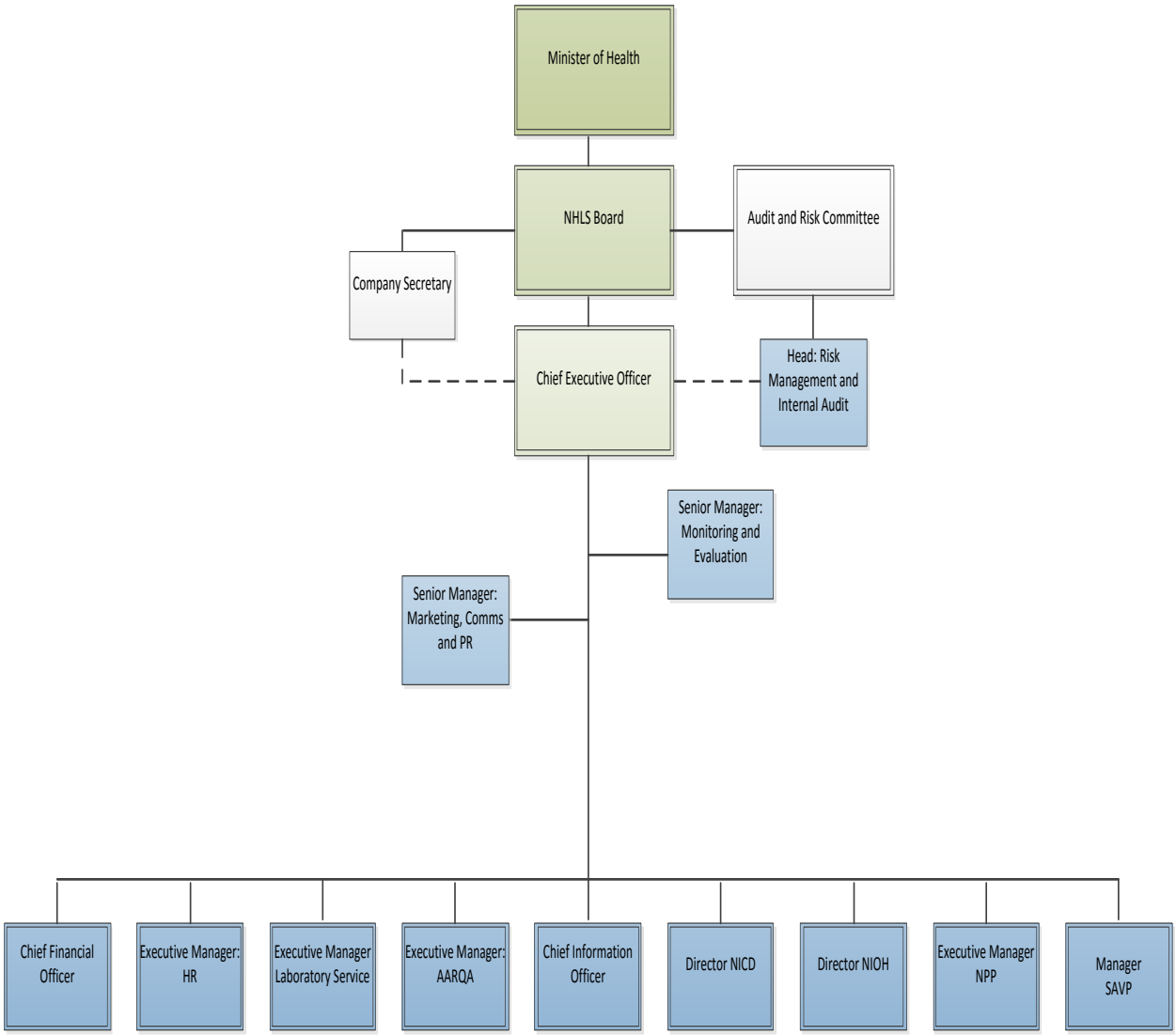
7.1. Organisational Structure – Management Structure

The NHLS Board of Directors (The Board) is the accounting authority of the NHLS in terms of the NHLS Act (Act 37 of 2000). Members of the Board are appointed by the Minister of Health.

The CEO is appointed by the Board. The Board further appoints the Executive Managers and they are accountable to CEO. The-Board Secretary and the Manager: Audit and Risk have dual reporting lines. They are accountable to the Board and the Audit and Risk sub-committee respectively. They both accountable to the CEO administratively.

The CEO appoints managers to his/her office for effective running of the office. The following managers are accountable to the CEO: Senior Manager: Monitoring and Evaluation; and the Senior Manager: Communications, Marketing and Public Relations.

The diagram below provides an indication of the high level organisational structure within the NHLS



7.2 Network of Laboratory Services

The National Health Laboratory Service (NHLS) is a national public entity established in terms of the NHLS Act) to provide quality, affordable and sustainable health laboratory and related public health services to

all public healthcare providers, other government institutions and any private healthcare provider in need of service. It was also mandated to support health research and provide training for health science education.

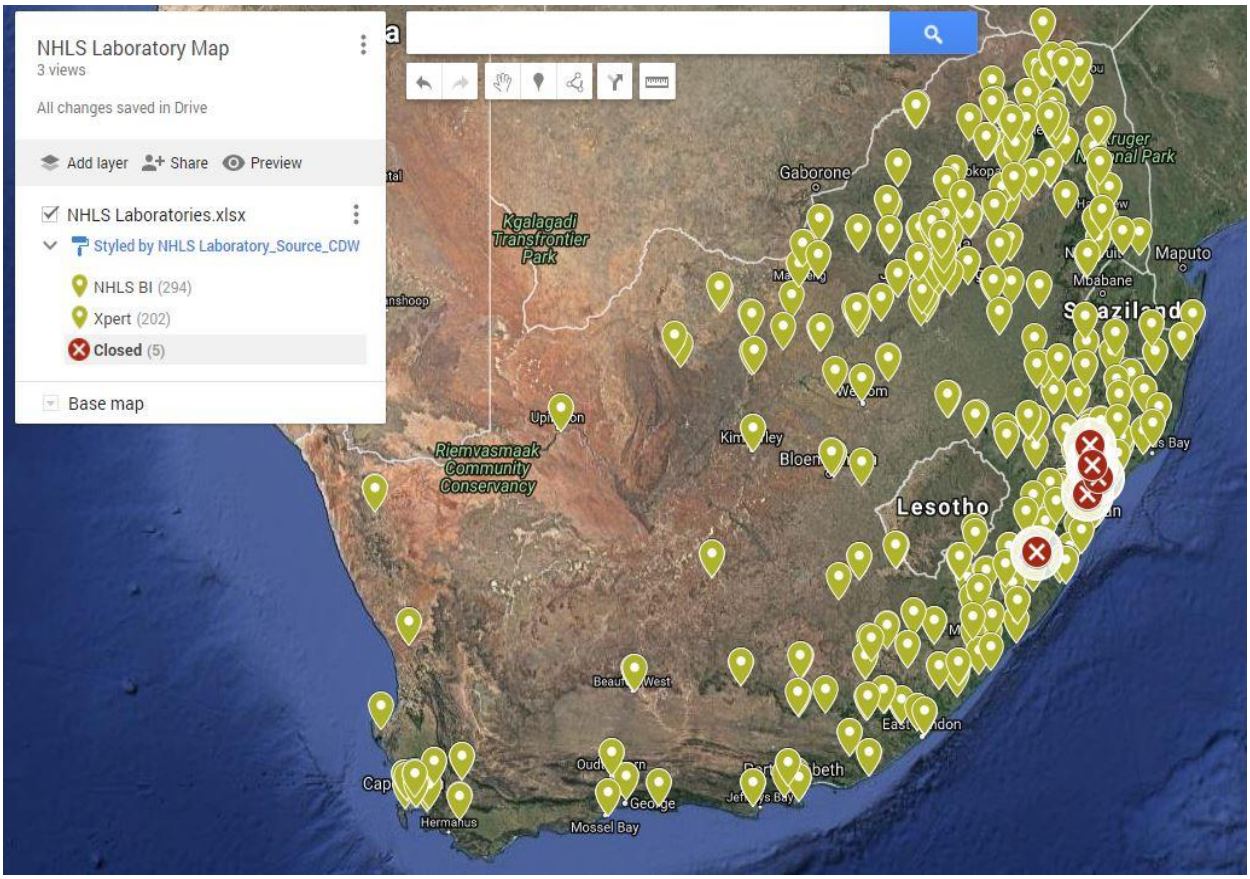
It was designed to be a self-funded body raising funds from the diagnostic tests for provincial health departments. The NHLS is the main provider of clinical support services to the national, provincial and local departments of health through its countrywide network of quality assured diagnostic laboratories. It conducts diagnostic tests, produces highly acclaimed research, and provides teaching and training for medical technicians, medical technologists and pathologist. The NHLS also provides surveillance support for communicable diseases, occupational health and cancer, and thus the endeavour to align its strategy to both the Department of Health priorities and the National and Regional Burden of Disease Surveillance.

According to the strategic overview by National Treasury, the NHLS is the largest diagnostic pathology service in South Africa, with a network of approximately 268 pathology laboratories. The NHLS is responsible for most HIV and tuberculosis tests in the public health system and plays a critical role in screening for cervical cancer. HIV and TB treatment depend on accurate and timely tests.

A unique feature of the NHLS is that all 268 public-sector laboratories are networked using a single laboratory information system (LIS) facilitating standardised reporting, monitoring and evaluation (see figure 1). All data are stored in a Central Data Warehouse (CDW), which has become a national resource for program design, monitoring and evaluation.

The NHLS was formed by bringing together several organisations; South African Institute for Medical Research (SAIMR), Institute for Virology (NIV), National Centre for Occupational Health (NCOH), and all provincial health laboratory services. The NIV and the NOCH are now known as National Institute for Communicable Disease(NICD) and National Institute for Occupational Health (NIOH) respectively. Since the formation of the NHLS in 2000, these Institutions have been cross-subsidised with revenues from the NHLS. This was a burden for the NHLS, which itself was facing financial concerns. However, the two Institutions (NICD and NIOH), currently receive funding from the Department of Health for teaching, training and research.

Figure1: National Distribution of Laboratories.



The NHLS laboratories are predominantly based in the health care facilities, in all 9 provinces, with their complexity increasing with the level of care of that facility. The highest level of care is provided at the National Central Hospitals and the lowest level at Primary Health Care Facilities.

The complexity of service requirements and the large number of health care facilities that require a pathology service means a renewed focus needs to be placed on innovation and new approaches to laboratory systems across the entire laboratory value chain. A multi-disciplinary approach to the service design and planning will need to be maintained. The increased demands mean appropriate workforce development with staff retention being an important focus as we move forward.

7.2.1 Linkages within the NHLS Laboratories

The National Central Laboratories(Academic) based in all ten (10) National Central Hospitals are:

Charlotte Maxeke National Central Laboratories, Chris Hani Baragwaneth National Central Laboratories, Dr George Mkhari National Central Laboratories, Tshwane Academic Division National Central

Laboratories, Inkosi Albert Luthuli National Central Laboratories, King Edward National central Laboratories, Groote Schuur National Central Laboratories, Tygerberg National Central Laboratories, Universitas National Central Laboratories and Nelson Mandela National Central Laboratories, offer routine and highly specialised laboratory services and act as referral centre for lower level laboratories. The National Central Laboratories also offer training for health professional in collaboration with the Medical Universities and the Universities of Technology.

The next level of care is the Provincial Tertiary Laboratories and the Regional Laboratories, and there are 17 Provincial Tertiary and 42 Regional Laboratories respectively. They also offer routine laboratory service and act as referral centres for lower level laboratories. The lowest level of care is provided at District Laboratories, and there are 199 District Laboratories. They offer limited routine laboratory service and some are depots. (Annexure A: All NHLS laboratories and Depots)

6.2.2 National Institute for Communicable Disease

The National Institute for Communicable Diseases (NICD) is a national public health institute for South Africa providing reference microbiology, virology, epidemiology, surveillance and public health research to support the government's response to communicable disease threats.

The NICD has served and continues to serve as a publicly-trusted source of data on communicable diseases, both during the outbreak threats and as part of its routine surveillance of priority infectious diseases.

The Centre for Tuberculosis (CTB) is part of the NICD and it conducts laboratory-based public health surveillance of TB in South Africa, serves as a National TB reference laboratory (NTBRL) and participates in microbiology and epidemiology-oriented training programmes. The CTB also initiates applied public health research aimed at providing enhanced intelligence on the drivers and protective factors that underlie the TB epidemic in South Africa. It furthermore advises and works closely with the Department of Health (DoH) on strategic planning and assists with policy and guideline formulation concerning the diagnosis and treatment of TB in South Africa. Global policies and guidelines are initiated through the World Health Organization (WHO) and their formulation has included representation from the CTB which assisted in developing these strategic documents (www.nicd.ac.za/index.php/centres/centre-for-tuberculosis)

7.2.3 National Institute for Occupational health

The National Institute for Occupational Health (NIOH) is a National Public Health Institute, which provides occupational and environmental health and safety (OEHS) support across all sectors of the economy to

improve and promote workers' health and safety. Among its core functions are research and surveillance and the provision of teaching and training in OEHS.

The NIOH provides discipline-specific advisory services to national and provincial government departments including the Medical Bureau for Occupational Diseases (MBOD) of the NDoH as well as most industrial sectors and the informal economy. Its laboratory work includes asbestos identification and counting; diagnostic lung pathology; analytical chemistry (e.g. for biological monitoring specimens); the identification of components of dusts (respirable crystalline silica in particular); microbial air sampling; allergy diagnostics; nanoparticles and in vitro risk assessments. Discipline-specific specialist services include occupational medicine, HIV and TB at work, occupational hygiene, occupational toxicology, immunology and microbiology and occupational epidemiology. Information services constitute a core public health activity and involve the production and dissemination of publications on important topical issues and respond to occupational queries from a multitude of clients. The unique national occupational health library continues to provide support and information well beyond the borders of South Africa. The NIOH currently houses a Biobank in development, oversees the Gender@Work Programme and implements and monitors the innovative Occupational Health and Safety Information System (OHASIS).

6.2.4 South African Vaccine Producers

The South African Vaccine Producers (SAVP), a wholly owned subsidiary of the NHLS, has continued to supply strategic products, with global reach. Excellent feedback was received from as far as Spain and Thailand, including a report from Kenya stating that "the antivenom has saved lives in these serious snakebite areas".

6.2.5 Diagnostic Media Products

There is currently three (3) Diagnostic Media Products (DMP) Units within the NHLS which are responsible for producing microbiological culture media and reagents for use in clinical diagnostic laboratories. The media produced are supplied internally to NHLS laboratories, as well as externally to private laboratories and some laboratories within Africa.

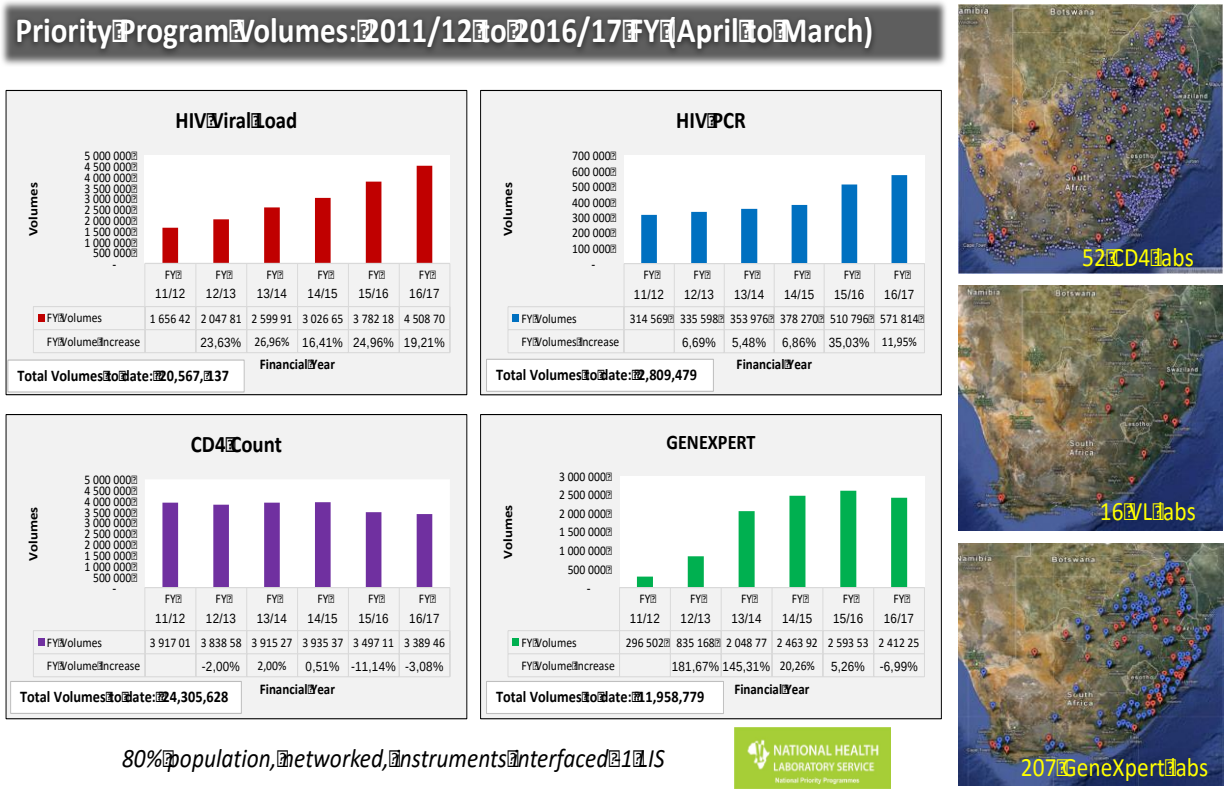
6.3 National Priority Programme

7.3.1 HIV and Tuberculosis (TB)

In line with the priorities of the National Department of Health, HIV and TB are generalized epidemics with high prevalence and incidence rates as previously described. The response by the NHLS to this crisis has been the establishment of a National Priority Programme (NPP) to manage these diseases. The National Priority Programme has been tasked to increase the capacity of HIV testing essential for diagnosis and monitoring in adults and infants, increase the capacity for diagnosis of TB and drug resistance and continuous engagement with the NDoH, and other stakeholders such as non-governmental organisations, donors and civil society involved in the execution of HIV prevention and treatment programs. These programmes have assisted in standardisation of assays, platforms and algorithms to facilitate monitoring and evaluation and to create the ability to scale testing as needed and to leverage on economies of scale. Assays that are core to the HIV programme currently include the HIV PCR assay for early infant diagnosis (EID) of HIV, the HIV viral load (VL) and CD4 assays for monitoring of clinical treatment success and the HIV drug resistance assay (HIV DR). The supporting assays include safety testing for diagnosis of adverse events and diagnosis of other opportunistic infections such as TB and hepatitis, amongst others. The NHLS has been instrumental in providing national access to molecular TB testing through a footprint of laboratories and assays including the TB Xpert assay for diagnosis of pulmonary and extra pulmonary TB, the line probe assay (LPA) and culture for the diagnosis of MDR and XDR TB, in an appropriately automated algorithm.

The HIV programme is highly centralised in 16 laboratories for the VL and EID assays with a potential annual capacity of 10 million assays should the service be used efficiently internally (NHLS CDW data, 2017). There is a footprint of 52 CD4 laboratories within the NHLS. For TB, as per NDoH request, the assays are conducted on the GeneXpert analyser in 207 laboratories nationally. The footprints and volumes are presented in figure 2 below which, not only provides a commentary on the volumes over the period of review but provides graphics of the laboratory locations GIS mapped to the location of healthcare facilities.

Figure 2: National Priority Tests: Volumes and Laboratory Footprint: 2011/12 – 2016/17



For the 2014/2015 financial year (FY) forming the baseline to the strategic plan development, just over 3 million viral loads were conducted. In the first two years of this review period (2015/16 and 2016/17), there was an unprecedented increase in annual volumes with 3 782 180 (a 24,5% increase over the baseline), and 4 508 700 (19,2% increase) viral loads conducted respectively. Virological suppression rates (defined as VLs <1000) remain at a national average of 80%, but there is a significant difference in suppression rates geographically between provinces, districts and at a facility level. As predicted by the change in national HIV treatment guidelines with less reliance on CD4 monitoring and more recently the implementation of the Universal Test and Treat (UTT) strategy (September 2016), there has been a 14% decline in CD4 volumes over the period of the review. There has been a noticeable increase in CD4 counts >500 reflecting an increase in general population wellness, but an alarming 10% are still presenting nationally with CD4 counts <100. HIV PCR testing for infants has increased significantly in the same period which is expected in line with global and national guideline changes, which require both birth and 6- week PCR assays to reduce the early infant mortality rates associated with any delay in treatment initiation.

The TB Xpert assay reached a peak in the 2015/2016 FY where 2,593 530 assays were performed but has shown a subsequent decline of nearly 7% in the 16/17 FY. It is uncertain whether this is a natural decline in passive diagnosis as TB decline occurs or whether this is due to financial pressure of the assay from a

clinical and laboratory perspective. It is clear a more sensitive assay is required for TB testing and thus the implementation of the Xpert ULTRA assay is underway.

Global trends likely to impact on the HIV and TB testing platforms include the need for HPV, HBV and antimicrobial resistance testing, amongst others. The polyvalence capabilities and increasingly random-access capabilities will enable re-purposing of molecular platforms.

7.4. Non Communicable Diseases

Stroke, Heart attacks, Diabetes, Cancer, Asthma and Depression are identified as other Non-Communicable Diseases (NCDs) (Debbie Bradshaw et.al). Little attention has been focused on risk factors associated with NCDs and management thereof (Debbie Bradshaw et.al.). The NHLS plays a role in supporting the Department of Health by:

- testing for blood glucose level and HbA1c, for management of diabetes,
- testing for lipids and blood cholesterol levels for the management of heart diseases, and
- screening for cancer.

The National Cancer Registry (NCR) is housed at the NICD and its core function is cancer surveillance through pathology based cancer registry and implementation of population based cancer registration as per Regulation 380 of the National Health Act, together with cancer research and training.

The year 2016/17 has been a year of extensive growth and change in NCR. Several posts for epidemiologists, medical scientists and surveillance officers were filled, allowing for adequate personnel to move surveillance and research forward. The backlog in cancer coding from previous staff shortages has been greatly reduced, with cancer coding for 2014 completed and 2012 incidence data published. Establishment of the pilot population based registry in Ekurhuleni is underway, with surveillance officers placed in both private and public health facilities.

The NCR published key research in breast cancer patterns in South Africa, which highlighted the increased risk of breast cancer and younger age at diagnosis in white and Asian women compared to other population groups. Using probabilistic record linkage techniques, we linked HIV cohort data to NCR data and demonstrated a high cancer incidence in the HIV-infected population. We also reviewed current evidence on HIV-related malignancies in children in the context of ART availability. We found that cancer risk remains high in children who start ART at older ages or more advanced immunosuppression. Starting ART before severe immunosuppression develops is key to cancer prevention in HIV-infected children.

7.5. Human Resources

Human Resources (HR) is one of the greatest challenges in the NHLS. The NHLS is currently facing the following workforce challenges:

- Recruitment and retention of skilled professionals.
- Fiscal constraints which impacts on the filling vacancies.
- Lack of an integrated performance management system which is linked to pay progression and incentives.
- Inequitable distribution of Human Resource between rural areas and urban areas within NHLS; and private sector and NHLS
- Migration of skilled professionals internationally
- Instability at the leadership level, which leads to lack of direction and low staff morale.

An in depth analysis of current and future Human Resource needs, which must be linked to workload and rational use of organisation's resources, is required to enable the organisation to achieve its set goals. Standards and norms need to be developed to develop the organisational structures across different tiers of laboratory facilities.

The NHLS has number of HR policies and strategies approved in order to attract and retain critical and scarce skills. Various strategies on the recruitment, retention, pay progression and proficiency assessment need to be integrated and harmonised.

The roll-out of the Reward and Remuneration Project is one of the interventions that reflects the NHLS' commitment to its employees.

The introduction of the workforce model will play a vital role in Human Resource planning to meet the organisation's mandate. This will be linked to comprehensive Human Resource plan to determine current and future needs both in service provision and training.

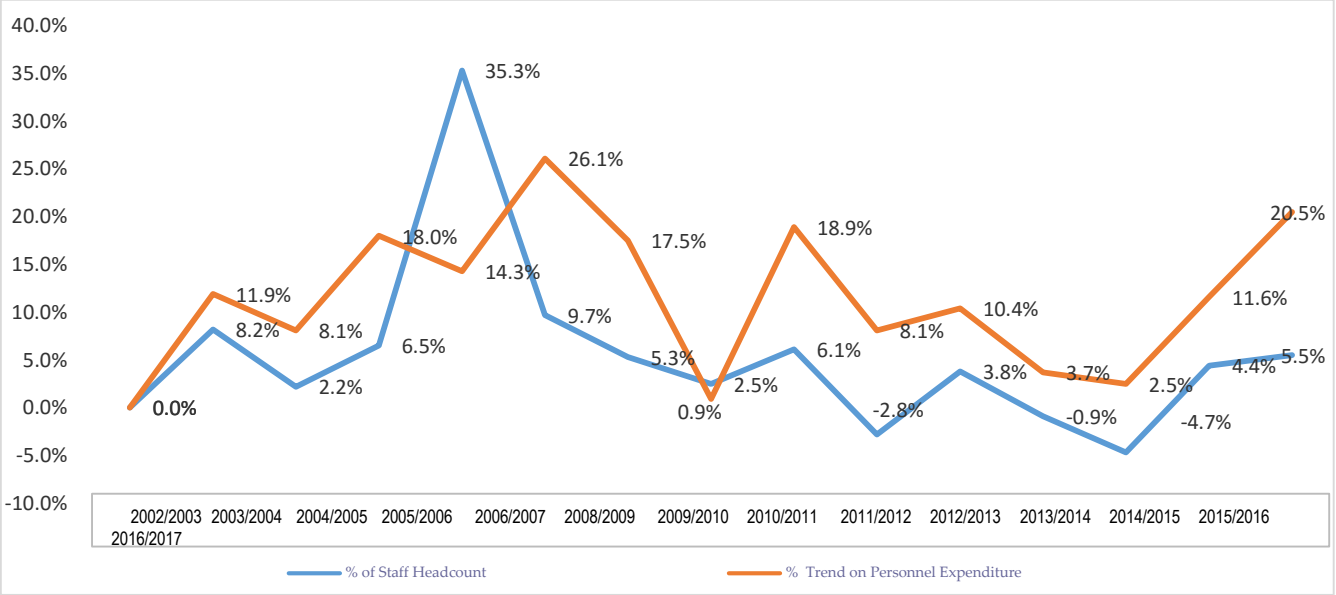
Training and development is one of the mandates of NHLS and provides a pipeline of the talented professionals for the NHLS and South Africa as a whole.

7.5.1 Human Resource Oversight Statistics

Table 1: Percentage changes of staff headcount compared to personnel expenditure – 2003 to 2017

Year	Staff Headcount	Nominal Increase	Trend % on Staff Headcount	R'000	Nominal Increase R'000	Trend %on Personnel Expenditure
2002/2003	3 509	0	0.0%	489,363	0	0.0%
2003/2004	3 797	288	8.2%	555,503	66,140	11.9%
2004/2005	3 880	83	2.2%	604,757	49,254	8.1%
2005/2006	4 132	252	6.5%	737,061	132,304	18.0%
2006/2007	5 591	1459	35.3%	859,829	122,768	14.3%
2007/2008	6 132	541	9.7%	1,163,943	304,114	26.1%
2008/2009	6 458	326	5.3%	1,410,751	246,808	17.5%
2009/2010	6 619	161	2.5%	1,424,235	13,484	0.9%
2010/2011	7 020	401	6.1%	1,755,575	331,340	18.9%
2011/2012	6 826	-194	-2.8%	1,910,695	155,120	8.1%
2012/2013	7 087	261	3.8%	2,131,458	220,763	10.4%
2013/2014	7 023	-64	-0.9%	2,212,252	80,794	3.7%
2014/2015	6 695	-328	-4.7%	2,268,476	56,224	2.5%
2015/2016	6 987	292	4.4%	2,565,987	297,511	11.6%
2016/2017	7 369	382	5.5%	3,228,470	662,483	20.5%

Graph 1: Percentage changes of staff headcount compared to personnel expenditure - 2003 to 2017

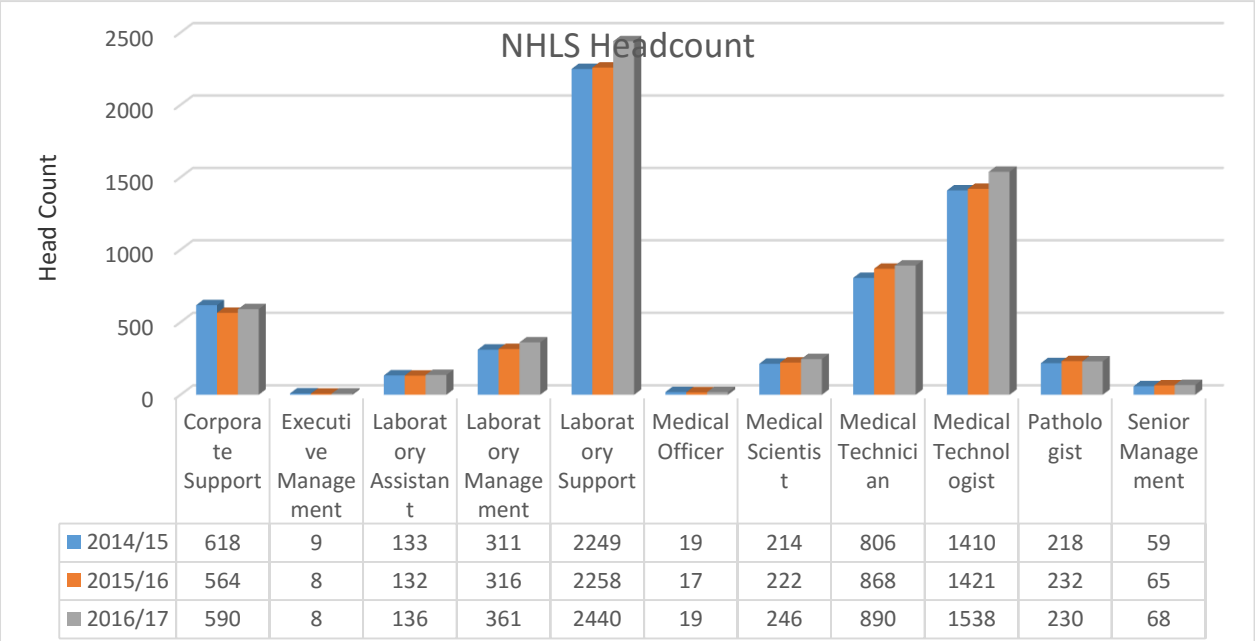


The first decade of NHLS 2003 to 2013, has seen its total staff complement growing from 3 509 employees to 7 087, whilst its total cost of compensation shifted from R 489,363 million to R2,131,458 billion – which represents a staff increase of about 49.5% and the staff personnel expenditure of 42% in 2013. This could be attributed to an expansion of our services across the country as well as incorporation of Kwa Zulu Natal Provincial Laboratory Services into the NHLS.

The NHLS has utilised various pay grading systems over the years. The Equates system was implemented during the transition process. The Hay system was thereafter implemented and then changed over to Paterson system.

Our key figures in the 2nd decade which we are in the 5th year reveals that our total labour numbers are remaining within the 7 369 inclusive of students with our total cost of compensation of 35% over total expenditure. The average total number of personnel for the previous 5years i.e. March 2013 – March 2017 is 7 032, while the total cost of compensation over total expenditure is 38.2%.

Graph 2: NHLS Headcount over the period 2014/15 – 2016/17



	Corporate Support	Executive Management	Laboratory Assistant	Laboratory Management	Laboratory Support	Medical Officer	Medical Scientist	Medical Technician	Medical Technologist	Pathologist	Senior Management
2014/15	618	9	133	311	2249	19	214	806	1410	218	59
2015/16	564	8	132	316	2258	17	222	868	1421	232	65
2016/17	590	8	136	361	2440	19	246	890	1538	230	68

The graph above indicates the NHLS headcount over three-year period (2014/15 – 2016/17). The medical technologists accounts for approximately 20% of the workforce and pathologists accounts for approximately 3%. The ratio of pathologists in NHLS to the total workforce compares with the private sector, which is approximately 2.8%, where else, the ratio of medical technologists in NHLS is 9 % less than the private sector, (29% in private sector) (National Pathology Group report, Submission to the Competition Commission of Health Market Enquiry into Private Health Care, 2016).

7.6. Academic Affairs, Research and Quality Assurance

Academic Affairs, Research and Quality Assurance (AAQRA) incorporates the Academic Affairs and Research (AAR) and the Quality Assurance departments. It shares the responsibility for the teaching and training with the learning academy, which is housed in the human resources department, and is responsible for research mandate of the NHLS and oversees the quality assurance support and management programmes for the organisation. AARQA strives to ensure consistent adherence to accreditation and compliance measures across all the laboratories through the benchmarking of quality assurance standards for the NHLS. The in-house Health Technology Assessment (HTA) programme focuses on the pre-evaluation of new *in vitro* Diagnostic Devices in order to facilitate the effective and reliable introduction of technology advancement in the service platform and provide an opportunity for competitive and open selection of innovative approaches to diagnostic technology.

AARQA has continuously supported these activities in conjunction with its academic partners to contribute towards the NHLS mission and to promote excellence in the delivery of high quality pathology services. A

formal relationship between AARQA and the ten South African Medical Universities and the Universities of Technology is endorsed through an "Umbrella Agreement" signed by all institutions.

In December 2016 the NHLS was included as a Schedule 1 Institution in terms of the Intellectual Property Rights from Publicly Financed Research and Development Act, No. 51 of 2008. This strengthens the position of the NHLS and the role it plays in research within the country.

6.6.1. Quality Management System

The NHLS has a well -developed quality management system and works according to ISO 15189 guidelines for medical testing laboratories. ISO 17025 guidelines apply to food sampling The office is managed at a central level and control resides in the national office for the overall organisational quality manual, the standard operating procedures, internal audit and national proficiency testing schemes.
During the review period, the department trained 143 Support Service Department staff members (45 in 2015/16) on ISO 9001:2015 through the NHLS Learning Academy. Little progress was made in addressing the non-conformities identified during the gap assessments conducted in the previous financial year. Human Resources remains the only department that has divisions where gap assessments had not been done by the end of March 2017.

The percentage of accredited laboratories per tier at the end of March 2016 was as follows:

- 94% (49/52) of national central laboratories
- 47% (8/17) of provincial tertiary laboratories
- 17% (7/42) of regional laboratories

NHLS Proficiency Testing Scheme (PTS) is ISO 17043 accredited. It provides PTS to all internal laboratories and well as some of the external laboratories in following, Bacteriology, Blood gas, Cardiac, CD4 (Flow cytometry), Cryptococcus Antigen, C Reactive Protein, Chemistry, Endocrinology, Erythrocyte Sedimentation Rate, Hematology (full blood count), HIV Early Infant Diagnosis, HIV Serology, Morphology (Blood), Mycology Moulds, Mycology Yeast, Syphilis RPR, Syphilis TPHA, TB Culture, TB Gene X pert, TB Line Probe Assay, TB Microscopy, Parasitology Blood, Parasitology Stool, and Therapeutic Drug Monitoring.

Countries with laboratories enrolled in NHLS PT Schemes: 2016/17Botswana., Ivory Coast, Nigeria, Cameroon, Kenya, Rwanda, Democratic Republic of Congo, Lesotho, Swaziland, Eritrea, Malawi, Tanzania, Ethiopia, Mauritius, Uganda, Gabon, Mozambique, United States of America, Ghana, Namibia, Zambia, Guinea, Niger, Zimbabwe

As part of the quality management system, turnaround times of test results are critical in service delivery. Below is a list of crude performance indicators for service delivery. The turnaround times for national priority tests performed continued to show an improvement. Additions have been made to address services beyond NPP and include full blood count and urea and electrolytes turnaround times.

On average all tests were performed within the defined time-frames in 2016/17 financial year, as indicated for some of the key tests in the table below:

Table: 6.6.1 A: Crude Performance Indicators for Service Delivery

Performance Indicator	2014/15	2015/16	2016/17
Percentage TB GXP tests performed within 48 hours [1]	92%	91%	96.68%
Percentage CD4 tests performed within 48 hours[1]	89%	89%	94.44%
Percentage Viral Load tests performed within 96 hours [1]	81%	64%	87.3%
Percentage HIV PCR tests performed within 96 hours	70%	73%	81.90%
Percentage Cervical Smear tests performed within 5 weeks [1]	57%	48%	96.87%

1 – the TB GXP and CD4, testing within 48 hours in 2014/15 and 2015/16 as opposed to 40 hours in 2016/17. The cervical smears were measured within 13 days in 2014/15 and 2915/16 as opposed to 5 weeks in 2016/17

7.6.2. Training and Research.

The NHLS's commitment to the development of its staff and the capacitation of new staff, with the intent of fulfilling the need ahead of demand, is undisputable. In addition to the regular training for learner ship and professional registrations, 103 scholarships were awarded to needy students across the country studying towards the National Diploma in Biomedical Technology and the Bachelor of Health Science, and bursaries were given to NHLS staff wishing to pursue their career development by way of formal qualifications.

In addition to training provided internally, the NHLS also delivered training on Minimum Standards for Reference Laboratories to 265 employees from 11 SADC member states in terms of a memorandum of understanding.

On average between 2012 and 2017 the NHLS trains 234 registrars per year in collaboration with its academic partners, with the number per year ranging between 225 and 242 (Figure 6.5.2 A). Of these, the majority are in the following disciplines, Anatomical Pathology, Medical Microbiology, Haematology and Chemical Pathology with an average registrar number of 78, 46, 44., and 30, respectively. However, there is low intakes in Human Genetics, Clinical Pathology and Medical Virology at registrar numbers of 2, 12 and 19, respectively. In order to attract candidates to pathology, the work back clause has been removed from the registrar policy because it was believed that it discouraged potential candidates. Furthermore, the unit is reviewing the training platforms to strengthen infrastructure and training capacity.

On average between 2014/15 and 2016/17, the NHLS has offered in-house training to 64 inter scientists, 43 laboratory assistant students, 498 medical technician students and 737 medical technologist students (Figure 6.5.2 B).

Figure 7.5.2 A: Registrars trained on the NHLS platform per year: Total Number Trained and Part II Examination Intake and Outcomes by year period

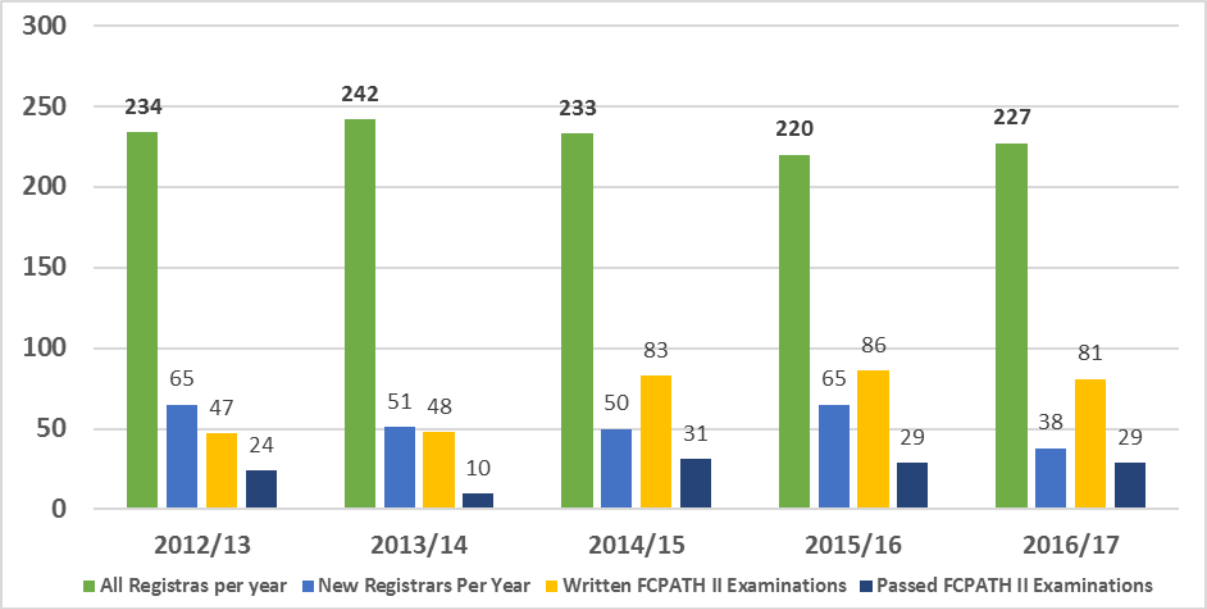
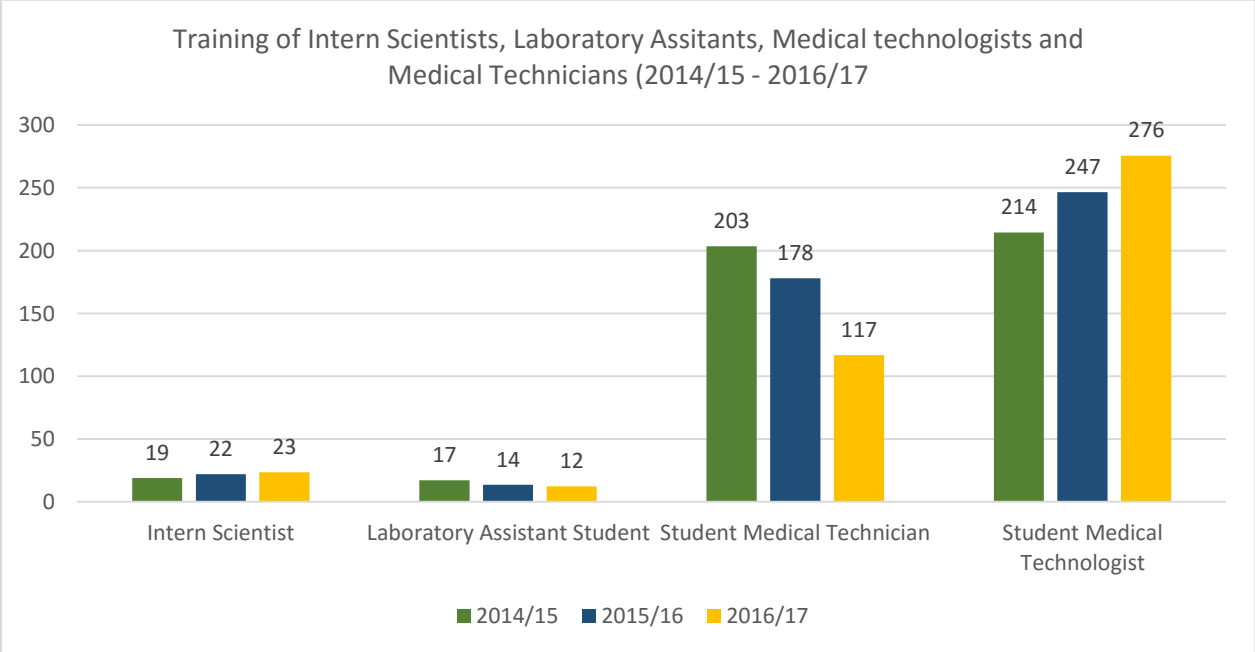


Figure 7.5.2 B: Intern Scientists, Laboratory Assistant students, Medical Technologists students and Medical Technicians students trained on the NHLS platform over the period 2014/15 – 2016/17



7.7. Planning, Monitoring and Evaluation

Monitoring and evaluation aims at informing policy makers about the progress towards achieving targets as set in the-performance plans and assist managers in making proper decisions. Currently there is the monitoring and evaluation unit in the office of the CEO. Monitoring and Evaluation is currently focusing on planning and monitoring the performance of the organisation in implementing the Strategy and achieving the goals set. It is however, important that the monitoring and evaluation function be fully cascaded to the laboratories to gather more data for future planning. It will be necessary to put in place automated monitoring tools for effective monitoring of the implementation of the plans and to also improve the integrity of data collected**.**

The monitoring and evaluation unit must develop a comprehensive monitoring and evaluation framework which will clarify the role of monitoring and evaluation in the NHLS and how it links to performance management.

7.7.1 NHLS Roadmap

The NHLS has developed the roadmap to align laboratory services with the National Health Insurance (NHI) Policy. The imperative of NHI is to provide equitable, cost effective and accessible quality health care.

Although there has been considerable development and improvement in the laboratory services within the last decade, additional refinement and cost controls are essential to keep pace with the significant development of clinical health services envisaged by NHI. Critical appraisal of current laboratory service delivery identified the ongoing deficiencies due to the following:

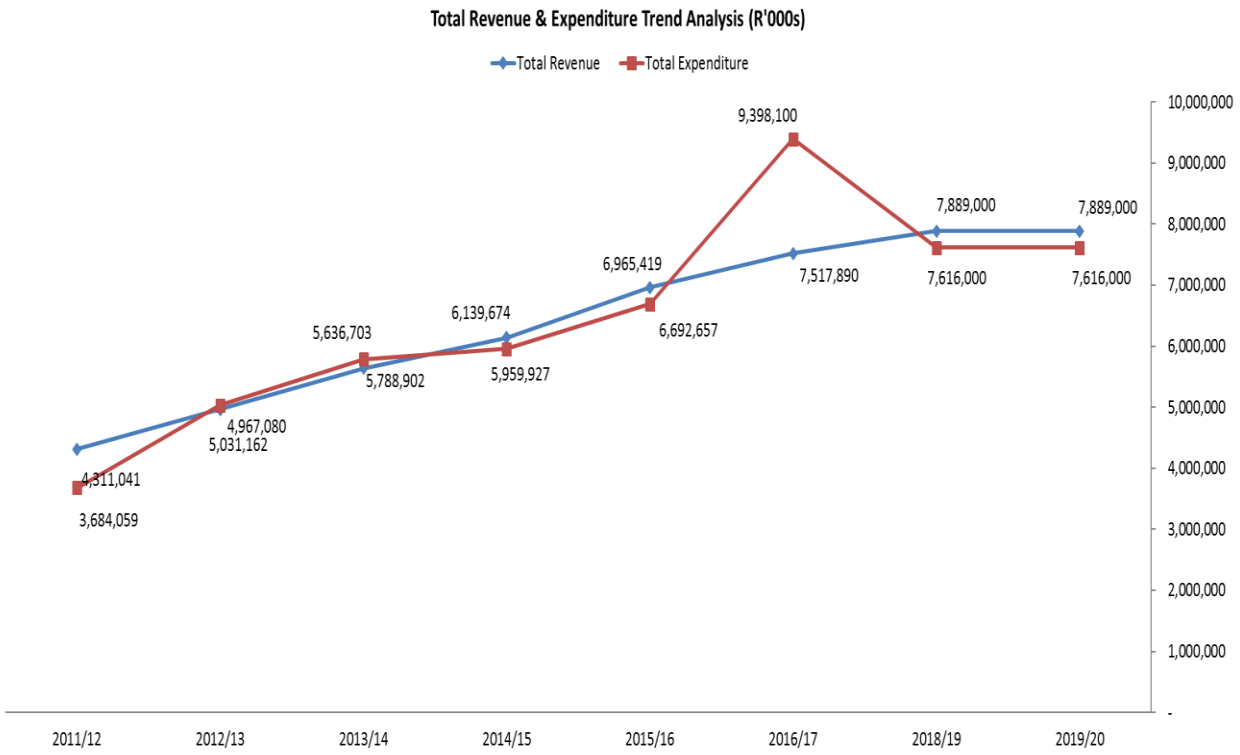
- Historic constraints and inequities due to previous political structures, resulting in a mismatch of service.
- Delivery sites to the population it claimed to serve is still not entirely eradicated.
- Inappropriate test baskets for the clinical requirements, either too little, inappropriate or excessive.
- Inheritance of multiple laboratories with variable levels of quality.
- Duplication of services in some instances, resulting in wasteful expenditure.
- Failure to keep pace with international trends and norms in laboratory services. The NHLS has more laboratories per capita than any other country in the world.

- Lack of standardisation of laboratory information technology – impeding effective national reporting of laboratory results to the NDoH.
- Mismatch of the laboratory services with the development plans of healthcare nationally.

The current historical laboratory service model of high numbers of laboratories is unsustainable in terms of finance, quality and standardisation of practice. The recent technological advancements employed in modern laboratories, provide the opportunity for substantial process improvements and delivery of results to clinical services. Centralisation and control of services improves pathologist cover, service delivery and rational utilisation of services with consequent savings to the NDOH.

7.8. Financial Performance

Graph 6.8 A: Total revenue and Expenditure Trend Analysis



The graph above illustrates that in 2012 the expenditure was increasing higher than the rate of revenue; therefore, a loss was experienced in that year. The expenditure increased remarkably in 2016/17 due to provisions made for the Kwa Zulu Natal and Gauteng historical debt. Projection for 2018-2020 indicate that expenditure in relation to revenue will be managed better.

The NHLS is forecasting to generate approximately R 7 billion in test revenue for the 2017/18 financial period. The NHLS still has severe cash flow problems due to the increasing debt being accumulated by the provinces, which as at the end of October 2017 stands at an outstanding amount of R 6,3 billion. The organisation has only been able to provide a maximum cash cover of one and a half months at best during the current financial period. To operate effectively the organisation would require a minimum 3 months' cash cover and this will require an amount of R 1,8 billion in cash to be on hand.

The NHLS has been engaging the Department of Health around a new funding model that will generate a simpler, more meaningful and shared risk tariff or reimbursement, modified capital reimbursement model (MCRM). It is expected that this funding model resonates with the budgetary constraints within the Public Sector; otherwise this will result in unaffordable and unsustainable services in the long term. The NHLS is ready to pilot the MCRM starting from April 2018 to assess its benefits when compared to the fee for service model.

NHLS received a qualified opinion for the 2016/17 financial year and this was mainly due to the almost R 1 billion of irregular expenditure that was incurred by the organisation. This was mainly due to expired contracts or non-existent contracts with suppliers. Management have been working towards eradicating incurring any irregular expenditure going forward however this will require proper systems and controls to be put into place. Some of the interventions may require substantial time to be implemented but management are dedicated to resolving all issues related to irregular expenditure.

The NHLS currently owes its suppliers approximately R 833 million as at the end of October 2017, however for the current financial year, NHLS has been invoiced for R 1,2 billion worth of goods and services and the organisation paid R 1,4 billion to all suppliers. This effectively means NHLS has paid R 219m to its prior year debt.

7.9. Governance

The Board as the Accounting authority, must provide oversight with regard to compliance with Public Finance Management Act, 1999 (Act No. 1 of 1999) ("the PFMA"). According to the King IV Report on Governance for South Africa, 2016, the governing body should lead ethically and effectively. They should:

- offer leadership that result in the achievement of strategy and outcomes over time.
- exhibit characteristics of integrity, competence, responsibility, accountability, fairness and transparency. govern the ethics of the organisation in a way that supports the establishment of an ethical culture.

- Steer and set the direction, purpose and strategy of the organisation.
- Ensure that the reports issued by the organisation enables stakeholders to make informed assessments of the organisation's performance, and its short term, medium and long term prospects.

The Board in playing its oversight role with regard to good governance and has implemented a fraud prevention and response plan. The plan is designed to assist staff in making sound decisions regarding the reporting of fraud, corruption and other criminal offences which might impact the NHLS in its operations. Whistle blowers are protected through the tip off anonymous fraud hotline, which is managed by an independent service provider. The Board received a tip off on a number of alleged misconduct issues and immediately conducted investigations and reported these irregularities to the AG's office.

7.10. Information Technology

The NHLS' Corporate Data Warehouse (CDW) is a national investment from which the following has emerged: the ability to produce Business Intelligence Reports, surveillance, dashboards for monitoring service delivery, and dashboards for monitoring priority diseases such as HIV and TB.

The NHLS, on request of the NDoH has put measures in place to reduce the inappropriate ordering and repeat of laboratory tests in a form of electronic Gate Keeping (eGK) in order to curb laboratory expenditure and promote the rational use of laboratory services. A set of rules have been configured on the Laboratory Information System against which requests are evaluated and cancelled if the rules are not met. These rules are the culmination of significant work in defining best pathology practice undertaken by the NHLS Expert committees and appropriate engagement of clinical stakeholders.

National Standardised Electronic Gate Keeping (eGK) rules were implemented successfully from October 2017. Only Northern Cape have elected to implement eGK at a later date. A joint pilot project with the CSIR and the NDoH has been implemented to support the rollout of the patient unique identifier. The ability to access electronic results is being improved with additional channels of access via direct interfaces to systems i.e. the Meditech Hospital Information System in KZN and Tier.Net. Direct lookup of results via the Internet continues to increase month-on-month.

The NHLS IT infrastructure continues to be a challenge. Priority has been given to projects that are upgrading and replacing old and obsolete equipment. The aim is to build a strong IT foundation based on robust and agile infrastructure with core laboratory and enterprise capabilities and innovative solutions that help build state of the art laboratory services in the country. Successful disaster recovery tests were conducted.

The ability to recruit and retain the required skilled staff remains a significant challenge. The IT organisational structure will be reviewed in line with the development of a long term IT Strategy for the NHLS. The plan is to review the IT service delivery model and staffing and adopt an approach that will best enable the IT Strategy.

8. The Private Pathology Market

8.1. Defining the Market

The three largest private pathology practices in South Africa are: Ampath, PathCare, and Lancet, which comprise about 90% of the market. Other smaller pathology practices in South Africa are spread throughout the country (National Pathology Group report, Submission to the Competition Commission of Health Market Enquiry into Private Health Care, 2016)

According to PathCare pathology practice, the market for pathology services is determined by the urgency of the test results required (PathCare Submission to the Competition Commission of Health Market Enquiry into the Private Health, 2016). The more urgent the test result is, the smaller the market and the potential competitors in the market, and the less urgent the test result, the larger the market with more potential competitors. Urgent pathology tests have a less than 2-hour turnaround time requirement and the laboratory must be in close vicinity to where the bloods were taken. Hospitals will require an in-house laboratory facility to process tests for its patients in cases where a turnaround time ranging from 2-24 hours is required. The market will therefore be limited to pathology service providers that either have a laboratory or depot facility within the hospital and can deliver the test result within the turnaround time required.

The private sector provides its services through laboratories and depots. A laboratory is a scientific centre and has the ability to analyse blood and other samples and deliver the results within that facility. Depots are typically facilities staffed by one or two nurses where patient samples are taken and received and then forwarded to a laboratory. Depot facilities can generally be found in a wide variety of areas including close to doctors consulting rooms, within managed care facilities, shopping centres, hospitals or close to specialist and general practitioner consulting rooms.

8.2. Comparisons Between Private and Public Sectors

According to a submission made to the Health Market Inquiry, Pathcare employs approximately 2600 employees which includes 79 pathologists, 206 medical technicians, 299 medical technologists, 342

nurses, 13 scientists, 100 laboratory assistants and 134 phlebotomists throughout the country. Pathcare has 63 laboratories and 116 Depots.

Lancet's submission to the Health Market Inquiry, states that Lancet employs approximately 4600 employees which includes 130 pathologists. Lancet does 1,8 million tests per month.

Ampath employs approximately 4500 employees which includes 130 pathologists. Ampath has 117 laboratories and 184 Depots. (Submission to Health Market Enquiry, 2016)

In a presentation to the Competition Commission Health Market Inquiry on 18 May, 2016, the National Pathology Group (NPG) which is the official subgroup of the South African Medical Association (SAMA), the following statistics were given: the total number of employees is reported to be 10 295, of which 295 are Pathologists, 50 Medical Scientists, 3 000 Medical Technologists, 1 000 Medical Technicians, 200 Phlebotomy Technicians, 3 000 Nursing Sisters. The number of tests performed per day are reported to be 3 000, which when calculated over a year they give a total of 78 000 000.

On the other hand, NHLS has reported in the annual report 2016/17 the following statistics: a total of 7 101 employees, of which 203 are Pathologists, 224 Medical Scientists, 1 473 Medical Technologists, 859 Medical Technicians, 248 Phlebotomy Technicians, 42 Nursing Sisters. Total number of tests performed per annum are reported to be 91 302 409.

According to the Council of Medical Schemes, the expenditure of approximately R8.1 billion was incurred in the private sector as opposed to approximately R7.0 billion spent by the NHLS.

This comparison is quite interesting as it shows the inequities between the private and public sectors. The NHLS services approximately 80% of the population which is mainly public sector and the private laboratories service the other 20% of the population. However, the resources for the 20%, both for human resources and financial resources are more than for the NHLS, which is in keeping with the trends seen in the private sector.

It must be noted that the expenditure for the NHLS includes the cost of training health professionals.

9. Strategic Planning Process

According to the Framework for Strategic Plans and Annual Performance Plans, a Strategic Plan should cover at least five years; however, it can be updated and changes can be made during the five-year period

that it covers. Such changes must be limited to revisions related to significant policy shift or changes in the service-delivery environment.

During the planning process the Strategic Outcome Oriented Goals were revised in line with the direction that the NHLS intend to take in the medium term. This process afforded the NHLS an opportunity to consolidate and simplify the goals. The indicators were updated to be compliant with the SMART principles.

The NHLS embarked on the Strategic Plan Revision and the Annual Performance Plan Review process as described below.

9.1. Strategic Planning Process

The table below provides an overview of the sequence of events followed to revise the Strategic Plan and review the Annual Performance Plan in order to submit the final revised and reviewed strategic documents for the 2019/20 financial year.

Table 1: Strategic Planning Process

Activity	Date
Circulate 2016/17 Strategic Plan and Annual Performance Plan to EXCO and Area Managers for review.	June 2017
Strategic and Annual Performance Plan Review workshop with all EXCO and Area Managers	14 August 2017
Consolidate all inputs from the workshop	15 - 21 August 2017
Compile 1st draft APP and SP	22 – 30 August 2017
Submit 1st draft documents to Department of Health	**31 August 2017**
Strategic Plan and Annual Performance Plan review workshop – 2nd draft	17 – 18 October 2017
Consolidate all the inputs from the workshop.	19-27 October
Present the process plan and discuss the way forward in EXCO meeting	30 October 2017
Distribute the Strategic Plan and the Annual Performance Plan to EXCO and Area Managers for further review.	7 November 2017
Consolidate all inputs from EXCO, Area Managers and the Department of Health	7 – 10 November 2017
Submit the Strategic Plan and the Annual Performance Plan to the Acting CEO for further review and revision.	17 November 2017

Submit the 2nd draft to the Board for consideration	27 November 2017
Submit updated 2nd Draft documents to Department of Health	**30 November 2017**
Presentation to the Department of Health	15 December 2017
Strategic Plan and Annual Performance Plan Review workshop with all Executive and Senior Managers – Final Draft	16 January 2018
Submit the revised Strategic Plan and Annual Performance Plan to the Board for approval – Final Draft	26 January 2018
Submission of the final draft documents to the Department of Health	**31 January 2018**

9.2. SWOT Analysis

The NHLS identified the SWOT analysis as a powerful tool to ensure that a better understanding of the current situation and environment will allow for a platform upon which planning can be performed. A clear understanding of the **S**trengths and **W**eaknesses will enable the NHLS to be in a better position to plan for any possible **O**pportunities or make plans to prevent **T**hreats becoming realities to manage.

The complete SWOT analysis is provided in the next page:

Table 2: Strengths, Weaknesses, Opportunities and Threats

Strengths	Weaknesses
• Strong academic base and sustainable partnerships through relevant research outputs; • Internationally renowned intellectual capital; • Trendsetting in quality assurance initiatives; (have we bench marked. Can it be validated) • National pathology laboratory footprints; • Exclusive national integrated data warehouse; • Leverage on the NHLS powers in the ACT; • Largest employer of pathology related services in the country; • Sustainable partnerships with (NDoH and other agencies, Universities and UoTs); • Influence in the National and Regional Societies on laboratory medicine; • Competitive remuneration structure; • Africa leader in laboratory medicine.	• Lack of succession planning and pipeline development due to scarce skills, both qualitatively and quantitatively; • Resistance to change; • Lack of workload standards; • High failure rate of registrars; • High failure rate of intern technologists; • Inequitable distribution of critical and scare skills; quantitative and qualitative; • Inadequate technology and ICT infrastructure capacity; • Lack of ownership of value chain from collection of samples to return of results; • Prolonged implementation of projects; • Poor communication both internally and externally; • Inability to cultivate team work; • Lack of consequences of poor performance by management; • Leadership instability

Opportunities	Threats
• Multi sectorial partnerships to enhance sharing of intellectual capacity; • Other source of income which can diverse our revenue stream such as GEMS and other Medical Aids; • Existing footprint in terms of the branch/regional laboratory network (enhance ownership of POCT);	• International reduction in grant allocation; • Private sector competition (Anatomical pathology); • Medical inflation in relation to goods and services – more than 80% of NHLS costs are directly related to health. Due to increasingly high growth in burden of

Opportunities	Threats
• Introduction of the National Health Insurance) NHI); • Trusted service provider by the health professionals; • Integrated IT systems with external stakeholders; • Additional work to be performed within the SADC region to generate additional revenues; • Increased volumes through universal test and treat (UTT) policy; • Utilise media coverage to promote on our brand / corporate image; • Remote oversight of laboratories by pathologists; • Opening of new medical schools will expand the teaching platform	diseases and increased demand for healthcare, medical inflation which is generally higher than CPI has become unpredictable; • Exchange rates – i.e. equipment purchased from overseas; • Inadequate training platform in Virology, Human Genetics and Haematology; • High debtors level; • Lack of investment on IT infrastructure; • Opening of new medical schools, the NHLS may not have enough resources to cover the need.

10. Strategic Outcome Orientated Goals

The goal statements and descriptions of each of the Strategic Outcome Orientated Goals (SOOG) are shown in the table below:

Goal	Goal Statement
Goal 1: **Modernised and Accessible Laboratory Service**	The vision for the NHLS is to provide 100% of hospitals at regional or above level with pathologist cover by 2020 and to provide a comprehensive, quality, cost effective and timeous pathology service which subscribes to international standards. This requires that all tests be carried out according to International Best Practice and that optimal use is made of technology to provide improved turnaround time
Goal 2: **Academic Excellence in Training and Research**	To produce highly competent pathology health professionals who spearhead service delivery and locally relevant research. It is the ultimate strategic intent of the NHLS to ensure that research ultimately strengthens laboratory systems and influences policy development for improvement of health outcomes
Goal 3 **Sound Governance and Improved Stakeholder Relations**	The NHLS must show accountability and transparency through communicating more frequently with its stakeholder on its strategic initiatives and key decisions, both internally and externally. The NHLS will ensure sound corporate governance through strict adherence and compliance with all relevant legislation, financial regulations, directives, policies and procedures.
Goal 4 **Effective, Efficient and Ethical Organisation for improved service delivery and implementation of NHI.**	Ensure effective management of the NHLS through efficient use of resources, integrated systems and improved monitoring and evaluation. With the introduction of National Health Insurance (NHI), it is

Goal	Goal Statement
	essential that there is optimisation of resources. For this reason, a comprehensive review of the NHLS in its entirety, including but not limited to governance, service model, financial and funding models and workforce planning models is being undertaken. The NHLS must be transformed into an even more dynamic, effective and efficient entity which meets the need of its patients, builds capacity and grow the NHLS footprint.
Goal	**Goal Statement**
Goal 5 **Efficient Financial Practices**	NHLS must ensure effective financial management, policy and practice and strengthen the management of financial resources and procurement processes. The NHLS must generate sufficient revenue to ensure financial viability and sustainability.
Goal 6 **Skilled, competent and motivated workforce**	Competent and motivated staff plays a vital role in ensuring organisational success. It is the intended goal of the NHLS to have the right number of staff with the right skills mix at the right level available and employed in appropriate positions within the organisation.

Strategies to achieve the above goals are detailed in the attached annexure A.

Table 10.1: Strategic Goal Alignment Matrix

National Development Plan	NDP Priority	NHLS Goals
Raise the life expectancy of South Africans to at least 70 years	a. Address the social determinants that affect health and diseases. d. Prevent and reduce the disease burden and promote health	Modernised and Accessible Pathology Service Effective and Efficient Organisation
Progressively improve TB prevention and cure		
Reduce maternal, infant and child mortality		
Significantly reduce prevalence of non-communicable diseases		
Universal health care coverage	e. Financing universal healthcare coverage	
Primary healthcare teams provide care to families and communities	b. Strengthen the health system c. Improve health information system h. Improve quality by using evidence	
Health system reforms completed	Improved health facility planning and infrastructure delivery	Sound Governance and Improved Stakeholder Relations
Fill posts with skilled, committed and competent individuals	f. Improved human resources for health sector g. Review management positions and appointments and strengthen accountability mechanisms.	Skilled, competent and motivated Workforce Academic Excellence in Training, Education and Research
	Efficient Health Management Information System for improved decision making	Effective and Efficient Organisation

In order for the NHLS to use these goals described above effectively, to drive and manage strategy implementation, it is essential that the NHLS must make these goals measurable. The saying “you can’t manage what you can’t measure” (Peter Drucker) and “you can’t improve what you can’t measure” (W Edwards Deming) become critically important in the development of a strategic plan. The following section

describes the intent, strategies and clear impact and outcome measurements per goal, whereby the NHLS is providing a clear direction of what needs to be achieved over the following three financial years.

Strategic Outcome Oriented Goal 1	Modernised and Accessible Laboratory Service
Goal Statement	NHLS aims to provide 100% of hospitals at regional or above level with pathologist' cover and to provide a comprehensive, quality, cost effective and timeous pathology service which subscribed to International standards. This requires that all tests be carried out according to International Best Practice and that optimal use is made of technology to provide improved turnaround time
Linkage to Strategic Objective	**2.1.** A robust and efficient communicable disease surveillance system, outbreak response. **3.1.** Robust and efficient Occupational and Environmental Health Services **4.1.** Improved Quality Management System. **5.1**. Improved turnaround time.

Strategic Outcome Oriented Goal 2	Academic Excellence in Training and Research
Goal Statement	To produce highly competent pathology health professionals who spearhead service delivery and locally relevant research. It is the ultimate strategic intent of the NHLS to ensure that research ultimately strengthens laboratory systems and influences policy development for improvement of health outcomes
Linkage to Strategic Objectives	**2.2** Training and Research in Surveillance and Communicable Diseases.

Strategic Outcome Oriented Goal 2	Academic Excellence in Training and Research
	3.2. Research and Training in Occupational and Environmental Health and Safety. **4.2** Increase pool of available pathology health professionals and pathologist national coverage. **4.3** Improved training platform **4.4** Develop and implement a national research agenda for laboratory service and the NHI.

Strategic Outcome Oriented Goal 3	Sound Governance and Improved Stakeholder Relations
Goal Statement	The NHLS must show accountability and transparency through communicating more frequently with its stakeholder on its strategic initiatives and key decisions, both internally and externally. The NHLS will ensure sound corporate governance through strict adherence and compliance with all relevant legislation, financial regulations, directives, policies and procedures.
Linkage to Strategic Objectives	**1.4.** Audit opinion of the Auditor General **1.5.** Strengthened oversight role of the Board

Strategic Outcome Oriented Goal 4	Effective, Efficient and Ethical Organisation for improved service delivery and implementation of NHI.
Goal Statement	Ensure effective management of the NHLS through efficient use of resources, integrated systems and improved monitoring

Strategic Outcome Oriented Goal 4	Effective, Efficient and Ethical Organisation for improved service delivery and implementation of NHI.
	and evaluation. With the introduction of National Health Insurance (NHI), it is essential that there is optimisation It is against this backdrop that the NHLS needs to confirm its place as a prominent role player in the South African health sector and further afield. For these reasons, a comprehensive review of the NHLS in its entirety, including but not limited to governance, service model, financial and funding models and workforce planning models is being undertaken. The NHLS must be transformed into an even more dynamic, effective and efficient entity which meets the need of its patients, builds capacity and grow the NHLS footprint.
	1.6. Effective monitoring and evaluation system. **1.7.** Modernised and efficient IT systems **5.2**. Laboratory services equipped, and functioning at a level that provides accurate, reliable results timeously. **5.3**. Enhance planning, management and operational capacity of the laboratory services, including the laboratory structure, roles, responsibilities and reporting lines for the provision of efficient and quality service for NHI

Strategic Outcome Oriented Goal 5	Efficient Financial Practices
Goal Statement	NHLS must ensure solid financial management, policy and practice and strengthen the management of financial resources and procurement processes. The NHLS must generate sufficient revenue to ensure financial viability and sustainability.
	1.1 Efficient financial management systems, policy and practice **1.2** Improved revenue collection, billing system and the liquidity position of the NHLS. **1.3**. Development of National Procurement Plan

Strategic Outcome Oriented Goal 6	Skilled, competent and motivated workforce
Goal Statement	Competent and motivated staff plays a vital role in ensuring organisational success. It is the goal of the NHLS to continue to attract and retain appropriately qualified staff in appropriate positions within the organisation.
	1.8 Appropriately trained human resources in adequate numbers to staff the service **1.9.** Human Resource Plan and Workforce planning tool to determine staffing norms and training needs. **1.10.** Implementation of integrated performance management system to retain staff.

PART B: STRATEGIC OBJECTIVES

11. Programme 1: Administration

11.1. Programme Purpose

The administration programme plays a crucial role in the delivery of the NHLS services through the provision of a range of support services, such as organisational development, HR and labour relations, information technology, property management, security services, legal, communication and the integrated planning function. NHLS depends highly on the effective management of financial resources and procurement process as administered within the financial department. Generating sufficient revenue remains a critical focus area for NHLS to ensure financial viability and sustainability. There are four sub-programmes, namely:

11.1.1. Financial Management

The purpose of this sub programme is to improve cash flow position of NHLS.

11.1.2. Governance and Compliance

The purpose of this sub-programme is to provide support services and ensure compliance with relevant legislation.

11.1.3. Information Technology (IT)

The purpose of sub programme is to build a robust and agile IT infrastructure and innovative digital solutions to facilitate and enable state of the art laboratory services at NHLS by 2020.

11.1.4. Human Resources Management

Purpose of sub – programme is to provide effective services through efficient processes, systems and adequate Human Resources.

11.2. Strategic Objectives

Sub-Programme – Financial Management	
Strategic Objective 1.1	Effective financial management systems, policy and practice
Objective Statement	Develop systems and policies which will govern effective financial management and good practices
Strategic Objective 1.2	Improve revenue collection, billing systems and the liquidity position of the NHLS
Objective Statement:	Develop a revenue collection plan and produce comprehensive invoices that meet the acceptable standards.
Strategic Objective 1.3	Develop and Implement the National Procurement Plan
Objective Statement:	The NHLS shall have active supplier contracts, appropriate and functional equipment and supplies to support uninterrupted service delivery.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Develop and implement the financial management policy and plan.	New	100% implementation of the approved policy and plan
Ratio of current assets to current liabilities	2.7 Times	2.6 Times
Cash flow coverage (operating cash flows/total debt)	2.0 Times	2.0 Times
Percentage of material cost to revenue	39%	38%
Number of Creditors Days	68	60
Number of Debtors Days	164	150
Contract management system implemented	New	100% implementation
Percentage turnaround time for awarding tenders within 90 days after closing date.	New	80%

Sub-Programme – Governance and Compliance	
Strategic Objective 1.4	Audit opinion of the Auditor General.
Objective Statement:	Clean audit outcome by ensuring continuous management practices through compliance with standards operating procedures and systems within the NHLS.
Strategic Objective 1.5	Strengthen oversight role of the Board

Sub-Programme – Governance and Compliance	
Objective Statement	The Board has a basic responsibility to ensure sustainable improvements in corporate valuations by providing strategic guidance and oversight.
Strategic Objective 1.6	Effective monitoring and evaluation system.
Objective Statement	Effective monitoring and evaluation systems are necessary to gather information which will inform policies and decision making.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Clean audit opinion of Auditor General	Qualified	Clean
Effective monitoring tool to measure compliance with Board decisions and resolutions	New	Implementation of the approved monitoring tool
Review and revise the code of conduct and ethics policy	New	Reviewed and revised code of conduct and ethics policy
Develop and implement methodology to collect and collate information to establish an effective monitoring and evaluation system	New	Implementation of the approved methodology
Develop and implement an integrated reporting system to show compliance with key indicators and governance practices.	New	100% implementation of the system.

Sub-Programme – Information Technology and Communication	
Strategic Objective 1.7	Modernised and efficient IT systems
Objective Statement	Invest in modernised, innovative and efficient IT systems that are patient centred.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Development of IT Strategy completed	New	Implementation and monitoring of the strategy
Development of the IT roadmap in alignment with the IT strategy	New	Implementation of the approved roadmap
Number of dashboard, analytics and customer channels projects implemented	New	4
Percentage System Uptime for Critical Systems at facility level	99%	99%
Number of Modernisation Projects completed	New	16

Sub-Programme – Human Resource Management	
Strategic Objective 1.8	Appropriately trained human resources in adequate numbers to staff the service
Objective Statement:	Provide effective services through efficient processes and adequate human resources. To improve the motivation and performance levels of all employees.
Strategic Objective 1.9	Human Resource plan and the workforce planning tool to determine staffing norms and training needs.
Objective Statement	Ensure that the laboratory service and supporting services have adequate number of staff necessary to provide service
Strategic Objective 1.10	Implementation of the integrated performance management system to retain staff..
Objective Statement	The implementation of the integrated performance management system, which is aligned to pay progression and proficiency assessments will assist in retaining staff.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Staff Turnover ratio	New	5%
Average staff recruitment turnaround time within 90 days	New	80%

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Percentage of Employment Equity achieved across grade C,D & E relative to EAP	89%	90%
Percentage of employees with approved and evaluated performance agreements	63%	95%
Percentage of employees trained as per the approved training plan (WSP)	91%	90%
Develop and implement Human Resource plan and the workforce model	New	100% Implementation
Develop and implement the integrated performance management system	New	100% implementation of the system

11.3. Resource considerations

It is imperative that corporate service functions are adequately resourced through financial and human resources over the duration of the 5-year period, thereby possessing the required capacity to deliver on the support services mandate. The identification and filling of critical posts is a necessary and important aspect of the resource considerations.

11.4. Risk Management

Risk	Mitigation Strategy
1. Liquidity and use of financial resources	Strict implementation of fraud prevention plan with zero tolerance to fraud and corruption.
2. Integrity of financial information	Effective audit committee to have oversight and encourage accountability within the NHLS for financial management.
3. Adequacy and suitability of ICT infrastructure	Service level agreements with all service providers with clear deliverables and penalties. Fully funded ICT governance plan.
4. Effective communication incorporating both internal and external communication	Broad consultation on Integrated Communication strategy. Monitoring of Implementation and effectiveness.
5. Critical skills attraction, retention	Implementation of recruitment and retention strategy

12. Programme 2: Surveillance of Communicable Diseases

12.1. Programme Purpose

The National Institute for Communicable Diseases (NICD) is a national public health institute for South Africa providing reference microbiology, virology, epidemiology, surveillance and public health research to support the government's response to communicable disease threats.

12.2. Strategic Objectives

Programme – Surveillance of Communicable Diseases	
Strategic Objective 2.1.	A robust and efficient communicable disease surveillance system and outbreak response.
Objective Statement:	Maintain comprehensive communicable diseases surveillance programs for leading infectious disease, and maintain an effective response time.
Strategic Objective 2.2	Training and Research in Surveillance and Communicable Diseases.
Objective Statement	To conduct relevant public health related research and train qualified professionals in communicable diseases .

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Percentage of identified prioritised diseases under surveillance	90%	90%
Percentage of outbreaks responded to within 24 hours after notification	100%	100%
Percentage of SANAS accredited NICD laboratories	100%	100%
Annual report of population-based cancer surveillance	New	1.
Maintain WHO reference laboratories status	New	100% maintenance
Number of articles published in the peer reviewed journals	128	130
***Number of field epidemiologists qualified**	14	5

*Number of qualified epidemiologists was 14 in 2016/17 because of a high number of repeating students

Resource considerations

The NICD has been cross subsidised through fee for service revenue from the NHLS since the establishment of the NHLS. The main aim of the NICD will be to ensure that laboratories and programmes are adequately capacitated and functional. Since 2015/16, the NICD has been funded through a direct transfer payment from

the National Department of Health. This change in approach to funding resulted in the national functions provided by the NICD not being reliant of recovery of fees.

10.4. Risk Management

Risk	Mitigation Strategy
1. Biosafety and Biosecurity relating to pathogenic organisms	NICD has implemented numerous internal controls to mitigate risk. It has an IBBC (Institutes Biosafety and Biosecurity Committee) with an action plan including appropriate training
2. Transition of NICD to NAPHISA	Organizational development initiatives, steering committee and preparation of NAPHISA business case

13. Programme 3: Occupational and Environmental Health and Safety.

Environment in this context refers to the environment that is contaminated through workplace activities or that can be protected from contamination through workplace in interventions. Safety in this context refers to the synergies between occupational health and occupational safety such as in risk assessments, ergonomic assessments, teaching and training and surveillance of occupational diseases and injuries.

13.1. Programme Purpose

The National Institute for Occupational Health (NIOH) is a National Public Health Institute, which provides occupational and environmental health and safety support across all sectors of the economy to improve and promote workers' health and safety. National and provincial government departments and public entities are important clients, including the Medical Bureau for Occupational Diseases (MBOD) of the NDoH. The Institute achieves this by i) providing occupational medicine, hygiene, advisory, statutory pathology and laboratory services, ii) conducting research and iii) providing teaching and training in occupational and environmental health and safety.

13.2. Strategic Objectives

Programme – Occupational and Environmental Health and Safety	
Strategic Objective 3.1.	Robust and efficient Occupational and Environmental Health Services.
Objective Statement:	Provide and improve Occupational and Environmental Health services including laboratory testing, hazard and health assessments surveillance reports, and NHLS OHS audits.

Programme – Occupational and Environmental Health and Safety	
Strategic Objective 3.2.	Research and Training in Occupational and Environmental Health and Safety.
Objective Statement	Promote and conduct research on occupational and environmental health, including gender issues, in South Africa; and advance capacity building to strengthen human resources in occupational and environmental health and safety.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Percentage of occupational and environmental health laboratory tests conducted within predefined turn-around time	93%	90%
Number of occupational, environmental health and safety assessments completed	22	30
Number of surveillance reports produced	New	3
Percentage of NHLS laboratories audited for health and safety which were below targeted compliance in 2017/18	New	95%
Number of articles published in the peer reviewed journals	24	27
Number of students, interns, registrars under supervision	24	26

13.3. Resource considerations

National Institute for Occupational Health was substantially cross subsidised through fee revenue since the establishment of the NHLS. Since 2015/16, the National Institute for Occupational Health has been funded through a direct transfer payment from the National Department of Health. This change in approach to funding resulted in the national functions provided by the National Institute for Occupational Health being only partially reliant on recovery of fees. However, the Institute, in spite of generating some revenue, cannot meet all its Public Health obligations and expectations of stakeholders. The aim is to grow the budget allocated to meet the provincial and national OEHS needs and expectations.

13.4. Risk Management

Risk	Mitigation Strategy
1. Future of the NIOH	Active stakeholder engagement to ensure decisions relating to the NIOH are undertaken in an inclusive and transparent manner.

Risk	Mitigation Strategy
2. Adequate funding to meet mandates	Continue efforts to increase revenue generation and grant funding to supplement budget allocations from the National Department of Health.
3. Attracting and retaining qualified and experienced staff	Challenge to develop a flexible remuneration structure to accommodate niche areas and their dynamics. Implementation of a well-designed rewards and remuneration strategy.
4. Building and laboratory infrastructure	Development of a priority capital expenditure plan. To improve and maintain existing infrastructure through greater stakeholder engagement.

14. Programme 4: Academic Affairs, Research and Quality Assurance

14.1. Programme Purpose

The main purpose of this programme is to strengthen the mandate of the NHLS of maintaining and providing quality assured and accredited laboratory medicine and the academic platform. Two of the focus areas within this programme are to ensure that research is conducted to contribute to service delivery improvement and quality and to ensure national coverage by NHLS pathologists. The aim is to oversee and collaborate with various training institutions that contribute to the development of qualified and skilled people operating within the scientific field of pathology services.

14.1.1. Sub-Programme - Quality Assurance

The purpose of this sub-programme is to improve Total Quality Management systems within laboratories and support structures to improve the quality of results issued by NHLS laboratories.

14.1.2. Sub-Programme - Academic Affairs

The purpose of this sub-programme is to promote capacity building of health professionals to strengthen a business case for sustained development for the NHLS through the development of Pathologists, Medical Scientists, Medical Technologists and medical Technicians.

14.1.3. Sub-Programme – Research and Innovation

The purpose of this sub-programme is to increase the knowledge base on diseases and influence the decision taken to diagnose, treat and care for these diseases through research outputs and articles published.

14.2. Strategic Objectives

Sub-Programme – Quality Assurance	
Strategic Objective 4.1.	Improved Quality Management Systems
Objective Statement:	Improve Total Quality Management systems within laboratories and support departments to increase certification of support structure and accreditation of laboratories.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Percentage compliance achieved by laboratories during annual quality compliance audits	83.0%	90%
Percentage of National Central laboratories that are SANAS Accredited	90.0%	100%
Percentage of Provincial Tertiary laboratories that are SANAS Accredited	47.0%	80%
Number of Regional laboratories with SANAS Accreditation status	5	12
Number of District laboratories with SANAS Accreditation status	2	10
Percentage of laboratories achieving proficiency testing scheme performance standards of 80%	87%	90%
Prepare gap analysis and work plan to prepare support service departments and laboratories for certification and accreditation processes in preparation for the NHI.	New	Implement and monitor the work plan.

Sub-Programme - Academic Affairs	
Strategic Objective 4.2.	Increase pool of available pathology health professionals and pathologist national coverage
Strategic Objective 4.3	Improved Training Platform
Objective Statement:	Promote capacity building of health professionals to strengthen a business case for sustained development for the NHLS through the development of pathologists, and medical scientists. Ensure adequate and relevant contribution to diagnose laboratory services outside Academic centres, access by and clinical interaction

Sub-Programme - Academic Affairs	
	with clinicians outside academic centres and contribution to the improvement of service delivery across the NHLS platform by pathologists
Strategic Objective 4.4	Develop and implement a national research agenda for laboratory service and the NHI.
Objective Statement:	Laboratories shall be encouraged to participate in the relevant health research to improve patient management, laboratory performance and disease control

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2020/21
Number of pathology registrars admitted and trained in NHLS	New	30 per year
Number of medical scientists admitted and trained in NHLS	New	50 per year
Number of student medical technologists admitted and trained in NHLS	New	100 per year
Number of student medical technicians admitted and trained in NHLS.	New	30 per year
Number of bilateral agreements signed with universities and universities of technology.	New	16

Sub-Programme - Research	
Strategic Objective 4.4	Develop and implement a national research agenda for laboratory service and the NHI.
Objective Statement:	Increase the knowledge base on diseases and influence the decisions taken to diagnose, treat and care for these diseases through research outputs and articles published and explore opportunities for innovation.

Key Performance Indicator (Measure)	Baseline 2016/17	Target 2019/20
Number of articles published in the peer reviewed journals	570	600
Develop and implement a proposal on research priorities .	New	Proposal approved by the Board and all priorities implemented

14.3. Resource considerations

Quality assurance is central in supporting of the Operations Platform and should be resourced adequately to support this function. With regional Quality Management staff forming part of Operations, the bulk of resources should be allocated to Operations, while the National QA Department requires sufficient resources to allow for adequate policy development, monitoring and auditing.

Since the establishment of the NHLS the costs related to Teaching Training and Research has been funded by the NHLS through fee for service. Starting in 2015/16, the costs of Teaching and Training have been partially funded through a direct transfer payment from the National Department of Health. This change in approach has resulted in the TTR not being fully reliant on the recovery of fees. It must be noted that until such time as the full academic function is appropriately funded a degree of cross subsidisation may still be required.

National Coverage is central to support of Operations and strengthening the NHLS footprint, this function would require adequate resources to cover an ever expanding mandate.

14.4. Risk Management

Risk	Mitigation Strategy
1. Attraction and retention of scarce skills	Poor retention of qualified staff due to migration to the private sector and internationally. The NHLS requires an effective retention strategy..
2. Lack of a plan to develop specialised skills in pathology and associated sub disciplines of pathology	The NHLS, jointly with the NDoH will develop a set of norms to determine the appropriate level of training, including annual intake of students.
3. Reduction in International Grant Funding of Research	There is a need to support alternative funding strategy.

15. Programme 5: Laboratory Service

15.1. Programme Purpose

This programme represents the core business of the NHLS as mandated by the NHLS Act to provide cost-effective and efficient health laboratory services to all public sector health care providers; any other government institution inside and outside of the South Africa that may require such services; and any private health care provider that requests such services. It is anticipated that the NHLS should provide a comprehensive, accessible, quality and timeous pathology service resulting in improved patient care. There are four sub-programmes namely:

15.1.2. Sub-Programme – Operational Efficiency

The purpose of this sub-programme is to improve the overall clinical relevant turnaround times of all tests within every laboratory across South Africa and improve levels of quality of tests performed in the laboratories.

15.2. Strategic Objectives

Sub-Programme – Operational Efficiency	
Strategic Objective 5.1	Improved turnaround times
Objective Statement:	Increase the overall turnaround times of all tests within every laboratory across South Africa.
Strategic Objective 5.2	Laboratory Service equipped, and functioning at a level that provides accurate, reliable results timeously
Objective Statement	All laboratories shall have appropriate functional equipment and adequate supplies to support uninterrupted delivery of service
Strategic Objective 5.3	Enhance planning, management and operational capacity of the laboratory services, including the laboratory structure, roles, responsibilities and reporting lines for the provision of efficient and quality service for NHI.
Objective Statement	The laboratory service need to have at least a three year resource plan to maintain continuity in service delivery.

Key Performance Indicator (Measure)	Baseline 2016/17 In percentage (%)	Target 2019/20
***Percentage TB Microscopy tests performed within 40 hours**	95.72 (833 563/870 812)	90%
***Percentage TB GeneXpert tests performed within 40 hours**	96.68 (2 276 816/2354 930)	90%
***Percentage CD4 tests performed within 40 hours**	94.44(3 193 157/3 380 991)	90%
Percentage Viral Load tests performed within 96 hours	87.30(3 920 964/4 491 312)	80%
Percentage HIV PCR tests performed within 96 hours	81.90 (465 627/568 571)	85%
Percentage Cervical Smear tests performed within 5weeks.	96.87 (883 168/911 720)	80%
Percentage of laboratory tests (FBC) performed within 8 hours	New	80%
Percentage of laboratory tests (U&E) performed within 8 hours	New	80%
Review all laboratory facilities to determine infrastructure and equipment needs.	New	Board Approved plan (at least three year plan)
Implementation of the pilot specimen tracking system	New	100% implementation
Develop the laboratory structure per level of care (organogram)	New	Review the approved organogram

*targets for TB Microscopy, TB GeneXpert and CD4 have dropped because the targets have been stretched from measuring turnaround time within 48 hours to 40 hours.

15.3. Resource Considerations

Laboratory service provision is the largest component of the NHLS budget. The NHLS budget for this programme sees a comprehensive, accessible, quality and timeous pathology service. The budget for human resources increases over the 5-year period, whereby there will be a reduction in current vacancies.

13.4. Risk Management

Risk	Mitigation Strategy
1. Significant volume increase due to change in national department of health policies.	NHLS should be advocate for increased resources when volumes increase.
2. Attracting and retaining qualified, appropriately registered and experienced staff.	Implementation of a well-designed rewards and remuneration strategy.
3. Building and laboratory infrastructure- NHLS does not own laboratories.	Development of an infrastructure development plan and priority capital expenditure plan.

Risk	Mitigation Strategy
4. Cash flow challenge due to untimely payments by Provincial Health Departments.	The NHLS will strengthen its billing systems and work with provinces at regional level to ensure accuracy in billing processes. Dispute resolution mechanisms will be introduced in all SLAs with the Provincial DoH to ensure disputes related to billing are addressed.

Part C: Link to other plans

1. **Conditional Grants**

   The NHLS does not receive any conditional grants.

2. **Private Public Partnerships.**

   The NHLS does not have any Private Partnerships.

3. **Infrastructure Plan**

   The table below indicates the NHLS infrastructure for the next three years.

Table 3.1: Infrastructure Plan (Highlight big CAPITAL Projects)

BUDGETED CAPITAL EXPENDITURE	2018/19	2019/20	2020/21
Buildings	140,000	140,000	140,000
Laboratory Equipment	140,000	130,000	125,000
Computers	160,000	150,000	120,000
Office Furniture + Fittings	10,000	10,000	10,000
Office Equipment	15,000	15,000	20,000
Motor vehicles	35,000	35,000	35,000
TOTAL	**500,000**	**480,000**	**450,000**

ANNEXURE A: STRATEGIES

Goal 1	Strategic Objectives	Strategies
Modernised and Accessible Laboratory Service	**2.1** A robust and efficient communicable disease surveillance system, outbreak response, research and training **3.1.** Robust and efficient Occupational and Environmental Health Services. **4.1.** Improved Quality Management System. **5.1**. Improved turnaround time.	• Enhance support for communicable disease prevention, surveillance and control for national and provincial government. • Increase coverage, reliability and completeness of cancer surveillance data • Development of the transitional plan for NICD and NIOH to NAPHISA. • Provide fast and effective support and responses in communicable diseases outbreak response • Increase the awareness of NHLS workplaces to become more occupational and environmental health and safety aware and compliant using targeted interventions identified during audits. • Provide information for action through monitoring trends in occupational lung disease in the mining industry, identification of industries with over exposure to chemicals and identification of settings with asbestos containing materials. Reduce burden of diseases and injuries attributable to workplace exposures through hazard and health assessments. • Increase involvement, accessibility and coverage of pathologists in the provision of diagnostic related service delivery • Automate External quality assurance

Goal 1	Strategic Objectives	Strategies
		• Improve mechanisms for tracking specimens and workflow • Modernisation and automation of laboratory equipment of appropriate state of the art equipment according to sample volumes and laboratory tier. world-class equipment and increased ability to deal with sample and test loads. • Increase the clinical interface by deploying pathologists into the regions • To accredit new test methods within the laboratories. • Position and identify mechanisms to improve access coverage and improved turnaround times. • Point of Care Testing policy development • Implement Point of Care Testing policy directives.

Goal 2	Strategic Objective	Strategies
Academic Excellence in Training and Research	**3.2.** Research and Training in Occupational and Environmental Health and Safety.	• Increase support for teaching of undergraduate and postgraduate learners. • To enhance education and training experiences for health professional • To improve the use of technology for training purposes
	4.2 Increase pool of available pathology health professionals and pathologist national coverage.	
	4.3 Improved training platform	

Goal 2	Strategic Objective	Strategies
	4.4 Develop and implement a national research agenda for laboratory service.	• To improve and increase research output from affiliated staff and student • To engage closely with and strengthen undergraduate training platforms to ensure sustainable flow of high calibre entry level laboratory staff into NHLS training platforms**.** • To demonstrate translation of NHLS research into policy • Active engagement and involvement with the NDoH regarding service delivery and policy. • Support the implementation and roll-out of the National Health Insurance initiative. • Develop and implement Customer Relations Management system to address all customer queries and complaints
	1.4. Unqualified audit opinion of the NHLS	
	1.5. Strengthened oversight role of the Board	

Goal 3	Strategic Objective	Strategies
Sound Governance and Improved Stakeholder Relations	**1.4.** Audit opinion of the Auditor General	• Implement improved efficient supply chain processes. • Improve contract and supplier management processes and procedures. • Review delegations, roles, responsibilities and functions of head office and regions. • Continuous management of irregular, fruitless and wasteful expenditure. · Effective utilisation of Corporate Governance Committees. • Maintenance of sound internal controls and governance (King IV) • Improve visibility to clients and to support more health related events hosted by stakeholders. • Active engagement and involvement with the NDoH regarding service delivery and policy. • Develop and implement integrated marketing and communication strategy and plan. • Support the implementation and roll-out of the National Health Insurance initiative.
	1.5. Strengthened oversight role of the Board	

Goal 3	Strategic Objective	Strategies
		• Implement Customer Relations Management system to address all customer queries and complaints

Goal 4	Strategic Objective	Strategies
Effective, Efficient and Ethical Organisation for improved service delivery and implementation of NHI	**1.7.** Modernised and efficient IT systems	• Leverage technology to build Innovative and digital solutions as well as to standardize and optimize laboratory and business processes through. • Provide dashboards with integrated data analytics and modelling tools for critical systems, including LIS. • Provide real-time data integration plan for owned and affiliated entities and more-advanced business intelligence tools to optimize the exploding volume of digital data, enable better
	1.6. Effective monitoring and evaluation system.	
	5.2. Laboratory services equipped, and functioning at a level that provides accurate, reliable results timeously.	
	5.3. Enhance planning, management and operational capacity of the laboratory services including the laboratory structure,	

Goal 4	Strategic Objective	Strategies
	roles, responsibilities and reporting lines for the provision of an efficient and quality service for NHI	decisions in care and risk management, improve quality and optimize performance • Develop and implement an integrated performance management system within an established and M&E unit). • Provide stronger analytics capabilities to evaluate healthcare data; predict and model revenue and laboratory services, and enable national comparisons. • Use digital healthcare data assets from modernized laboratory applications to differentiate the business. • Leading transformational initiatives that shape the longer-term future products, services and operations of the business, delivering the strategic business outcomes the NHLS aims for.

Goal 5	Strategic Objective	Strategies
Efficient Financial Practices	**1.1** Efficient financial management systems, policy and practice	• Maintenance sound internal controls • Implement mechanisms to improve debt recovery /collection • Develop accurate goods and services costing model • Strengthen a performance based budgeting system • Develop and maintain a contract and tender management system
	1.2 Improved revenue collection and billing system	
	1.3. National Procurement Plan	

Goal 5	Strategic Objective	Strategies
		• Implement improved efficient supply chain processes • Improve contract and supplier management processes and procedures.

Goal 6	Strategic Objective	Strategies
Skilled, competent and motivated workforce	**1.8** Appropriately trained human resources in adequate numbers to staff the service	• Establish an Integrated Talent Management System to improve NHLS Talent Strength. • Develop a systemic approach to employee capability development through Learning Academy. • Improve NHLS leadership capability to deliver greater results through effective performance management of teams. • Develop strategies and mechanisms to recruit and retain qualified staff. • Develop supervisory and leadership skills for managers and supervisors. • Cultivate productive inclusive working relationship between leadership and organised labour**.** • Implement workforce model**.**
	1.9. Workforce planning tool to determine staffing norms.	
	1.10. Laboratory structure, systems, roles , responsibilities and reporting lines for services are defined and operational	