NATIONAL HEALTH
LABORATORY SERVICE

NHLS Strategic Plan 2020 - 2025

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LIST OF ABBREVIATIONS

AARQA	Academic Affairs, Research, and Quality Assurance
AIDS	Acquired Immune Deficiency Syndrome
AG	Auditor-General
BSL	Bio-Safety Level
CCMI	Competition Commission Market Inquiry
CCMT	Comprehensive Care, Management and Treatment
CD4	Immune-level indicator
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CMSA	Colleges of Medicine in South Africa
DMP	Diagnostic media Products
DNA	Deoxyribonucleic Acid
EDL	Essential Diagnostic List
EOC	Emergency Operations Centre
FBC	Full Blood Count
FMPPI	Framework for Managing Programme Performance Information
GWME	Government-Wide Monitoring and Evaluation
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
HPRS	Health Patient Registration System
ICT	Information and Communication Technology
ILO	International Labour Organisation
IP	Intellectual Property
ISO	Organisation of International Standards
LIS	Laboratory Information System
MBOD	Medical Bureau for Occupational Diseases
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

NEPAD	New Partnership for Africa's Development
NHA	National Health Act
NHI	National Health Insurance
NHLS	National Health Laboratory Service
NICD	National Institute for Communicable Diseases
NIOH	National Institute for Occupational Health
NPG	National Pathology Group
NSI	National System of Innovation
NSP	National Strategic Plan
OHSACT	Occupational Health and Safety Act
PLWHIV	People Living with Human Immunodeficiency Virus
PFMA	Public Finance Management Act
PMTCT	Prevention of Mother to Child Transmission
POCT	Point-of-Care-Testing
PTS	Proficiency Testing Scheme
QMS	Quality Management System
SANAS	South African National Accreditation System
SAMA	South African Medical Association
SAVP	South African Vaccine Products
SONA	State of the Nation Address
SOP's	Standard Operating Procedures
TAT	Turnaround Times
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTO	Technology Transfer Office
U&E	Urea and Electrolytes
UHC	Universal Health Coverage
XDR	Extreme Drug Resistance

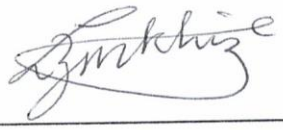
STATEMENT BY THE MINISTER OF HEALTH

I hereby endorse this National Health Laboratory Service (NHLS) Strategic Plan developed by the Board of the NHLS under the guidance of Professor Eric Buch, Chair of the NHLS Board and Dr Karmani Chetty, NHLS Chief Executive Officer.

This NHLS 2020/21-2024/25 Strategic Plan considers all the relevant policies, legislation and other mandates for which the National Health Laboratory Service is responsible and accountable for.

It also accurately reflects the strategic goals and objectives which the National Health Laboratory Service will endeavour to achieve over the period 2020/21 – 2024/25.

Dr Zwelini Mkhize (MP)
Minister of Health

Signature: 

STATEMENT BY THE CHAIRPERSON OF THE NHLS

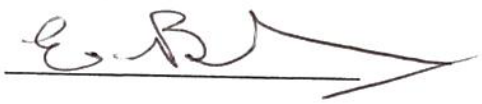
Sixty to 70% of clinical decisions and patient diagnoses are linked to pathology and laboratory services. The National Health Laboratory Service plays a critical role in providing these services for the 80% of South Africans who use public health care. Thus, in order to serve our people better, the NHLS has focused on improving its efficiency, quality, governance and finances in the last strategic period. Liquidity is much improved.

This 2020 – 2025 Strategic Plan will gear the value proposition of the NHLS to reach a new level and position it as a preferred service provider to National Health Insurance. It focuses on new strategies to advance services in line with opportunities of the fourth industrial revolution and place emphasis on clinical effectiveness and efficiency, high quality of testing and better value for public money. The NHLS will continue to value and advance the conditions for its staff. Resources will be mobilised through a more sustainable service model, tighter procurement measures and improved operations. Tariff increases will continue below inflation.

Amongst our priorities for the next five years are advancing the national footprint of diagnostic pathology services, aligning to the needs of National Health Insurance; and improving access and turnaround times and the quality of our work. We will leverage innovation and new technology to improve efficiency and focus on enhancing health professional and patient experience.

In all, this strategic plan aligns with and contribute to the National Development Plan Implementation Plan Medium Term Strategic Framework 2019-2024 for Priority 2 "Education, Skills and Health" and Outcome 2: "A long and healthy life for all South Africans."

I would like to thank the Minister of Health and the Director General for their commitment to and support for the NHLS and the Board of the NHLS for their diligence and upholding public trust in them. The NHLS now has a stable Executive and I wish the CEO and her team every success as move to implement this challenging strategy in a time of rapid changes in the health system and in the technology of pathology and laboratory services



Professor Eric Buch

Chairperson of the Board (NHLS)

OFFICIAL SIGN OFF

It is hereby certified that this Strategic Plan was:

- Adopted 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; and
- Accurately reflects the outcomes and outputs which the NHLS will endeavour to achieve over the period 2020 - 2025.

Prof Koleka Mlisana
EXECUTIVE MANAGER: ACADEMIC AFFAIRS, RESEARCH AND QUALITY ASSURANCE

Prof Lynn Morris
INTERIM DIRECTOR: INSTITUTE FOR COMMUNICABLE DISEASES

Dr Spoponki Kgalamono
ACTING DIRECTOR: NATIONAL INSTITUTE FOR OCCUPATIONAL HEALTH

Dr Mojaki Mosia
EXECUTIVE MANAGER: HUMAN RESOURCES

Mr Sibongiseni Hlongwane
CHIEF INFORMATION OFFICER

OFFICIAL SIGN OFF

Ms Violet Gabashane
SENIOR MANAGER: MONITORING AND EVALUATION

Mr Michael Sass
CHIEF FINANCIAL OFFICER

Dr Karmani Chetty
CHIEF EXECUTIVE OFFICER

Professor Eric Buch
NHLS BOARD CHAIRPERSON

Approved by:

Dr Zwelini Mkhize, (MP)
EXECUTIVE AUTHORITY, MINISTER OF HEALTH

PART A: OUR MANDATE

1. Constitutional Mandate

In terms of the provisions of the Constitution of the Republic of South Africa, 1996 (as amended), the NHLS is, amongst others, guided by the following sections and schedules and its role is to contribute towards:

1) The Constitution, which places obligations on the state to progressively realise socio-economic rights, including access to health care.
2) Section 27 of the Constitution, which states as follows: with regards to health care,

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

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

(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.

2. Legislative and other mandates

The legislation outlined below makes provision for NHLS planning, monitoring of performance, reporting and evaluation.

2.1 Public Finance Management Act (PFMA), 1999 (as amended)

Section 27(4) of the PFMA makes provision for the development of measurable objectives that must be included in the annual budgets of national and provincial institutions. Sections 40 (3) (a) and 55 (2) (a) make provision for the reporting of performance against predetermined objectives in institutions. The PFMA promotes reporting against predetermined measurable objectives that are outlined in short and medium-terms plans. Section 51 (c) of the PFMA states that the Accounting Officer has the responsibility to manage, safeguard and maintain assets and to

manage the liabilities of the department or entity. Section 51 (a) (iv) in turn makes a provision for a system for properly evaluating all major capital projects prior to a final decision and managing available working capital efficiently and economically.

2.2 The National Health Laboratory Service Act, 37 of 2000

The National Health Laboratory Service (NHLS) was established in terms of the National Health Laboratory Service Act, 2000 (Act No.37 of 2000) in order to provide quality affordable and sustainable health laboratory and related public health services.

The objects of the service are to:

- provide cost-efficient health laboratory services to all public-sector health care providers, any other government institution inside or outside of the Republic that may require such services; and any private healthcare provider that requests such services;
- support health research; and
- provide training for health science education.

2.3 The National Health Laboratory Service Amendment Act, 5 of 2019

The National Health Laboratory Service Amendment Act, 2019 (Act No. 5 of 2019) was signed into law by the President on 29 April 2019.

The NHLS amendment Act serves to amend the National Health Laboratory Service Act 2000 (Act No.37 of 2000) so as to define certain expressions and to amend certain definitions; to make the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000) applicable to the NHLS, to adjust the objects and duties of the service; to strengthen the governance and funding mechanism of the service and to provide for matters connected therewith. The NHLS amendment Act is pending proclamation.

1.4 The National Health Act, 61 of 2003

The above Act provides a framework for a structured uniform health system within the Republic of South Africa, 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 the 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 inquiry and advocacy which encourages participation;
- promote a spirit of co-operation and shared responsibility among public and private health professionals and providers as well as other relevant sectors within the context of national, provincial and district health plans; and
- create the foundations of the health care system, which are to be understood alongside other laws and policies that relate to health.

3. Applicable Policies and planned Legislative and Policies

3.1 National Health Insurance Bill

The National Health Insurance (NHI) Bill, provides for the establishment of the National Health Insurance (NHI) Fund as a legally defined organ of the state.

The Bill seeks to:

- establish the NHI Fund, its functions, power, and duties. It further provides for the control of the NHI Fund by the Board;
- define beneficiaries of services covered by the NHI Fund, including population registration;
- provide for contracting of accredited providers of personal health care services; and
- allows the Minister to determine health care benefits that will be reimbursed through the NHI Fund, as well as the service coverage and cost measurement provision.

Key Features of the NHI Bill

The purpose of the NHI Bill is to establish and maintain an NHI fund through mandatory prepayment that aims to achieve sustainable and affordable universal access to quality health care services.[25] This will be achieved by; (i) serving as the single purchaser and single-payer of health care services in order to ensure the equitable and fair distribution and use of health care services; (ii) ensuring the sustainability of funding for health care services; and (iii) providing for equity and efficiency in funding by pooling of funds and strategic purchasing of health care services, medicines, health goods and health-related products from accredited and contracted health care service providers. This is applicable to all health establishments, excluding military health services and establishments.

The NHI Fund is to purchase health care services as determined by the Benefits Advisory Committee (BAC), on behalf of (i) citizens, (ii) permanent residents, (iii) refugees and (iv) inmates. A person seeking health care services from an accredited provider must be registered as a user of the fund. The user must also present proof of registration to the fund to the health care service provider so as to claim the health-care service benefits to which he or she is entitled. The NHI fund will be established as an autonomous public entity in line with the Public Finance Management Act (PFMA). The NHI Board is accountable to the health Minister and has to govern the fund in accordance with PFMA provisions.

The Board shall consist of not more than 11 persons appointed by the Health Minister that are not employed by the fund and one member who represents the Minister. Board members are appointed for a term not exceeding five years, which is renewable only once. The criteria for board members are as follows; (i) be a fit and proper person; (ii) have appropriate technical expertise, skills and knowledge or experience in health care service financing, health economics, public health planning, monitoring and evaluation, law, actuarial sciences, information technology and communication; (iii) be able to perform effectively and in the interests of the general public; (iv) not employed by the State; and (v) not have any personal or professional interest in the fund. The health minister may appoint a chairperson and deputy chairperson from amongst the members of the board.

3.2 National Development Plan: Vision 2030

The National Development Plan (NDP) is a long-term vision for the country, which provides a broad strategic framework to guide key government choices and actions and focuses on the critical capabilities needed to transform the economy and society. The plan highlights that accelerated development in South Africa requires the active support of all citizens, leadership in all sectors that puts the country's collective interests ahead of narrow, short-term goals, and radically improved government performance.

The 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, while the other four deal with aspects of strengthening health systems. NHLS's role is to contribute to and align its services with the National Development Plan vision 2030.

By 2030, South Africa should have achieved the following:

- Raised the life expectancy of South Africans to at least 70 years;
- Progressively improved TB prevention and cure;
- Reduced maternal, infant and child mortality;
- Significantly reduced the prevalence of non-communicable diseases;
- Complete health system reforms;
- Primary healthcare teams that provide care to families and communities;
- Universal health care coverage; and
- Filled posts with skilled, committed and competent individuals.

3.3 Sustainable Development Goals

The Sustainable Development Goals 2030 built on the Millennium Development Goals 2015 were adopted as the Global Goals by world leaders on 25 September 2015. They formulated seventeen (17) Sustainable Development Goals (SDGs) to end poverty, fight 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. 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;

7. 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;

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

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

The vision of the NHLS is to provide a high-quality patient-centred laboratory service that is clinically efficient and cost-effective. This will contribute significantly to goal 3 of the SDG, namely to, “Ensure healthy lives and promote well-being for all at all ages”, as well as to the vision of the South African health system “A long life for all South Africans”.

3.4 Alignment with the National Department of Health's (NDoH's) Medium-Term Strategic Framework and National Development Plan Implementation Plan 2019-2024

The NHLS plan is aligned with the National Department of Health's plan that responds to the priorities identified by the Cabinet of the sixth administration of a democratic South Africa, which are embodied in the Medium-Term Strategic Framework (MTSF) for the period 2019-2024. It is aimed at eliminating avoidable and preventable deaths (***survive***); promoting wellness, and preventing and managing illness (***thrive***); and transforming health systems, the patient experience of care, and mitigating social factors determining ill health (***transform***), in line with the United Nation's three broad objectives of the Sustainable Development Goals (SDGs) for health.

Over the next five years, the NHLS responses are structured into four outcomes and 11 outputs which are aligned to the NDoH goals as well as the Pillars of the Presidential Health Summit Compact, as outlined in table1.

Table 1: Alignment of NHLS Outcomes and Outputs with NDoH Goals and the pillars of the Presidential Health Summit Compact.

	NDoH MTSF 2019-2024 Goals	NHLS Outcome	NHLS Outputs	Presidential Health Summit Compact Pillars
Survive and Thrive	Goal 1: Increase Life Expectancy, improve health and Prevent Disease	Clinical effectiveness and efficiency High-Quality Service Cost-effective services Good Governance	Modernised Laboratory Services Improved Total Turnaround Times Appropriately trained human resources in adequate numbers Performance driven workforce Equitable service coverage Improved stakeholder relations Reduced cost of pathology services to the clients Audit opinion of the Auditor General	N/A
Transform	Goal 2: Achieve UHC by Implement NHI			Pillar 4: Engage the private sector in improving the access, coverage, and quality of health services; and Pillar 6: Improve the efficiency of public section financial management systems and processes
	Goal 3: Quality Improvement in the Provision of care	High-Quality Services	Strengthened total quality management systems	Pillar 5: Improve the quality, safety, and quantity of health services provided with a focus on primary health care,
				Pillar 7: Strengthen Governance and Leadership to improve oversight, accountability and health system performance at all levels
				Pillar 8: Engage and empower the community to ensure adequate and appropriate community-based care
				Pillar 1: Augment Human Resources Health Operational Plan
				Pillar 2: Ensure improved access to essential medicines, vaccines, and medical products through better

	NDoH MTSF 2019-2024 Goals	NHLS Outcome	NHLS Outputs	Presidential Health Summit Compact Pillars
				management of supply chain equipment and machinery Pillar 6: Improve the efficiency of public sector financial management systems and processes
				Pillar 9: Develop an Information System that will guide the health system policies, strategies, and investments
	Goal 4: Build Health Infrastructure for effective service delivery	Clinical effectiveness and efficiency	Modernised information technology systems	Pillar 3: Execute the infrastructure plan to ensure adequate, appropriately distributed and well-maintained health facilities

3.5 Framework for Managing Programme Performance Information (2007)

The Framework for Managing Programme Performance Information (FMPPI) outlines key concepts in the design of management systems to define, collect, report and use performance information in the public sector. The FMPPI emphasises that performance information is essential to focus the attention of the public and oversight bodies on whether public institutions are delivering value for money, by comparing their performance against their budgets and service delivery plans, and to alert managers to areas where corrective measures are required.

3.6 Policy Framework for the Government-Wide Monitoring and Evaluation System (2005)

The Framework for the Government-Wide Monitoring and Evaluation (GWME) System identifies programme performance information as one of the data terrains underpinning GWME, focusing on information that is collected by government institutions in the course of fulfilling their mandates and implementing the policies of the government.

3.7 National Public Health Institute of South Africa (NAPHISA)

The establishment of the National Public Health Institute of South Africa (NAPHISA) is envisaged, and will comprise divisions dealing with the following:

- Communicable Diseases;
- Non-Communicable Diseases;
- Injury and Violence Prevention;
- Occupational Health and Safety;
- Environmental Health

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 advise to the government to achieve improvements in the health of the population. It will also provide coordinated disease and injury surveillance, research, training, and workforce development, and it will monitor and evaluate services and interventions directed towards major health problems affecting the population. NAPHISA will provide training, conduct operational research and support interventions aimed at reducing the burden of communicable; non-communicable diseases; injuries and violence and occupational diseases.

The NAPHISA Bill was approved by Parliament on 25 February 2020 however, the anticipated implementation date is currently not known. Once assented to by the President, regulations will still need to be drafted before the Act is proclaimed.

NAPHISA will impact the functioning of the NHLS, as there will be a demarcation between roles and functions and initially this separation may not be as obvious. Planning will need to be undertaken to take into account the separation of functions, human resources, administration, support functions, finance, and research and training.

3.8 Relevant Court Rulings

There are no court rulings that will have a significant ongoing impact on operations or service delivery obligations.

PART B: OUR STRATEGIC FOCUS

1. Vision

To provide a high-quality pathology and laboratory services that are clinically efficient and cost-effective.

2. Mission

The NHLS will provide pathology and laboratory services through competent professionals and state-of-the-art technology, supported by evidence-based research, training, and innovation to enhance integrated service delivery to meet the needs of the population.

3. Values

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

Table 2: NHLS Values

#	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.
3.2	Unity of purpose, Shared Vision and Teamwork.	All employees should be united by a common vision and support each other to contribute to a beneficial and safe working environment.
3.3	Service excellence	This represents being committed to working with customers and building good relationships with them by understanding their needs, responding quickly and providing appropriate solutions.
3.4	Transformation	We will invest in the professional growth of staff by sharing knowledge and experience, peer networking, education through training and seeking opportunities to develop.
3.5	Innovation	We are committed to fostering an environment that supports research, with particular emphasis on innovative approaches to diagnostics, surveillance and the strengthening of health systems to support national programmes.
3.6	Integrity	We will set and achieve goals, consistently delivering business results while complying with standards and meeting deadlines
3.7	Continuous improvement	The constant drive of process improvement is the key to a successful organisation. The NHLS needs to create a culture of continuous improvement by empowering ALL team members within the organisation to continuously seek opportunities for improvement.

4. Situational Analysis

4.1 External Environment Analysis

4.1.1. The Role of pathology and laboratory service in health care.

Pathology and laboratory information enables physicians and other healthcare professionals to make appropriate evidence-based diagnostic or therapeutic decisions for their patients. Clinical laboratory services have a direct impact on many aspects of patient care including, but not limited to, length of stay, patient safety, resource utilization, and customer satisfaction.

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 its laboratories are networked using a single laboratory information system. All the data are stored in a Central Data Warehouse (CDW) which is a national resource for programme design, monitoring and evaluation.

4.1.2. Population

The population of South Africa is growing rapidly with recent figures suggesting 58.8 million individuals who currently require healthcare compared to the 55.5 million of the 2017 mid-year population estimates. Gauteng continues to record the largest share of South Africa's population, with approximately 15.2 million people (25.8%) living in the province. The second largest population of approximately 11.3 million people was recorded in KwaZulu-Natal. Northern Cape maintained its status as the province with the lowest population in the country with an estimated population of 1.26 million people.

Table 3: Mid-year population estimates by province, 2019 (STATS SA)

	Population estimate	% of total population
Eastern Cape	6,712,276	11.4
Free State	2,887,465	4.9
Gauteng	15,176,116	25.8
KwaZulu-Natal	11,289,086	19.2
Limpopo	5,982,584	10.2
Mpumalanga	4,592,187	7.8
Northern Cape	1,263,875	2.2
North West	4,027,160	6.9
Western Cape	6,844,272	11.6
Total	**58,775,022**	**100.0**

4.1.3. Burden of Disease

4.1.3.1. Communicable Diseases

The NDP has called for South Africa to achieve a “generation free of HIV AIDS”, while Goal 3 of the SDG has set the target to “end the epidemic of AIDS, tuberculosis, and malaria” by 2030.

The estimated overall HIV prevalence rate is approximately 13.5% among the South African population. The total number of people living with HIV (PLWHIV) was estimated at approximately 7.97 million in 2019. For adults aged 15 to 49 years, an estimated 19.07% of the population is HIV positive.

The number of AIDS-related deaths would need to reduce by 41% (from 115 167 in 2018 to 68.301 by 2024 and 21 436 by 2030) for South Africa to reach its target of ending the HIV epidemic by 2030.

The 90-90-90 strategy aims to reduce premature mortality and onward transmission of AIDS. The country is driving interventions to ensure that by 2020, 90% of all people with HIV will know their status, 90% of those who know their status and are HIV positive are put on treatment and 90% of those on antiretroviral treatment are virally suppressed and by 2024/25 the targets are 95% for each cascade. South Africa is currently at 91-68-83 in terms of performance against 90-90-90..

The coverage varies and is 94-72-85 for women, compared to 89-62-80 for men, and 77-60-62 for children. The reach is particularly poor among men and children younger than 15 years.

Tuberculosis (TB) remains the leading cause of mortality in South Africa, despite an almost 25% reduction over three (3) years (39 695 deaths in 2014 to 29 513 in 2016). Improvements in case detection and retaining patients in care will be essential to reduce premature mortality, and to prevent MDR and XDR-TB. The global End TB strategy has called on WHO member states to reduce the number of deaths caused by TB by 75% by 2025, and 90% by 2030 when compared to 2015 baselines. This translates to a target of not more than 8 510 deaths by 2025, and 3 404 by 2030, to ensure that South Africa achieves its SDG target of "ending the TB epidemic by 2030". This will require the health system to intensify case finding, and placing those diagnosed on treatment, and to ensure that they successfully complete their treatment because TB is curable.

The rapid acceleration plan for HIV and TB treatment access will have a knock-on effect on the NHLS in that it will require significant programme review aimed at the automation, modernisation, consolidation and integration of laboratory platforms and services to ensure affordability.

4.1.3.2. Non-Communicable Disease

A non-communicable disease (NCD), is medical condition or disease which by definition is non-infectious and cannot be passed from person to person. NCDs may be chronic diseases for long duration and slow progression, or they may result in more rapid death. According to the World Health Organisation (WHO) the four main types of NCDs are cardiovascular diseases (like strokes and heart attacks), cancer, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes.

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 were 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 five times as many deaths as communicable diseases in low and middle-income countries (Hofman,2014: SAMJ).

4.1.3.3. Causes of death in South Africa.

There were 456 612 deaths recorded in 2016; of whom 52.7% were females and 47.3 were males Most deaths occurred in Gauteng, followed by KwaZulu-Natal and Eastern Cape

Figure1: Causes of Deaths 1997 - 2016

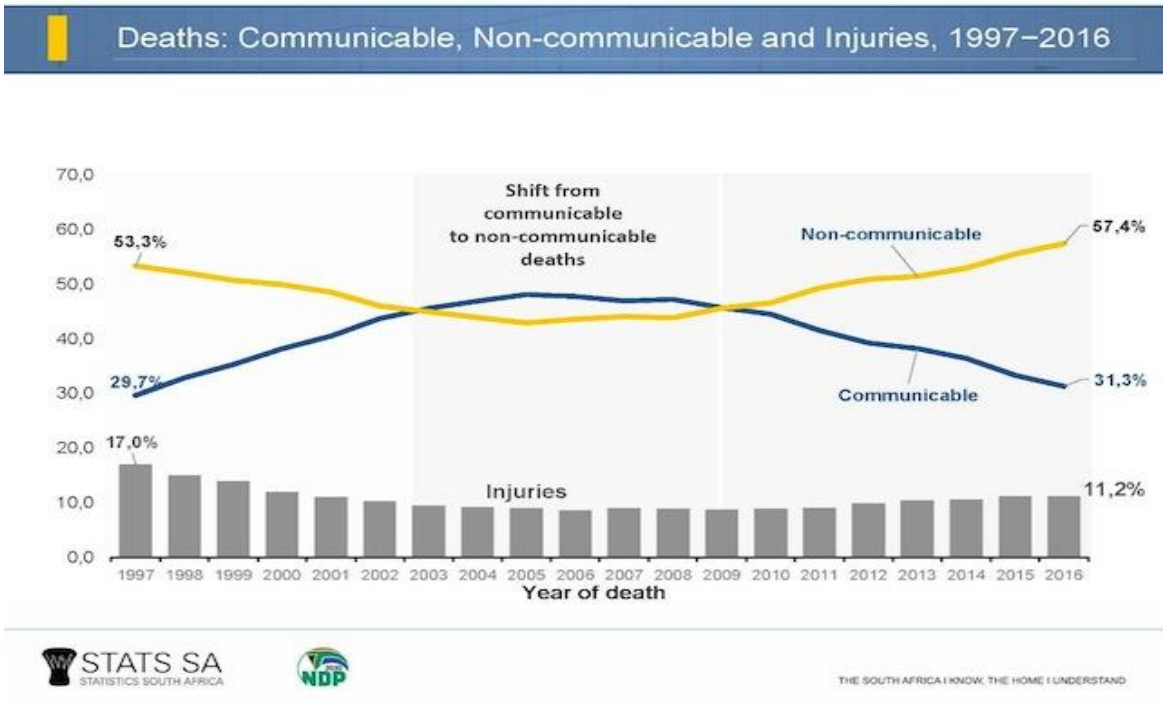
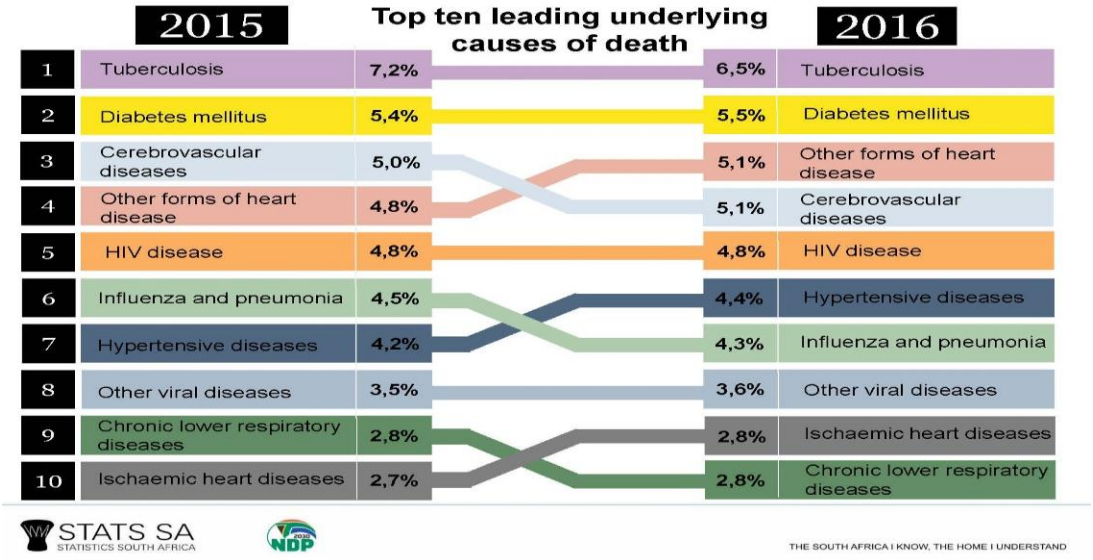


Figure 2: Top ten leading underlying cause of death 2015 vs. 2016



Although Tuberculosis (TB) remained the number one cause of death in 2016, there is an indication that non-communicable diseases are now taking over as the major causes of death in South Africa; with diabetes, various forms of heart diseases and cerebrovascular diseases (strokes) taking a lead.

The NHLS will, therefore, strengthen its services in the diagnosis of these diseases and ensure that it provides rapid and reliable results at affordable prices to support the NDoH in detection, screening and treatment of these diseases.

4.1.3. Comparison of private and public market in pathology: South Africa

Medical testing laboratories are distributed across the public and private health sector in South Africa.

To be able to come up with strategies to prepare for the implementation of the NHI, it is important to compare the staffing, expenditure and test volumes of the private pathology practices and the NHLS. Consideration was given to the NHLS expenditure data and the health sector data that was reported by the Competition Commission Market Inquiry (CCMI), to analyse differences in pathology provision. The National Pathology Group (NPG) is a specialist subgroup of the South African Medical Association (SAMA) that represents pathologists. The three main private pathology practices within the NPG are Pathcare, Lancet and Ampath followed by smaller

practices. The NPG reported in its submission to the CCMI that approximately 200 000 tests are performed daily by the private laboratory groups. This was extrapolated to 53 million to determine the number of tests done annually. The annual expenditure for private pathology groups was obtained through the Council of Medical Schemes Report. The annual expenditure, as reported by CCMI, was divided by the estimated number of tests to determine a crude average expenditure per test.

There are approximately 91 million tests performed in the public sector compared to 53 million in the private sector. *(*Table 4). When comparing annual test volumes, the average expenditure per test was approximately R78 and R154 for the public and private sector respectively. Using the population estimates of Statistics South Africa (STATS SA), the per capita (pc) expenditure for the public sector was approximately R153 for the public sector compared to R702 for the private sector based on the assumption that twenty percent (20%) of the population (medical aid population) utilise the private sector.

It must be noted that the NHLS average expenditure per test and per capita, ex is much lower than the private sector, notwithstanding the additional cost of training and research it incurs.

Table 4: Analysis of public and private sector pathology expenditure and staffing.

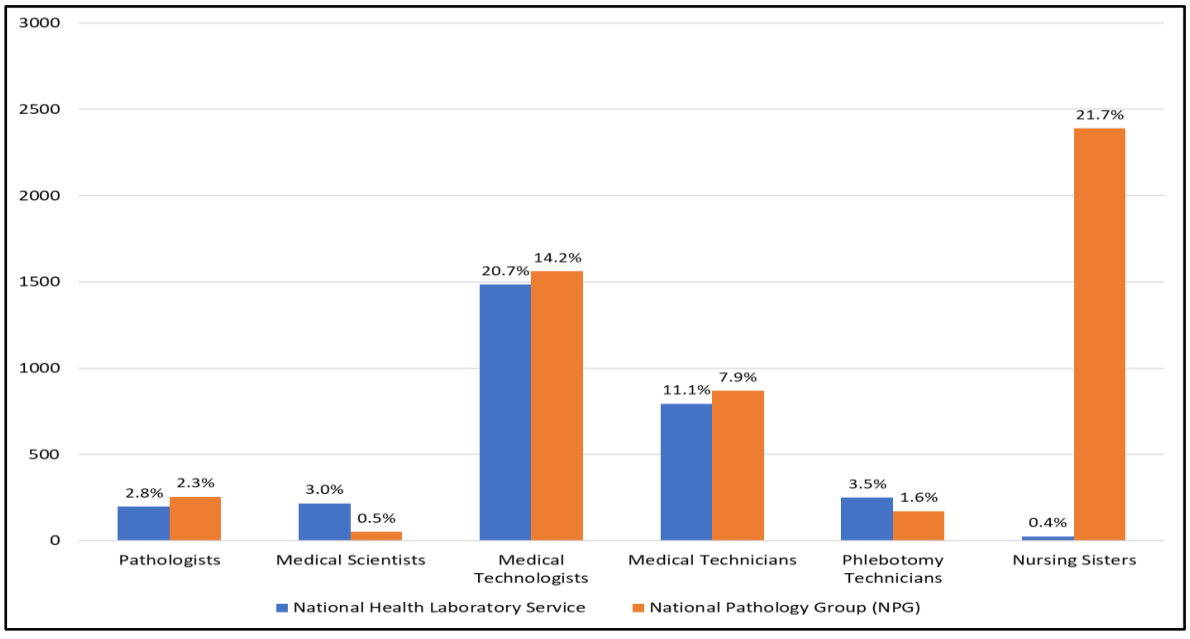
Category	National Health Laboratory Service	National Pathology Group (NPG)	Total NHLS + Private
Annual test volumes	91 302 409	*53 000 000	144 302 409
Annual expenditure	R7 094 905 000	R8 160 000 000	R15 254 905 000
Average expenditure per/test	**R78	**R154	**R106
Total population	46 499 860	11 624 966	58 124 826
Per capita expenditure	153	702	262
*Annual test volumes extrapolated from data provided to the Competition Commission			

**Calculates as annual expenditure as reported by CCMI divided by annual test volumes extrapolated to the CCMI vs. NHLS annual expenditure divided by NHLS annual test volumes.

Staffing distribution in the public and private sector were compared. The majority of the pathology workforce 10 993 (60.5%) are employed within the private pathology sector as opposed to 7 163 (39.5%) in the public sector.

The staff breakdown for the following categories was analysed; (i) pathologists, (ii) medical scientists, (iii) medical technologists, (iv) medical technicians, (v) phlebotomy technicians and (vi) nursing sisters. Very similar percentages were reported for pathologists at 2.8% and 2.3% for the public and private sectors (Figure 1). However, scientists represented 3.0% of the public sector compared to 0.5% for the private sector. These two categories reflect the teaching and training, research and national institutes that are delivered within the public sector. There were fewer medical technologists and technicians in the public sector, despite providing more tests per day which may indicate better productivity. There was a marked difference for nursing sisters with the private sector, offering a seamless phlebotomy service. This is a huge advantage that private pathology practices control all aspects of laboratory service delivery from sample collection to results delivery.

Figure 3: Distribution of key staff categories in the public and private pathology sector



4.2. Internal Environment Analysis

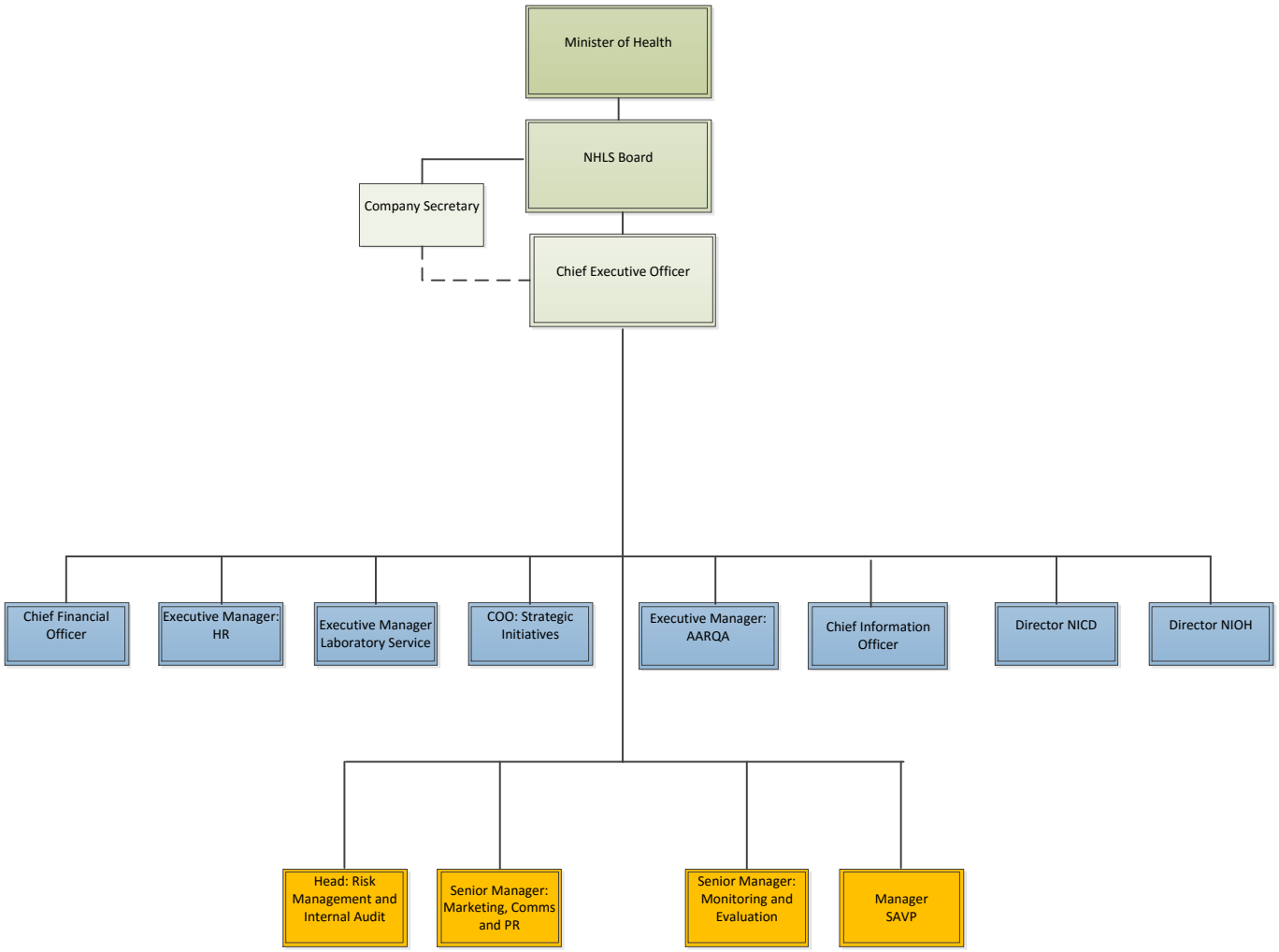
4.2.1. Organisational Structure

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 following nominations from different constituencies. The Minister will then appoint, from the nominated persons, an appropriate person or persons who qualify to be appointed in terms of the NHLS Act.

The Chief Executive Officer is appointed by the Board. The Board further appoints the Executive Managers and they are accountable to the CEO. The Company Secretary has dual reporting lines. He/she is accountable to the Board functionally, and to the Chief Executive Officer (CEO, administratively.

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

Figure 4: Indicates the high-level organisational structure within the NHLS



4.2.2. Laboratory Services

The NHLS's mandate is to ensure that services provided represent the best quality and value for public resources. The NHLS laboratories are predominantly based in public hospitals, in all nine provinces, with their service package increasing with the level of care of that hospital. The recent technological advancements employed in modern laboratories, provide the opportunity for substantial process improvements and delivery of results to clinical services.

Turnaround time (TAT) of test results is one of the most prominent indicators of laboratory service performance and quality of service and it is often used as a key performance indicator. The NHLS has in the past years shown to have achieved good TAT during the analytical phase (in-lab TAT: **Figure 5: stage 5 only**), however, clinicians and patients have not experienced the impact of the reported in-lab TAT. The NHLS will continue to improve its systems to ensure that the total turnaround times (from the time the specimens are collected by the NHLS drivers from the health facilities until the time the results are received in those facilities: **(Figure 5: stage 2 – stage 7**) are improved to ultimately add value to the care of the patients.

Figure 5: The overview of the entire laboratory process value chain (from the time the specimen is collected from the patient and registered on the HPRS to the time the results are communicated to the patient).

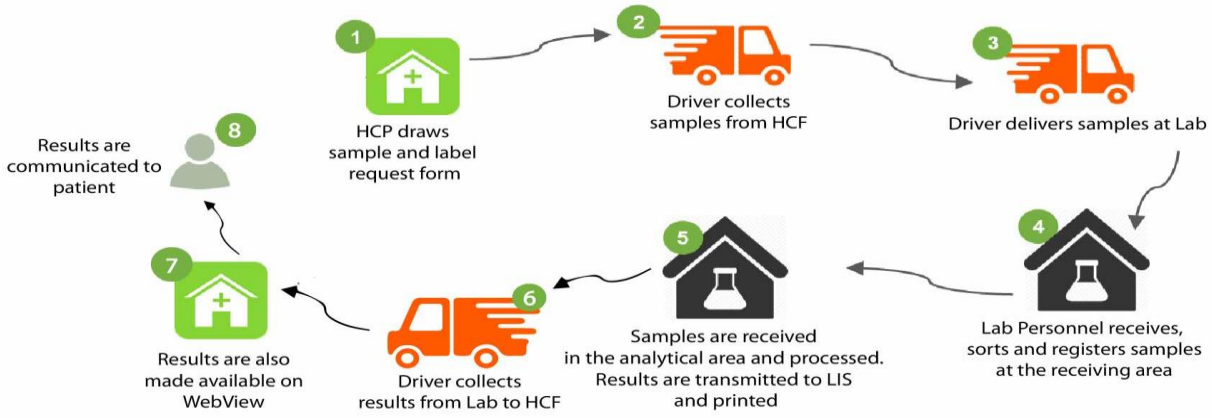


Diagram adapted from the NPP presentation.

Table 5 below generally demonstrates good analytical TAT. The NHLS will be developing and implementing the specimen tracking system, which will enable the measurement of the pre **(Figure 5 above; from stage 2 – 4)** and post-analytical **(Figure 5 above; from stage 6-8)** TAT to demonstrate the laboratory process value chain and enable the identification of gaps and implementation of improvement plans where necessary.

Table 5: Analytical turnaround times trend in the past five years (2015-2019)

Performance Indicator	2014/15	2015/16	2016/17	2017/18	2018/19
	Percentage Turnaround time (Analytical)				
Percentage of TB microscopy tests performed within 40hours	92%	91%	96%	94%	94%
Percentage of TB GeneXpert tests performed within 40 hours	New	New	97%	91%	94%
Percentage of CD4 tests performed within 40 hours	90%	89%	94%	91%	91%
Percentage of viral load (VL) tests performed within 96 hours	86%	64%	87%	82%	86%
Percentage of HIV PCR tests performed within 96 hours	82%	73%	82%	77%	76%
Percentage of cervical smear tests performed within five weeks	63%	48%	97%	90%	84%
Percentage of laboratory tests (FBC) performed within eight hours	New	New	80%	94%	95%
Percentage of laboratory tests (U&E) performed within eight hours	New	New	80%	91%	94%

The NHLS will continue the process of enhancing the provision of rapid, reliable and efficient service delivery at low cost through, state of the art laboratories, the right people with the right skills at the right level, effective and efficient procurement services, cutting edge information technology whilst ensuring that it remains financially stable to sustain its operations.

The NHLS service model will also be aligned with the implementation of the NHI and NDP five-year implementation plan.

4.2.3. Academic Affairs, Research and Quality Assurance

Academic Affairs, Research and Quality Assurance (AARQA) 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, 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.

4.2.3.1. Accreditation:

The National Health Insurance (NHI) Bill states that all services must obtain accreditation in order to receive funds from the NHI Fund. This has major implications for the NHLS facilities. The NHLS will implement a concerted drive to ensure that all the facilities are accredited for the implementation of the NHI.

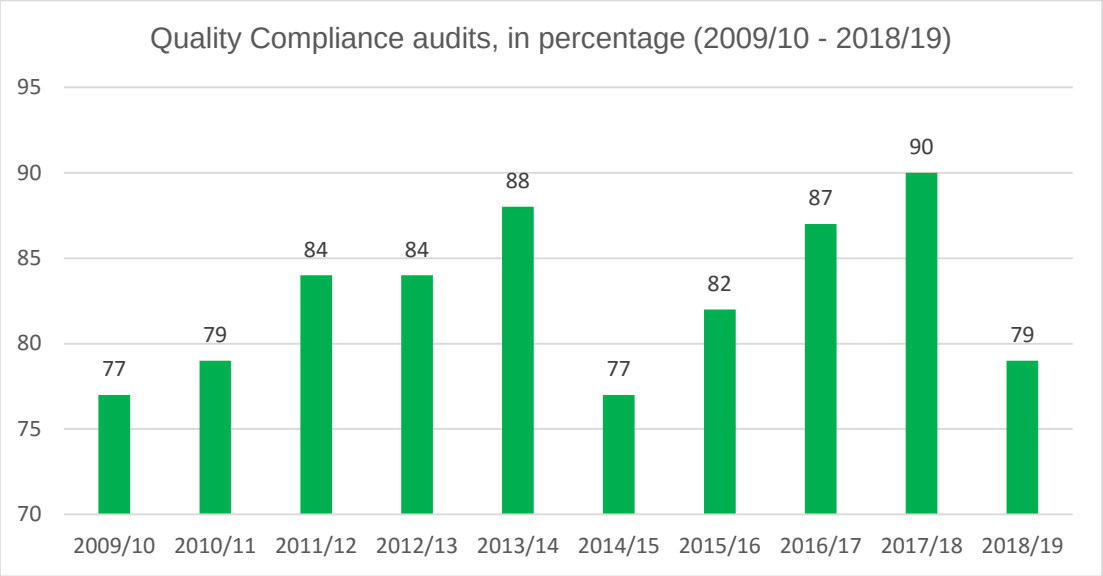
The percentage of accredited laboratories per tier at the end of March 2019 was as follows:

- 50/53 of national central laboratories
- 12/17 of provincial tertiary laboratories
- 17/44 of regional laboratories, and
- 11/147 of the district laboratories.

Whilst, the NHLS will be focusing on increasing the number of accredited laboratories, especially district laboratories, so that it is ready for the implementation of the NHI, it will continue to uphold high-quality service in the laboratories that are not yet SANAS accredited. That will be done by continuously performing quality compliance audits and enrolling all its laboratories in the proficiency Testing Schemes.The table below demonstrates the quality compliance results.

The drop in the performance in 2018/19 was due to the review of the checklist, aligning it to the SANAS ISO 15189 checklist.

Figure 6: Quality Compliance audit score (%) 2009/10-2018/19.



4.2.3.2. Proficiency Testing Schemes

NHLS Proficiency Testing Scheme (PTS) is ISO 17043 accredited. It provides PTS to all internal laboratories as well as the external laboratories both in and outside South Africa in the following, Bacteriology, Blood gas, Bets HCG, Cardiac Markers, CD4 (Flow cytometry), Cryptococcus Antigen, C Reactive Protein, Chemistry, Endocrinology, Erythrocyte Sedimentation Rate, Hematology (full blood count), hepatitis B surface antigens, HIV Early Infant Diagnosis, HIV Serology, HIV Viral Load, Malaria Rapid Diagnostic Tests, Morphology (Blood), Mycology Moulds, Mycology Yeast, Non-Treponemal Syphilis, Treponemal Syphilis, TB Culture, TB Line Probe Assay, TB Microscopy, Parasitology Blood, Parasitology Stool, reticulocyte Count and Therapeutic Drug Monitoring.

Countries with laboratories enrolled in NHLS PT Schemes: 2019/20 are Angola, Botswana, Burkina Faso, Cameroon, Democratic Republic of Congo, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Ivory Coast, Kenya, Lesotho, Malawi, Mozambique, Namibia, Niger, Nigeria, Sierra Leone, Swaziland, Tanzania, Uganda, United States of America, Zambia, and Zimbabwe. The strategy will focus on strengthening the PTS unit by establishing a fully automated PTS laboratory that will service all NHLS laboratories, the private sector laboratories in SA and laboratories across the African continent.

4.2.3.3. Research and Innovation:

In furthering its mandate of supporting health research and training for health science education, The NHLS conducts research in collaboration with the universities and national and international researchers. The research within the NHLS is mainly driven by the burden of disease in the country and this aligns with the priority focus areas of the NDoH and the strengthening of health systems as aligned in the National Strategic Plan (NSP). While there is still a tendency for the individual disciplines within the pathology to conduct research in silos, cross-disciplinary research is encouraged. The NHLS research output has been commendable to date, however, research should not only have an academic focus but also include other forgotten areas such as: operational research; entrepreneurial research, that will influence policy and benefit the community. A strategic innovation plan has recently been developed creating an enabling step that will allow the organisation to improve efficiencies. The plan is designed to enhance innovative ideas that will result in cost saving as well as novel mechanisms of delivery of laboratory services, improving competitiveness of the NHLS. The AARQA office will manage the establishment of the innovation office providing the necessary internal systems and secure funding to support and guide the innovations, including procedures to test/evaluate new products and processes.

Innovation must be viewed and managed as a positive, enabling step that will allow the NHLS to improve efficiencies and effectiveness, therefore, saving on the overall costs of providing diagnostic services to the nation and providing a service that is tailor-made to South African requirements. Furthermore, an innovation-enabled NHLS will be better integrated into the National System of Innovation (NSI), allowing it to guide and benefit from existing infrastructure, competencies and support, thereby strengthening both the NHLS and the system. The internal ability to support innovation and a potential income stream from successful innovations will encourage interested staff to contribute to a positive culture of the organisation. Innovation remains a strong value proposition of the NHLS which should be fully leveraged to support its strategic positioning.

The NHLS has a track record demonstrating innovative processes and products. However, there is a need to deepen and embed innovation more firmly into the strategic plans, structures, and operations as a means of ensuring that the NHLS remains at the forefront of diagnostic services and also to maintain efficiency and effectiveness as a core responsibility in the NHLS. This directly supports the intent of the National Development Plan and will align the NHLS as a key institution of the South African National System of Innovation. Academic Affairs and Research (AAR) Department will concentrate on technology transfer, innovation and Intellectual Property (IP)

management. There is currently funding available to stablish a Technology Transfer Office (TTO) that will manage all IP.

The AAR Department continues to improve operational efficiencies of the Grants Office by establishing well defined processes that ensure optimal support and accountability to both the funders and the principal investigators. The AAR will actively explore new funding sources to broaden the current pool of grantors as the US funding gets reduced.

4.2.3.4. Teaching and Training

The NHLS is the sole provider of training of pathologist registrars. It also trains intern medical scientists, intern medical technologists and student medical technicians in the country. To date, the pass rate of registrars, who are trained to be pathologists, has been a huge challenge within the NHLS. The high failure rates in pathology registrar training limit the outputs of new pathologists thus compounding the shortage of pathologists. The NHLS being the sole training platform for pathologists in the country, means that the organisation becomes the pool for the private pathology sector as well. This has resulted in the current aggressive recruitment by the private sector of pathologists. The private sector has an advantage over the NHLS in that it is able to attract pathologists at much higher salaries. There is, therefore, an urgent need to train and qualify more pathologists to be able to meet the demand of both the NHLS and the private sector. In order to increase the number of qualified pathologists in the country, the NHLS must increase pathology awareness amongst undergraduates, contribute through the Colleges of Medicine in South Africa (CMSA) towards the development of the curriculum and create; communicate and fund a rotation plan to areas of expertise to maximise training exposure to the registrars.

The NHLS experienced a huge challenge in the 2018/19 financial year with regards to placing the intern medical technologists for training. The HPCSA regulations on the approval of the laboratories as training laboratories dictates that there must be sufficiently qualified medical technologists in the training laboratory who will be responsible for the training of intern medical technologists and student medical technicians as well as other practitioners who work under supervision. This puts a lot of pressure on the NHLS in terms of the available capacity for training of inter medical technologists and student medical scientists. The NHLS will look into identifying laboratories as training centres and capacitate them accordingly.

Other factors which need to be considered with regards to training within the NHLS are:

- the number of intern medical scientists and intern medical technologists vs. the demand in the industry;
- the number of students who qualify from the universities and universities of technology vs. the available capacity for training within the laboratories;
- the number of student medical technicians and student laboratory assistants we need to train vs. the NHLS demand on medical technicians and laboratory assistants; and
- the integration of the Bachelor of Science in Medical Laboratory Science graduate into the NHLS working platform.

4.2.4 National Institute for Communicable Disease

The National Institute for Communicable Diseases (NICD) is the national public health institute of South Africa, providing reference microbiology, virology, epidemiology, surveillance and public health research and training in communicable diseases. It serves as a publicly-trusted source of information, both during outbreaks and as part of its routine surveillance of priority infectious diseases.

The NICD works in close collaboration with the National and Provincial Departments of Health in the planning of policies and programmes to support communicable disease control and elimination efforts and provides specialised laboratory testing. A key role is to detect, respond and report timeously during communicable disease outbreaks by providing technical support and critical laboratory diagnostic services.

Several NICD laboratories are the World Health Organization (WHO) collaborating partners, providing reference diagnostic services and surveillance for communicable diseases such as influenza, poliomyelitis, tuberculosis and measles, among others. The NICD houses biosafety level (BSL) 3 laboratories and the only suited high containment BSL 4 laboratory in Africa, making it a premier research, surveillance and diagnostics institution in the area of communicable diseases. The Sequencing Core Facility at the NICD conducts next-generation sequencing for diagnosis and outbreak support. Surveillance for malaria and arbovirus vectors is a key function of the NICD, which also houses five insectaries for culturing a wide range of mosquito species that are of public health importance.

The NICD monitors disease trends using a variety of methods and data repositories. This includes the Central Data Warehouse and the recently established Notifiable Medical Conditions mobile

application that collects real-time data on certain communicable diseases of public health importance. This enables the collation and interpretation of up-to-date intelligence on communicable disease incidence in South Africa. This information can be used to calculate outbreak response thresholds, predict future disease trends, and inform control policies and regulatory practices.

The National Emergency Operations Centre (EOC) based at the NICD serves as a coordination centre for responses to public health emergencies such as the Listeriosis outbreak of 2017/2018. It aims to collate, organise and deploy resources, both internal and external, in response to a major infectious disease incident, outbreak or related event, which has been declared a Public Health Emergency by the Director-General of the National Department of Health.

The NICD has established partnerships and cooperative agreements with the Centres for Disease Control and Prevention, the National Institute of Allergy and Infectious Diseases, the Africa Centres for Disease Control and Prevention, the European Centre for Disease Control and Prevention, as well as WHO, and many other internationally recognised institutions. The NICD has a significant footprint and is a major global role player in the field of communicable disease surveillance and related research.

South Africa's public health needs and priorities guide the NICD's research agenda. Research is conducted from the genetic and environmental factors that govern transmissibility, virulence, epidemic behaviour and distribution of the most significant pathogens. Investigating the impact and effectiveness of interventions such as vaccines and drug treatments, including monitoring biological resistance to these interventions, is used to develop new guidelines and policies. Technology development and intervention-driven research are used to improve communicable disease surveillance, diagnostics, and control.

Through a variety of educational programmes in public health, the NICD offers training in unique settings such as the BSL 3 and 4 laboratories. The institute offers formal and informal training to field epidemiologists through the Field Epidemiology Training Programme, medical registrars, and field and laboratory personnel, including intern medical scientists, environmental health practitioners, and post-graduate students.

Staff generate new knowledge and disseminate information through numerous publications such as the Communiqué and the Public Health Surveillance Bulletin as well as reports, guidelines, and scientific journals.

Strategic objectives of the NICD

- To be the national public health institute for surveillance of communicable diseases in South Africa.
- To detect outbreaks or epidemics at an early stage in order to be able to timeously and effectively respond to them, or to anticipate imminent outbreaks or epidemics by investigation, research and analysis of data and to communicate accordingly.
- To engage in directed and relevant research to answer questions related to national and regional public health communicable diseases problems, their surveillance and management.
- To provide a reference function for communicable diseases laboratories in the public and private sectors nationally, regionally and internationally.
- To build capacity for communicable diseases nationally and regionally.

4.2.5 National Institute for Occupational Health

The NIOH is a division of the National Health Laboratory Service. It provides occupational and environmental health and safety support across all sectors of the economy to promote workers' health and safety through surveillance of occupational diseases, specialised laboratories, and health hazard evaluations, applied laboratory and epidemiological research, statutory autopsy services in terms of the Occupational Diseases in Mines and Works Act, as well as teaching and training of critical occupational health and safety skills.

Specialised advisory services are provided to national and provincial government departments, the Medical Bureau for Occupational Diseases (MBOD) and most industrial sectors including the informal sector.

Specialised laboratory work includes asbestos identification, monitoring, and evaluation; diagnostic lung pathology; analytical chemistry for biological monitoring specimens; dust component identification; microbial air sampling; allergy diagnostics; ergonomic assessments; nanoparticles and in-vitro risk assessments.

The Institute has also established a specialised HIV and TB Unit which concentrates on interventions in workplaces and contributes to mitigating the burden of disease. The National

Biobank is located on the NIOH premises and it secures and manages the collection of human biomaterial resources and data to boost research for health and biotechnology development.

The NIOH is a World Health Organization Collaborating Centre and has been recognised as a Centre of Excellence. It collaborates with various local and international universities, governments, and organisations including NEPAD and the ILO on matters including research, skills development, and policy advisory support. The institute is also home to Africa's occupational reference library which contains an extensive amount of occupational health knowledge that has been in existence for over 60 years.

4.2.6 South African Vaccine Producers

The South African Vaccine Producers (SAVP), a wholly-owned subsidiary of the NHLS, is a national asset that supplies strategic products to a global market. The focus of the SAVP is the production of world-renowned antivenom products, which are regarded as the gold-standard for treating bites from the deadliest African snake species.

SAVP is registered as a pharmaceutical manufacturer and has been producing antivenoms to treat the bites of snakes and arthropods for more than 80 years. These therapeutic animal antibodies remain the only specific treatment for envenomation. Worldwide antivenom production is threatened by being economically unattractive. SAVP is the sole manufacturer of this antivenom on the African continent and current antivenom stores meet less than half the antivenom requirement in Africa. However, there is now a resurgence of interest in antivenom production with a view of improving production methods. Increasing the SAVP antivenom output will require an investment in infrastructure, modern plasmapheresis equipment, and overall capacity.

Current antivenom effectiveness is limited by its impurity and lack of specificity. In the short term, interventions are aimed at the rational improvement of current antivenom products using geographically relevant snake species, as well as a more targeted immunization strategy that will replace crude venom with research-guided toxins with the greatest medical importance. These modernized immunizations could be supplemented with diverse consensus antigens, epitope strings, and DNA vaccines aimed at eliciting higher titres and a more cross-reactive immune response.

Only 10% of antivenom antibodies in a vial of antivenom are snake toxin specific. The majority are non-functional foreign animal by-products which can induce anaphylaxis in envenomed individuals. Current antivenom composition could also be improved using more scientific purification methods, such as on-column toxin-directed affinity purification to select for the most relevant and potent immunoglobulins.

Going forward, the SAVP will partner with local and international initiatives aimed at discovering next-generation antivenom that can be recombinantly produced in the laboratory, with improved breadth and specificity. This collaboration will set out to comprehensively understand which components of current SAVP antivenom are responsible for its potent and broad activity, and generate recombinant products in the laboratory that could supplement existing antivenom, and replace the current products in the longer-term.

4.2.7. Diagnostic Media Products

There are 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. The NHLS aims to consolidate these departments under single management and strengthen it to become one of the revenue-generating units.

One of the biggest advantages of DMP's products currently in its pricing. DMP is currently the lowest priced supplier in the market for both its internal customers and external customers.

Further, it is expected that DMP already produces a higher volume making it more capable to deliver on national laboratory testing needs.

Customer satisfaction is key and they consider suppliers based on various factors including the production TAT, price, and quality of the product, availability of stock, service excellence and administrative efficiency. This has to be supported with after-sales service, a trustworthy relationship and the capability to resolve challenges that are encountered. In effect, a true business unit with an appropriate full shop of resources. The certification status (ISO 9001: 2015) gives clients confidence in DMP to deliver competitive and quality products.

The current sales and client base were acquired with no marketing or strategic market assessment. Engagement with clients to understand needs will help focus on understanding what capacity to invest in. One of DMP's external clients is the WHO whose geographic reach and labs-related scope is wide. DMP will seek strategic partnerships with key industry role players including the WHO, CDC and reference laboratories to build a closer understanding of their laboratory needs and hone in on the best opportunities for growth.

4.2.8 Administration

The effective and efficient functioning of the laboratories is as strong as its administration. It is for this reason that the NHLS must invest in the support department to create an enabling environment for the delivery of its core mandate.

The administration programme plays a crucial role in the delivery of 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, monitoring, and evaluation function. NHLS depends highly on the effective management of financial resources and the procurement process as administered within the financial department. Generating sufficient revenue remains a critical focus area for NHLS to ensure financial viability and sustainability.

4.2.8.1. Finance

The entity after several years of financial difficulties has largely stabilised its finances and produced a surplus of R996 million in 2018/19. The surplus of R996 million in 2018/19 is due to an increase in diagnostic services to provinces, improved payments from provinces and cost containment measures implemented. The surplus will be used to fund essential capital expenditure that was severely curtailed in previous years due to cash flow constraints.

The revenue increased from R7.9 billion to R8.5 billion. The revenue from provincial budgets amounted to 87% of the total revenue generated.

The NHLS received a net cash inflow of R9.1 billion compared to R8.0 billion in the previous financial year. The better collection of outstanding debt is attributed to improved relations with customers (notably Provincial Departments of Health), including payment agreements. Of this R9.1 billion, R3.6 billion was utilised for personnel cost and R4.2 billion was utilised for goods and services.

Production costs, which include direct labour and material grew by 7% from R6.2 billion to R6.7 billion. This increase can mainly be attributed to an increase in labour, test volumes, consumable price increases and fluctuations in the exchange rate. Labour costs comprised 42% of the total revenue compared to 40% in the previous financial year, while operational costs increased by 67% due mainly to R458 million increase in debt impairment and a R54 million increase in employee costs. A stringent cost containing plan has yielded results in that indirect and controllable expenses have been significantly reduced in recent years.

The long outstanding accounts payable balance from procurement of good and services were significantly reduced, resulting in a reduction of the creditor days from 59 days in the previous financial year, to 29 days in the year under review. Improved financial stability enabled the NHLS to significantly reduce outstanding debt.

Years of financial instability has led to the NHLS under-investing and maintaining necessary capital equipment and infrastructure. This is being addressed by an accelerated CAPEX programme, but requires that surplus funds be prioritised for this matter. The significant cost of equipment and infrastructure (including the cost of leasing buildings where required) is progressively forcing the NHLS to look at outright purchase options rather than leasing

The NHLS is implementing better procurement policies and procedures to eliminate irregular expenditure. System enhancements are assisting in this process. Embedded bad procurement practices are being addressed through continual procurement training interventions. Notwithstanding the above, the NHLS acknowledges that further improvements are required, especially in terms of turnaround times in relation to capital expenditure.

Most of the consumables (reagents) required by the NHLS to perform its tests can only be used in the machines of the specific manufacturers. It is therefore essential that a diverse equipment fleet is used to guard against a single dominant supplier reneging on its contracted obligations and putting the NHLS at risk.

4.2.8.2. Information and Communication Technology

Information Technology plays a strategic role in enabling the NHLS achieve its mandate. It is therefore important that the NHLS as a key role player in the South African healthcare ecosystem applies information technology successfully in order to transform its business processes and deliver value to customers.

Information and Communication Technology Infrastructure

The information and communication technology (ICT) infrastructure remains a challenge in the NHLS. Network connectivity (MPLS) for the Wide Area Network's capacity does not meet the traffic demands. Faults are not resolved on time leading to laboratories being down without any commitments for uptime. Plans are in place to acquire services from other institutions and service providers. The server and storage infrastructure requires upgrades and capacity increase due to data increase. Procurement processes have already been initiated to procure the servers. The NHLS will investment more in digital solutions to enable standardisation and optimisation of laboratory and business processes.

Laboratory Information System

The Laboratory Information System (LIS) refers to the centralised IT system supporting our laboratory operations. The LIS is the primary system for this support with integration to testing instruments, processing, capturing and reporting of results. The LIS should interface to available healthcare systems to allow clinicians to access the test results as soon as they become available. In the future, the LIS will leverage the use of HPRS and mobile applications to provide a real-time communication system with patients.

Enterprise Resource Planning

The NHLS has invested in the use of Oracle E-Business Suite (EBS) Enterprise Resource Planning (ERP) solution to manage the following business functions: finance, supply chain management, contract management, payroll and human resources. The ERP system has been customised overtime to suit the business needs which has resulted in complications on the administration of the system. Additional requirements on talent management from HR and sourcing from SCM are currently being considered for procurement. Oracle has been engaged for different alternatives for the future of the ERP whether to continue owning the entire system and upgrade it, switch over to cloud services or a hybrid environment. A decision will be formally made as soon as we get the performance history of the system that we own to assess its capability for the near future.

Digital Transformation Initiatives

Digital transformation is the integration of digital technology into all areas of a business, fundamentally changing how the organisation operates and delivers value to customers. The NHLS has identified the following areas that are in urgent need of digital transformation:

- Laboratory processes through digital pathology.
- Specimen tracking using GPS and/or RFID technology.
- Mobile App for access to patient results and patient engagement.
- Digitizing Supply Chain Management Processes
- Order Entry System for laboratory test orders

These areas will be prioritised in this medium term.

Information Technology Service Delivery Model

There is an increasing drive in the NHLS to reduce costs and improve operational efficiencies through technological innovation. This often translates into the need for a growing number of Information Technology (IT) services, where success or failure of the business can hinge on its ability to facilitate these services on time, within budget, and to specification.

Developing in-house IT capabilities to complete projects or provide services can be a costly and risky venture, particularly when the IT needs of an organisation are constantly changing. The IT department will review its service delivery model with the objective to improve its operational efficiency.

4.2.8.3. Human Resources

A highly trained and skilled pathology workforce is essential to the provision of quality pathology services and the healthcare services that rely on them. Internationally it has been identified that at least 70% of all healthcare decisions involving diagnosis or treatment are informed by pathology.

Despite the reliance on diagnostic services, there are numerous challenges in the pathology sector and a growing threat about the future capacity of the pathology workforce as a whole to

continue to support the quality of care at existing levels and likely increased demand for services into the future.

Notwithstanding this, the excellence of our organisation demands parallel distinction in all aspects of the workplace if we are to sustain our global stature. These demands include upholding and living our Code of Conduct as well as our values. The Code of Conduct is the ethical foundation of our operations and supports our values. Our values are the beliefs we all share, that drives our organisational culture and priorities. They provide a framework for making decisions and defining how all employees are expected to conduct themselves in a professional and responsible manner. This is critical in our journey of providing high-quality patient-centred laboratory service that is clinically effective, efficient and cost-effective.

Taking from one of our values; unity of purpose, shared vision and teamwork, we are “One Team” and we are expected to execute our strategic plan with a unified national focus. To this end, we are expected to create and sustain a workplace culture of excellence and high engagement, foster innovation and growth, promote inclusion and respect diversity and enable the integration of the demands of career and life.

We commit to enabling NHLS’s mandate of excellence in teaching, research, and diagnostic service through strategic, innovative, and flexible policies, practices, programmes, and services that:

- Attract, develop, reward, and retain a diverse and talented workforce;
- Foster a productive work environment where people feel valued and respected;
- Support the changing nature of work and the work environment;
- Add value and reflect good stewardship of resources; that are fair, ethical, and legally compliant.

The above shall be detailed in our people strategy and be underpinned by a detailed implementation plan, that sets out clear actions and measures of success that must be deployed by the collective leadership across NHLS. This is achieved by creating an environment in which all colleagues are equally valued, honestly supported and truly recognised for their contributions. Thus we said, our staff lies at the heart of our work and it is only through their skills, commitment and motivation, that the NHLS is able to fulfil its mandate.

Our key objectives for the period that lies ahead can be summarised as follows:

- Develop our employer reputation to further enhance our overall brand identity and standing, to attract top talent;
- Embed our remuneration and reward principles to equal remuneration for work of equal value, by further identifying key jobs in which grade discrepancies exist;
- Establish clear performance objectives and expectations to ensure differentiation of performance across different levels, and to provide clarity on roles. This, to necessitate the development and implementation of the workload-benchmark framework;
- Celebrate diversity and inclusion within our workforce, recognise the contribution of all staff, and enhance the overall success of the organisation by facilitating various individual, team and organisational development programmes; and
- Continually identify, grow and manage our internal talent and staffing profile, to uphold our international profile. This will require preparing (reskilling and retraining) staff in the face of technological changes for newly modified roles.

Our staff profile to this date is reflected below and it reflects our commitment to providing sustainable employment while addressing matters of patient care. Though the below is reflective of our profile as of 31 March 2019, the picture is similar for the past many years.

Table 6: Workforce profile as of 31 March 2019

Occupational Level	Male				Female				FN		Total Staff
	A	C	I	W	A	C	I	W	M	F	
Top Management	3	0	0	1	2	0	1	1	0	0	**8**
Senior Management	8	1	4	9	8	2	8	20	0	0	**60**
Professionals	110	24	50	98	258	29	109	205	4	3	**890**
Skilled (Academically Qualified)	625	66	51	57	1 407	158	162	255	13	9	**2 803**

Semi-skilled	728	67	42	11	1 413	184	61	67	0	0	**2 573**
Unskilled	293	9	0	1	463	24	1	0	0	0	**791**
Total workforce	**1767**	**167**	**147**	**177**	**3 551**	**397**	**342**	**548**	**17**	**12**	**7 125**
Total %	**25%**	**2%**	**2%**	**2%**	**50%**	**6%**	**5%**	**8%**	**0.2%**	**0.2%**	-
NATIONAL EAP %	**42.8%**	**5.3%**	**1.8%**	**5.3%**	**35.1 %**	**4.5%**	**1.%**	**4.2%**	**-**	**-**	**-**

We are a leading national pathology and laboratory service organisation devoted to research which improves clinical outcomes and patient care while helping to reduce the overall cost of patient care. Thus our stakeholder agreement with various universities remain critical as it enables our experienced health staff to be an integral part of the teaching platform and allow the transfer of competency to the future generational cohort of pathologist, scientist, medical technologist and medical technician

We may not be able to maintain our competitive advantages if we are not able to attract and retain key skills across various levels of the healthcare cohort; our executive, information technology and other key support staff. While we will be taking steps to retain such key staff, the challenge will be the global competition for such which could lead to compensation costs being unsustainable.

Table 7: Training profile across NHLS

Training type	Personnel expenditure R'000	Training expenditure R'000	Training expenditure as a % of personnel cost	No. of employees trained	Average training cost per employee
Non-PIVOTAL* programmes (short courses, workshops, seminars, congresses and CPD interventions)	3 603 009	17 655	0.49%	5 631	3 135
PIVOTAL programmes (for non-employees higher education qualifications)		3 120	-	48	65 000
PIVOTAL programmes (for non-employees participating in learnerships, on-the-job training, and workplace experience)	20 814	20 814	-	226	92 100

*PIVOTAL = Professional, vocational, technical and academic learning programmes that result in occupational qualifications or part qualifications on the National Qualifications Framework.

The NHLS continues to fulfil its role in promoting and prioritising skills development through the analysis of its employees' skills needs by implementing the WSP. Multiple learning programmes will be offered through short learning programmes, in-service conferences and congresses, as well as CPD programmes to enable the organisation to comply with legislation, improve quality of services, ensure business continuity and assist in the mitigation of risks.

In the financial year under review, the NHLS achieved 81% of the planned training target as compared to the legislated target of 60%. This figure is represented by a training headcount of 5 631 employees who attended technical and non-technical short learning programmes, workshops, seminars, on-the-job training and conferences in the 2018/2019 period. This picture is consistent to previous years.

In addition to the regular training for learnerships and professional registrations, 48 scholarships were awarded to needy students across the country who are studying towards the National Diploma in Biomedical Technology and the Bachelor of Health Science, and 290 bursaries to the value of R6,1 million were issued to NHLS staff who wish to pursue their career development by way of formal qualifications. Furthermore, our commitment to provide training to the registrars, medical scientists and medical technologists is continuing. In the year past, March 2019 – we had 531 medical interns on our various training platforms.

Table 8: Learnership for Registrar, Scientist & Technologist

Job Title	Headcount
Registrar	243
Medical Scientist Intern	64
Medical Technologist Student	224

To this end, our relationship with Organised Labour shall become even more critical if shared understanding could be achieved and meaningful alternatives are explored and agreed to.

We intend to execute on our vision of providing high-quality patient-centred service through a reliance on the performance of our information technology systems. The failure to operate these systems and/ or navigate across available functionalities could have an adverse effect on our services and performance. It is for this reason, the focus shall also be on re-skilling and re-training our staff to transition to the new technological world which requires new competencies. Our business requires the continued operation of sophisticated information technology systems and network infrastructure.

Running our operation with excellence is a prerequisite for delivering our core mandates, this will need us to invest in extraordinary people. This era also calls for us to anchor our efforts in integrity, ethics, inclusion, and human welfare. It's time to affirm and lead with our values.

4.2.8.4. Governance

The Board as the Accounting Authority, must provide oversight with regard to compliance with the 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:

- Offer leadership that results 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 enable 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.

Furthermore, the board provides leadership by steering and setting the direction, purpose, and strategy of the organisation. It creates an enabling environment for the organisation so that it achieves its strategy and outcomes over time.

4.2.8.5. Planning, Monitoring and Evaluation

Monitoring and Evaluation (M&E) aims at informing policymakers about the progress towards achieving targets as set in the-performance plans and assist managers in making proper decisions.

The functioning of the entire NHLS needs to be carefully monitored so as to maintain a high level of service. This includes, amongst others:

- Evaluation of services in relation to accreditation/certification and turnaround of test results;
- Evaluation (internal and external) of all training programmes to ensure that they remain relevant to the services being provided;
- Evaluation of staff establishment and staff performance;
- Evaluation of systems in financial management and supply chain management;
- Monitoring and evaluation of the implementation of all NHLS strategic projects;
- Prevention of disease through effective monitoring of people.

NHLS is a custodian of a wealth of valuable health data that could inform policy and guidelines through collaborative engagement, diagnostic and monitoring services. The data is critical in contributing to the reduction of disease progression, improving quality of care, quality of life and ultimately reduce premature deaths.

The M&E unit was established in 2016 with the appointment of the Senior Manager: Monitoring and Monitoring and Evaluation. It has since been focusing on Monitoring and not Evaluation because of resource constraints. Its monitoring function is also limited to the Strategic objectives but is not cascaded to the operations and support function. For the NHLS to realise the full benefits of having a M&E unit, it will:

- Identify M&E coordinators in the regions and other support departments and train them on collecting, collating and reporting data to the M&E unit. The automation of the reporting tool is also critical for maintaining data integrity.
- Perform evaluation of programmes to improve accountability, performance, learning, communication and decision making.
- Establish the business intelligence unit in the CEO's office to develop dashboards and real-time monitoring information.
- Use automated monitoring tools to maintain the integrity of the reported data.

By so doing, the NHLS will be able to cascade monitoring to the laboratory and departmental level and enable the Executive Managers and the Board to have complete oversight of the organisation.

4.2.9. 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 below:

Table 9: Strengths, Weaknesses, Opportunities, and Threats

Strengths	Weaknesses
• Strong academic base; • Sustainable partnerships through relevant research outputs; • Sustainable partnerships with NDoH, Universities, and UoTs etc.; • Internationally renowned intellectual capital; • National pathology laboratory footprint; • Exclusive national integrated data warehouse; • Leverage on the NHLS powers in the Act; • The largest employer of pathology professionals in the country; • Influence in the National and Regional Societies on laboratory medicine; • Competitive remuneration structure; • Africa leader in laboratory medicine.	• Lack of succession planning and development across various levels; • Lack of workload standards; • The high failure rate of registrars; • Inequitable distribution of critical and scare skills; • Inadequate ICT infrastructure capacity; • Limited advance technology in certain areas; • Limited ownership of value chain from collection of samples to return of results; • Inadequate communication both internally and externally; • Lack of consequences management; • Lack of coordinated research and innovation activities within NHLS; • The inadequate interface between LIS and billing. • Complacency due to perceived security from being a designated public sector service provider; • The limited performance monitoring system

Opportunities	Threats
• Multi sectorial partnerships to enhance sharing of intellectual capacity; • Other sources of income to enhance revenue streams; • Existing footprint in terms of the national and regional laboratory network; • Implementation of the National Health Insurance (NHI); • Trusted service provider by the health professionals; • Strengthening integrated IT systems; • Increased volumes through policy changes; • Utilise media coverage to promote our brand / corporate image; • Remote oversight of laboratories by pathologists; • Opening of new medical schools will expand the teaching platform; • Automation of technology; • Digital technology; • Central Data Warehouse repository of information; • Advances in logistics systems.	• International reduction in grant allocation; • Private sector competition especially in Anatomical pathology; • Medical inflation in relation to goods and services is generally higher than CPI; • Exchange rates; • Lack of investment in IT infrastructure; • Opening of new medical schools, the NHLS may not have enough resources to cover the need. • Sub-optimally functioning grants office; • The progressive erosion of the training platform; • Insufficient throughput from training platform; • Operational costs increasing higher than tariff increases; • Increased competition with the implementation of NHI; • The decrease in budget allocations from the National Treasury for teaching and training. • Highly dynamic and rapidly changing industry and the NHLS may not adapt as rapidly; • Perceived inefficiencies and high cost of pathology services

5. Stakeholder Analysis

The NHLS Strategy will require significant stakeholder buy-in to achieve the impact envisioned in the strategy. The NHLS aims to:

- Create a shared understanding of stakeholder engagement;
- Provide a set of principles to which the NHLS commits in the management of its stakeholder relations;
- Identify and categorising stakeholders;
- Define the engagement models for the different stakeholders; and
- Provide a high-level programme and plan for engagement with each group of stakeholders.

Stakeholder analysis is a systemic way to analyse stakeholders by power and interest. Table 10 below demonstrates the interest the different stakeholders have on the NHLS.

Table 10: Stakeholder analysis by interest.

		Interested in the impact on:						
Stakeholder Group	Category	Legislation	Finance	Governance	Reputation	Business as usual	Research	Services/ Product
Government	National Department of Health	✓	✓	✓	✓	✓	✓	✓
	Provincial Department of health		✓	✓	✓	✓	✓	✓
	District Department of Health		✓	✓	✓	✓	✓	✓
	National Treasury	✓	✓	✓	✓	✓	✓	✓
	Chief Procurement Officer	✓	✓	✓	✓	✓	✓	✓
	Portfolio Committee	✓	✓	✓	✓	✓	✓	✓
Public Entities	Medical Research Council						✓	✓
	Council for Medical Schemes		✓					
Regulatory Bodies	Office of Health Standards Council	✓			✓	✓		
	South African Health Product Regulatory Authority	✓			✓	✓	✓	✓
	Health Professional Council of South Africa	✓			✓	✓	✓	
Private Sector	Hospitals					✓		✓
	Sector Laboratories		✓			✓		✓
	Pharmaceutical Companies		✓			✓	✓	✓
	Medical Devices				✓	✓	✓	✓
	Funders		✓	✓	✓	✓	✓	✓
	Distributors		✓					✓
	Sector Suppliers		✓		✓	✓	✓	✓
	Donor Funders		✓	✓	✓	✓	✓	✓
Mining Sector	Mineral Council of South Africa							✓

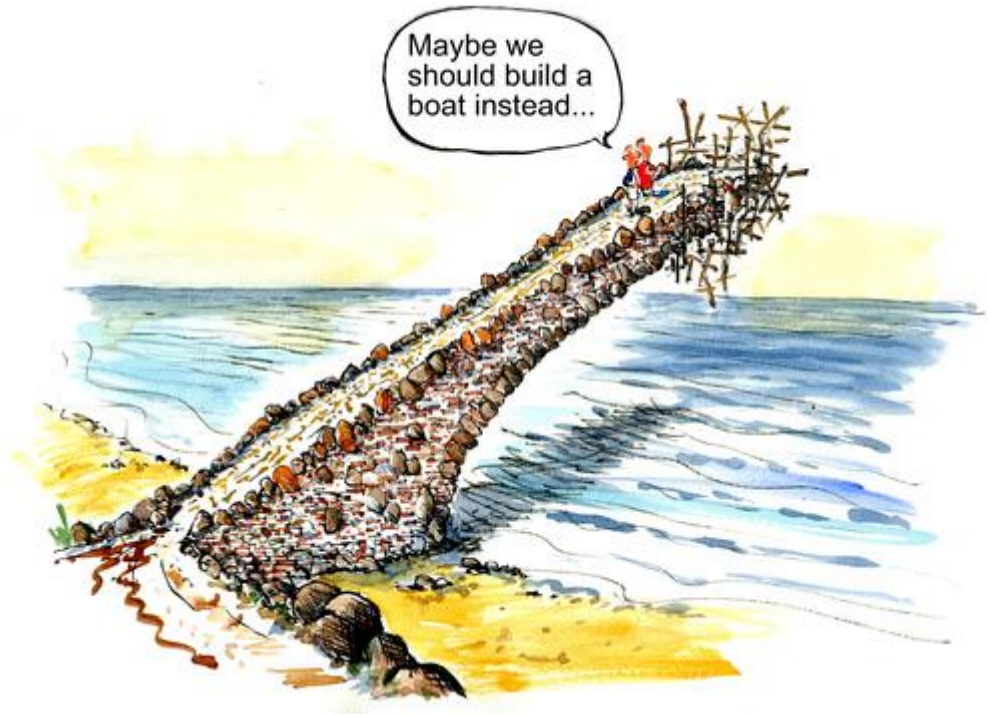
		Interested in the impact on:						
Stakeholder Group	Category	Legislation	Finance	Governance	Reputation	Business as usual	Research	Services/ Product
Customers	Clinicians		✓		✓	✓	✓	✓
	Patients		✓		✓	✓	✓	✓
Health Science Faculties	Health Science Faculties				✓	✓	✓	✓
Universities and Research organisations	Universities and Research organisations				✓	✓	✓	✓
Universities of Technology	Universities of Technology				✓	✓	✓	✓
Professional bodies	Professional bodies				✓		✓	
NGO's	NGO's						✓	✓
Media	Media				✓			
Organised Labour	Organised Labour		✓	✓	✓	✓	✓	
NHLS Board of Directors	NHLS Board of Directors	✓	✓	✓	✓	✓	✓	✓
NHLS employees	NHLS employees	✓	✓	✓	✓	✓	✓	✓

6. Theory of Change

The term ‘Theory of Change’ first emerged in the 1990s. Its purpose at that time was to address some of the problems that evaluators faced when trying to assess the impact of complex social development programmes. These included poorly articulated assumptions, a lack of clarity about how change processes unfolded, and insufficient attention being given to the sequence of changes necessary for long-term goals to be reached. Theory of Change (ToC) thinking has progressed rapidly since then and is becoming increasingly popular.

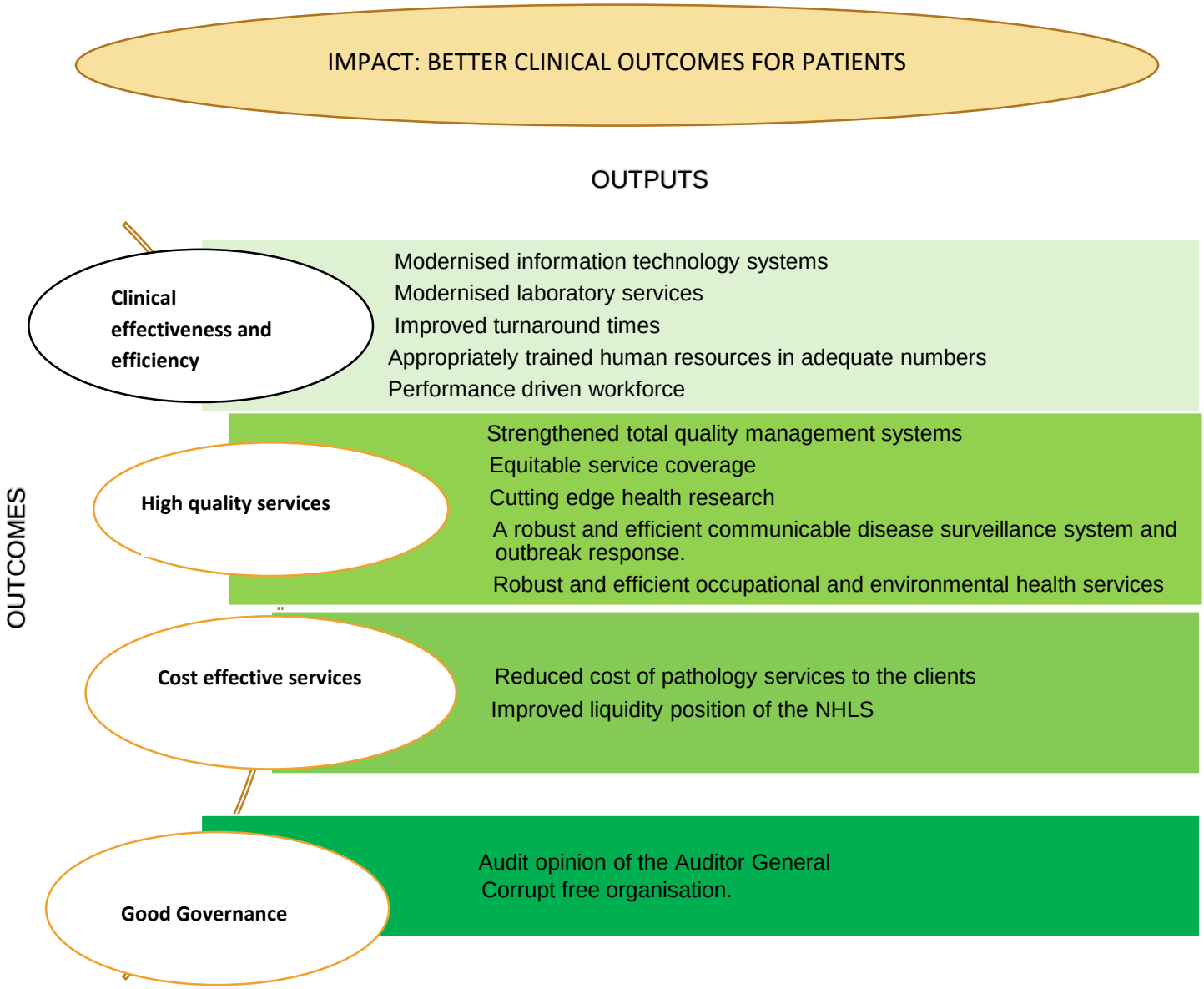
Theory of Change is essentially a comprehensive description and illustration of how and why the desired change is expected to happen in a particular context. It is focused in particular on mapping out or “filling in” what has been described as the “missing middle” between what a programme or change initiative does (its activities or interventions) and how these lead to desired goals being achieved. It does this by first identifying the desired long-term goals and then works back from these to identify all the conditions (outcomes) that must be in place (and how these related to one another causally) for the goals to occur. These steps are all mapped out in an Outcomes Framework.

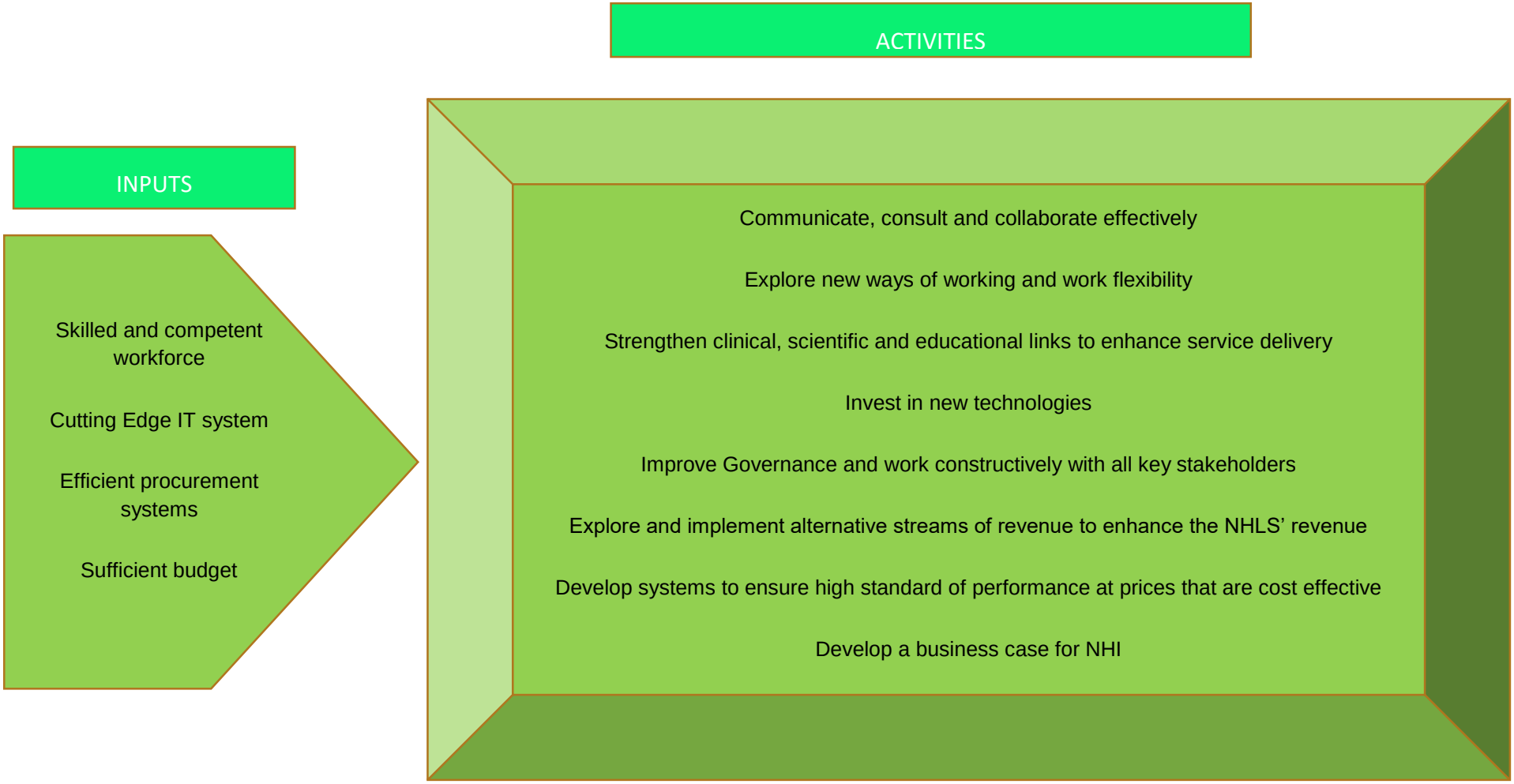
Figure 7: Approach to Theory of change (taken from: theoryofchange.org/what-is-theory-of-change/)

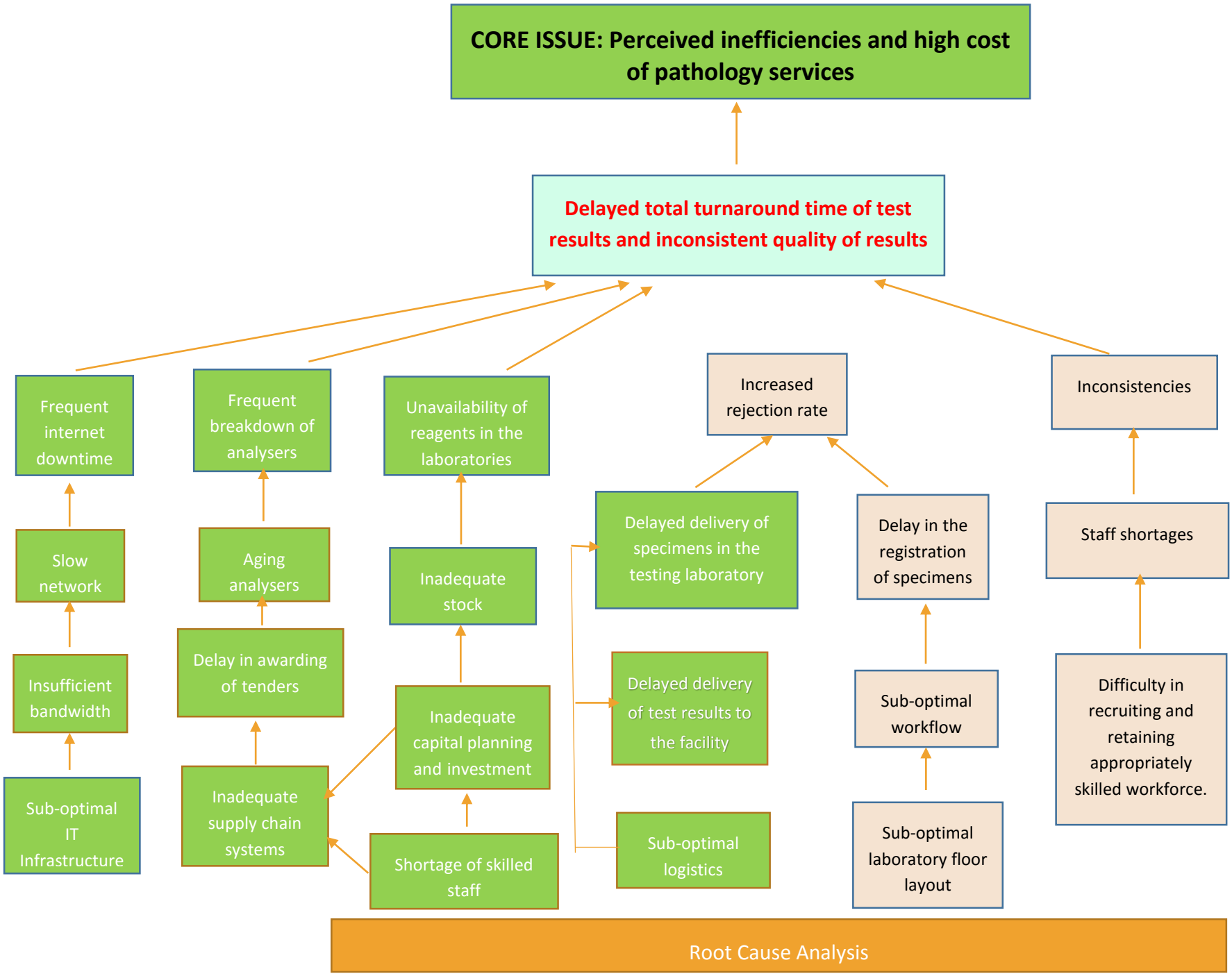


In support of the National Department of Health's (NDoH) vision: "A long and healthy life for all South Africans', which is consistent with Goal 3 of the SDGs to: Ensure healthy lives and promote well-being for all at all ages. The NHLS endeavours to continuously enhance its services to contribute towards the NDoH vision. The NHLS's ultimate aim is to provide better clinical outcomes for patients.

The NHLS adopted the Theory of Change as detailed below to determine the outcomes and outputs which will contribute to "A long and healthy life for all South Africans".




ACTIVITIES
INPUTS
Skilled and competent workforce
Cutting Edge IT system
Efficient procurement systems
Sufficient budget
Communicate, consult and collaborate effectively
Explore new ways of working and work flexibility
Strengthen clinical, scientific and educational links to enhance service delivery
Invest in new technologies
Improve Governance and work constructively with all key stakeholders
Explore and implement alternative streams of revenue to enhance the NHLS' revenue
Develop systems to ensure high standard of performance at prices that are cost effective
Develop a business case for NHI


CORE ISSUE: Perceived inefficiencies and high cost of pathology services
Delayed total turnaround time of test results and inconsistent quality of results
Frequent internet downtime
Frequent breakdown of analysers
Unavailability of reagents in the laboratories
Increased rejection rate
Inconsistencies
Slow network
Aging analysers
Inadequate stock
Delayed delivery of specimens in the testing laboratory
Delay in the registration of specimens
Staff shortages
Insufficient bandwidth
Delay in awarding of tenders
Inadequate capital planning and investment
Delayed delivery of test results to the facility
Sub-optimal workflow
Difficulty in recruiting and retaining appropriately skilled workforce.
Sub-optimal IT Infrastructure
Inadequate supply chain systems
Shortage of skilled staff
Sub-optimal logistics
Sub-optimal laboratory floor layout
Root Cause Analysis

7. Future delivery of Pathology Service in South Africa: NHLS Strategy in the next five years.

The National Health Laboratory Service (NHLS) in the Republic of South Africa provides essential diagnostic services to primarily the public health sector which treats about eighty percent (80%) of the population, which is approximately forty-eight (48) million people. The NHLS is mandated by the NHLS Act of 2000 to provide pathology services for the public health sector and training and research for the whole country. The NHLS has historically delivered increasing work volume with relatively small increases in funding, whilst maintaining an affordable service without compromising quality and cost-efficiency.

Pathology and laboratory services are advancing rapidly and these services perform a central role in healthcare. At least 60%-70% of clinical decisions and patient diagnoses are dependent on laboratory tests, at a relatively small overall cost to the healthcare budget. In South Africa, this represents approximately 4% of the national expenditure on health for the public sector. Considering the central and invaluable role that the NHLS plays inpatient care, 4% of health care expenditure represents true value for money.

The South African government has a far-reaching reform plan to revitalise and restructure the South African health care system, including:

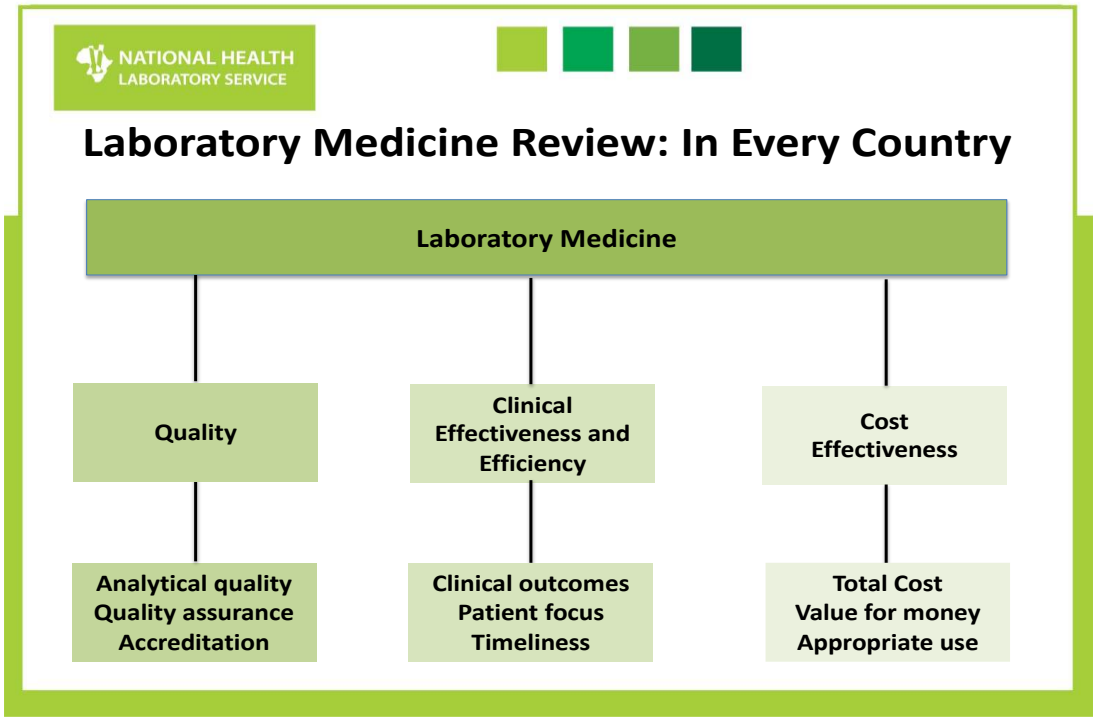
- Fast-tracking the implementation of a National Health Insurance scheme, which will eventually cover all South Africans.
- Strengthening the fight against HIV and TB, non-communicable diseases, as well as injury and violence.
- Improving human-resource management at state hospitals and strengthening coordination between the public and private health sector.
- Deploying “health teams” to communities and schools.
- Regulating costs to make health care affordable to all.
- Increasing life expectancy at birth of 61.5 years in males and 67.7 years in females in 2019 to 70 years, in line with Goal 1 of the NDP, Vision 2030.

Internationally, because of the importance of pathology and laboratory medicine in determining diagnoses and clinical outcomes, a large number of countries are conducting reviews of their pathology services. The International Federation of Clinical Chemistry and Laboratory Medicine

(IFCC) stated that whilst the reviews may differ there are essentially three components to most of the reviews:

- **Improving quality** across the spectrum from analytical quality, quality assurance to quality management to laboratory accreditation.
- **Improving clinical effectiveness** by targeting the use of laboratory medicine to improve clinical outcomes. This entails timeous results, clinical interpretation, and advisory service and patient-focused medicine.
- **Improving cost-effectiveness** by doing more at equal or higher quality for a lower total cost. This requires the appropriate use of laboratory services and demonstrating value for money.

Figure 7: Outcomes expected from Pathology and Laboratory Medicine



In the future delivery of pathology services, within the context of universal coverage and the national health insurance, the above themes have been adapted to include efficiency. The NHLS themes are clinical effectiveness and efficiency, cost-effectiveness and quality to improve the provision of healthcare.

This document sets out how the NHLS can offer modernised pathology services of high quality that is responsive to the needs of patients. The document outlines the principles and priorities that will help us shape the future direction of NHLS pathology services and provides guidance for the development of our strategic plan.

7.1 Defining pathology

"Pathology is the motor that drives healthcare to understand disease"

Pathology is the study of disease. The term pathology describes clinically-led diagnostic and laboratory services. The services cover a range of tests on blood and other human material necessary for the diagnosis and monitoring of a wide range of clinical conditions so that the appropriate treatment can be given. The NHLS provides a range of important diagnostic support services to help primary, secondary and tertiary care clinicians to diagnose and treat diseases and other medical conditions.

7.2 Pathology disciplines

The pathology services are divided into a number of disciplines,

Chemical pathology is responsible for the analysis of the chemistry of blood and other samples. Chemical pathologists deal with the diagnosis of patients with metabolic disorders.

Genetics comprising cytogenetics (the analysis of chromosomes) and molecular genetics (the analysis of DNA sequence level) is responsible for the analysis of genes and samples from patients suspected of having genetic diseases or predisposition to common conditions.

Immunology is responsible for the identification of different types of immune reactions and the management of patients affected by diseases of the immune system.

Haematology is responsible for the analysis of blood and related cells in the safe provision. Clinical haematologists are heavily involved in the direct clinical care of patients with diagnoses such as leukaemia, lymphoma, haemophilia and other blood disorders.

Histopathology and cytopathology are responsible for the diagnosis of cancer and non-malignant conditions by the microscopy and analysis of tissue samples from patients.

Microbiology is the study of the causes and management of infectious diseases. This can be caused by viruses, bacteria, microfungi, protozoa, and parasites.

Virology is a study of viruses and virus-like agents, including (but not limited) to their taxonomy, disease-producing properties, cultivation and genetics. In some countries is considered as part of microbiology.

8. Future trends that will impact on pathology services

With advances in technology pathology services needs to adapt to strengthen the delivery of healthcare. The following trends will impact on the future of pathology services:

- A population that has the quadruple burden of disease: i.e. a high prevalence of communicable diseases; a high burden of HIV and TB, illnesses related to social instability; and an increasing burden of chronic diseases.
- Advances in technology may enable us to achieve higher quality, more rapidly. Examples of technological advances include nanotechnology and point of care testing (POCT), automation including robotics and integrated systems, bioinformatics to analyse big data, genomics driving personalised and precision medicine, proteomics and metabolomics facilitating new biomarkers
- Innovation in genomic technologies has initiated more personalised medicine, which allows for the assessment of genotype and phenotype of the patient so that they can undergo specific and tailored treatment.
- Prevention of disease through effective monitoring of people
- Changes in information technology and communication have influenced demands for fast and direct delivery of results.
- Global and national epidemics

- Point of Care Testing (POCT) and ‘Precision Medicine’ are particularly important areas of development in Pathology that have the potential to change the way health services are provided in the future for the benefit of patients.
- Increased availability of point-of-care technology will support urgent pathology testing at sites with no or little access to on-site laboratory services.

- Improved software interfaces between Information Systems will improve access to the results of pathology testing.
- Digital pathology will increase access to expertise in central laboratories.
- Market pressures may lead to the consolidation of private pathology providers, who may offer standardised pathology services to boost efficiencies of scale and maximise returns.
- The NHLS has over the years built a considerable consolidated intellectual capital through the Central Data Warehouse, which is available to provide unbiased intelligence for South Africa for future policy-making.

8.1 Strategic Intent

The NHLS is driven by a clear purpose: to deliver an affordable service that is of high quality and cost-effective, efficient and responsive to the needs of the patients and clients.

The NHLS can be proud of the achievements thus far. The NHLS is known for its competent staff and expertise, its innovation in research and diagnostics, the high calibre teaching and training capabilities and its contribution to better health care for the people of South Africa.

The NHLS, however, cannot stop there. Over the next few years, there will be fundamental changes in the health system through the introduction of National Health Insurance (NHI). The NHLS will be operating in an increasingly competitive and demanding environment and will need to have a strong, sustainable and efficient service to deliver for the NHI and the future.

Technology will be advancing at a rapid pace and we need to be able to speedily respond to such changes through how we structure and deliver our services.

To deliver for the NHI the NHLS will improve on the value we bring, at highly competitive prices, with quick turnaround times, increased efficiency and ultimately with better outcomes for patients.

9. Modernisation strategies and Future Direction of Pathology Services

The NHLS's mandate is to ensure that services provided represent the best quality and value for public resources. The themes that the priorities are grouped under are clinical effectiveness and efficiency, cost-effectiveness and quality. The NHLS must move towards providing an even more rapid, reliable and efficient service delivery at low cost through, state of the art laboratories, the right people with the right skills at the right level, effective and efficient procurement services, cutting edge information technology whilst ensuring that it remains financially stable to sustain the existing operations.

In the next five years the NHLS will:

- Provide a clinically **acceptable** diagnostic pathology service on a national basis, through a service model that is fully aligned to the district based National Health Insurance.
- Provide access to appropriate high-**quality** patient-centred pathology services at the right time and the right place.
- Deliver value in pathology services through improved **cost-effectiveness**.
- Improve the customer and patient experience through enhancing **quality**.
- Be responsive to users through the provision of highly efficient accessible services.
- Leverage innovation and new technology to improve **efficiency**.
- Invest in information technology, digital technology, communication links and logistical services to improve **efficiency**.
- Build capacity in the workforce, Information Technology, and logistics to support future pathology services.
- Strengthen partnerships to advance teaching, training, knowledge, and research to improve **clinical effectiveness**.
- Redesign pathology systems and service models to maximise **efficiency** and **effectiveness** and improve access to speciality pathology services and expertise to improve patient outcomes.
- Re-organise the pathology system in preparedness for the National Health Insurance (NHI) system.
- Develop information management systems to improve **efficiency**, enhance decision making, and monitor performance.

- Maintain and strengthen the teaching and research mandates of the NHLS;
- Enhance support for communicable and non-communicable diseases prevention, surveillance and control for the national and provincial government;

9.1. Clinical Effectiveness and Efficiency

A clinically excellent and efficient services must be based on evidence, have well-trained staff and make use of innovative technology. It must also be responsive to users through the services being highly efficient, accessible, convenient, safe and effective.

9.1.1. Building Capacity in the workforce

A workforce plan will be developed to ensure that there is enough staff with the appropriate mix of skills and competencies, with effective leadership and management skills, to deliver high-quality diagnostic services for clinicians and patients. The workforce plan will reflect the requirements of the pathology service.

Currently, there is a lack of integration in workforce planning and development. Technological advances will change the skill sets required to deliver pathology service but this is not necessarily reflected in the current workforce. Other backroom functions will be reviewed within workforce modelling and planning and determine if it can be done differently.

Any service design should take into account the workforce requirements in relation to the skills mix and new ways of working to support efficiency and effectiveness.

9.1.1. 1. Role demarcations

There is a blurring of boundaries between some disciplines and specialities which should lend itself to greater workforce flexibility. There will be a flexible deployment of staff especially in smaller departments, and greater scope for multidisciplinary teams.

Workforce numbers and a workforce planning model will take into account the changing requirements of the pathology workforce and be based on skills and competencies.

There have been some significant recruitment and retention issues especially with regard to pathologists and in certain disciplines. A recruitment and retention strategy will be developed and implemented.

BUILDING CAPACITY IN THE WORKFORCE
Attracting, recruiting, developing and retaining quality, competent staff
♦ **Implement a Human Resource Strategy to support efficient service delivery.** ♦ **Benchmark and review staffing norms and roles.** ♦ **Develop a Workforce Plan with an appropriate skills mix to enhance quality service delivery.** ♦ **Develop and implement a recruitment and retention strategy.** ♦ **Implement staff development and performance programmes.** ♦ **A skills escalator to enhance career pathways**
Effectively communicating, consulting and collaborating
♦ **Develop strategies to engage effectively with staff** ♦ **Enhance effective communication with all stakeholders** ♦ **Utilise modern, appropriate communication to enhance communication flows**
Explore new ways of working and work flexibility
♦ **Investigate flexible working and shift patterns for 24/7 working.** ♦ **Explore opportunities for greater cross-discipline working and flexible deployment.** ♦ **Provide support to pathologists to spend more time on diagnosis.** ♦ **Review the concept of service only posts for pathologists** ♦ **Explore new roles for medical scientists.**
Strengthen clinical, scientific and educational links to enhance service delivery and training.
♦ **Build strong relations with clinicians to support good clinical outcomes.** ♦ **Work with Higher Education Institutes to increase focus on pathology.**

9.1.2. Making use of new technology

"*We want a South Africa with high-tech economy, with advances in e-Health, robotics and remote medicine, as we roll out the NHI"*

President Cyril Ramaphosa (SONA 2019)

The NHLS has a long experience of validating specialist tests, as well as developing and adopting new technologies. Efficiencies can be maximised by sharing equipment and supporting staff to work in a multidisciplinary way.

Appropriate application of technology is an important consideration in developing new ways of working including: relevant to the NHLS are:

- Deciding which services to deliver centrally or locally
- A modern pathology service will rely on a wide range of technologies to expand and improve the services
- A technology strategy will monitor new opportunities as they emerge, assess the relevance, costs, and benefits. Key areas to consider are:
    - Developing pathology diagnostics: have in place mechanisms to scan for promising technologies, assess the cost benefit and integrate them as appropriate to the overall laboratory services.,
    - Integrated point of care testing. There is increasing use of point-of-care testing and systems will be implemented to ensure that results from point-of-care testing are collected into the electronic patient record and also captured for health surveillance purposes by integrating such devices into pathology networks.
    - Clinical data should be used to support clinical governance through evidence-based care, decision support and performance reporting.

9.1.2.1. Improved turnaround and throughput through automation of processes

New technology is an opportunity for greater investment in automated processes which will benefit the internal working of the laboratories as well as downstream benefits to the users of the service. The use of appropriate automation in pathology laboratories should be maximised. Increased automation is essential where workloads are increasing within a constrained budget.

Examples of automation envisaged and consequent benefits include:

- Pre-analytical sample recognition and preparation in chemical pathology, haematology, and immunology.
- In histopathology tissue processing systems and block identification systems

- Greater use of automation during analysis and molecular testing systems in microbiology
- More automated serology testing
- Integration of similar analytical systems across disciplines
- Automated storage of slides and tissue blocks.

The benefits would include:

- Reduction in lost samples
- Reduction in sampling errors
- Reduction in the use of qualified staff time
- Reduction in the potential for human error.
- Reduction in overall test turnaround times and
- Reduction in sample retrieval time

9.1.2.2. Information technology

The monitoring of the analytical processes and initial storage of results is facilitated by a laboratory information management system or LIMS. Ideally, the LIMS should interface to an electronic patient care record to allow clinicians to see the test results as soon as they become available, and for the future, the LIMS should be interfaced with General Practitioner's computer systems to deliver the results to primary care. It is essential that the LIMS is integrated across systems, to ensure that all sites are linked to the lab information system.

To run a service effectively management has to have relevant and timely information. Communication is also important because it gives management notice of workload demand decisions. Improving information management by improving the quality of information management is crucial for successful patient-focused care.

The NHLS will achieve this by focusing on:

9.1.2.3. Order Entry system

Whilst all laboratories have an information system, coverage of the systems beyond the laboratory is limited. There is a reliance on paper rather than electronic communication. Such a system is inefficient, susceptible to a number of risks as well as the risk of repetition of tests.

Information technology will be maximised through electronic requesting of pathology tests, which will improve efficiency and improve the appropriate use of laboratory tests.

A key inefficiency is the lack of management of demand. Test requested at a primary care level are often repeated following the patient's admission to the hospital. This is exacerbated by the poor quality of IT links between Laboratory Information Systems and hospitals and primary care systems. Electronic gatekeeping and an enhanced LIMS will strengthen control over these areas.

9.1.2.4 Unique patient identifier

In order to improve service efficiency, the NHLS will use a consistent and unique patient, in line with the identifier, in line with the NDoH Health Patient Record System, to minimise risks of mistaken identity and improve sample tracking.

9.1.3. Phlebotomy

Pathology should be developed as an end-to-end service i.e. they will draw specimens from patients and then receive the results at the facilities. Transport and phlebotomy services are critical determinants of service efficiency and offer opportunities to regulate the flow of work into laboratories. Where pathology service does not provide these services they should be specified through a well-constructed service level agreement with the health service.

In South Africa, there are different systems of collecting samples from patients for analysis by the laboratory. The system will need to be standardised. In the USA, Australia and Sweden there is an increasing provision of patient service centres in locations that are convenient to the patient specifically for the collection of samples.

9.1.4. Transport Logistics

One of the biggest challenges is the logistics of transporting samples. When samples need to be moved between different sites the main challenge arises in the transport of samples between primary care and hospital laboratories. A clear objective to facilitate the delivery of an efficient and high-quality service that is responsive to the needs of patients with samples collected at times and in places that are convenient for patients. The transportation of samples does not optimally enhance laboratory performance. For example, samples may be collected and delivered to the laboratory only once a driver has completed his entire journey. The samples then arrive at the laboratory at the end of the afternoon when staff are completing the day's work. The samples then have to be stabilised and stored overnight so they could be analysed the following morning. Laboratories operating a shift system would process these tests in the evening.

Information Technology, Technology and Systems
Investing in New Technologies
♦ Use of appropriate automation in pathology laboratories should be maximised. ♦ Improve access to the appropriate point of care testing that is integrated into the Laboratory Information System (LIMS). ♦ Information technology should be maximised through electronic requesting of pathology tests through an order entry system and unique patient identifier. ♦ Enhance the Laboratory Information System (LIMS) and integrate it across systems, to ensure that all sites (including GPs and clinics) are linked. ♦ Invest in improved technology and communication links to enhance the LIS. ♦ Invest in digital technology to increase access to pathology expertise across the country. ♦ Invest in mHealth solutions.
Appropriate and timely access to services
♦ Improve access to appropriate services irrespective of location. ♦ Develop an end-to-end service in pathology through the integration of phlebotomy services to improve service efficiency. ♦ Facilitate the delivery of an efficient and high-quality transport logistics service that is responsive and convenient to the needs of patients.
Strengthening clinical governance
♦ Clinical data should be used to support clinical governance through evidence-based care, decision support and performance reporting. ♦ Strengthen the pathologist's role in clinical settings to enhance patient outcomes. ♦ Improve information management by improving the quality of information for successful patient-focused care.

♦ Establish business intelligence systems to facilitate benchmarking and inform decision making.
Improve Governance and work constructively with all key stakeholders
♦ Develop a stakeholder engagement framework to enhance relationships with strategic partners and other key stakeholders. ♦ Ensure services have increased visibility and involvement in national, provincial and district levels. ♦ Standardise policies, procedures and business processes to deliver an efficient service.

9.2. Cost-Effectiveness

9.2.1. Costs of pathology services

The method of estimating overall costs such as the share of hospital overheads, the transport costs attributable to pathology, costs of training, research and development must be standardised. Point of Care testing raises a different financial issue. The advantages to point-of-care testing such as when a fast result is required for the patient, the management of a long-term condition, when the patient may not return for the result, or in triage. However, point-of-care testing is also more expensive. Such investment decisions need to weigh the costs and benefits at a level beyond simply the pathology department.

9.2.2. The private sector

In the previous chapter, an analysis was done of the comparison between the public and private sectors. A strategy on the private sector such as how and when services can be outsourced, at what cost, and on collaborating with the private sector with regard to training will be developed. This should include an analysis of the cost-effectiveness of private pathology services and the types of services provided by the private sector.

9.2.3. Revenue Enhancement

One of the greatest challenges that the NHLS has faced over the years has been financial instability caused by fluctuating cash flow. With decreasing budgets and freezing of budgets in the public sector, the NHLS could be facing further financial challenges over the next few years.

Increasing personnel costs, as well as goods and services and equipment, will exacerbate the financial challenges. There is an urgent need to investigate alternative sources of revenue to enhance the current revenue source.

Cost-Effectiveness and Resource Accountability
Delivering competitive value for money services
♦ Develop and implement strategies to ensure NHLS services are competitive and contestable in the market place.
Manage resources well
♦ Improve resource utilisation through effective cost containment strategies. ♦ Maximise economies of scale through the implementation of a national logistics strategy. ♦ Strengthen supply chain management though maximising economies of scale at a national level and strengthening local delivery. ♦ Ensure appropriate delegations are in place to streamline business processes and enhance efficiency.
Improvement of revenue.
♦ Explore and implement alternative streams of revenue to enhance the revenue of the NHLS. ♦ Standardise costing and pricing practices across the regions. ♦ Improve the billing systems and reduce the no price reports.

9.3. Quality

9.3.1. Quality

Quality can be defined as the ability of a product to satisfy the needs and expectations of the customer. The NHLS has tended to restrict discussion of quality to analytical quality, focusing on imprecision and accuracy, whilst on the other hand, the clinicians are interested in total quality which encompasses rapid, reliable and efficient service delivery at low cost. These are the parameters that the NHLS must satisfy to rise above the competition from the private sector and position itself as a preferred pathology service provider for the NHI.

The three dimensions of quality

- Service quality: the quality of the service experienced by a member of the public.
- Clinical quality: the quality of the service provided by professionally qualified staff.
- System quality: the quality of the management of the end-to-end service.

9.3.2. Accreditation

The National Health Insurance (NHI) Bill states that all services must obtain accreditation in order to receive contracts with the NHI Fund. This has major implications for the NHLS facilities. There will be a concerted drive to ensure all facilities are accredited for the implementation of the NHI.

9.3.3. Research and Innovation

In furthering its mandate of supporting health research and training for health science education, The NHLS conducts research in collaboration with the universities and national and international researchers. The research within the NHLS is mainly driven by the burden of disease in the country and this aligns with the priority focus areas of the NDoH and the strengthening of health systems as aligned in the National Strategic Plan (NSP). While there is still a tendency for the individual disciplines within the pathology to conduct research in silos, cross-disciplinary research is encouraged. The NHLS research output has been commendable to date, however, research should not only have an academic focus but also include other forgotten areas such as operational research; entrepreneurial research, that will influence policy and benefit the community.

The innovation plan has been developed and is recognised as a strategic intervention that aims to provide a strategic framework for deepening the culture of innovation, supporting innovative products and process development. The NHLS will establish the innovation office that will set targets that will advance innovation in the NHLS. The office will also develop mechanisms for supporting innovation and form partnerships with other research and innovation organisations.

Quality Assurance, Innovation and Research
♦ Develop systems to ensure high standards of performance at prices that are cost-effective. ♦ Facilitate a common approach to quality improvement for the NHLS. ♦ Develop a Performance Pathology Framework, including how performance will be monitored, evaluated, managed and reported.
Research and Innovation
♦ Implement the NHLS Pathology Research and Innovation Framework to improve the management and monitoring of research and innovation technologies. ♦ Work with clinicians, universities, universities of technologies and other relevant bodies to advance knowledge and research. ♦ Investigate the challenges facing the Grants Office and implement solutions to resolve the problems and attract further funding. ♦ Foster and support innovation to enhance clinical and scientific excellence.

10. Future Planning of Pathology Services for National Health Insurance (NHI)

Under strategic intent, it has been stated that with the introduction of the NHI, the NHLS will be operating in an increasingly competitive and demanding environment and will need to have a strong, sustainable service to deliver for the NHI and the future.

To sustain the service and deliver for the NHI the NHLS has to prove that the services are value for money, at highly competitive prices, with quick turnaround times, increased efficiency and better outcomes for patients. In order to do this the future direction that the NHLS must take are:

10.1. Prepare the Organisation for Implementation of National Health Insurance (NHI)

10.1.1. Develop a business case for NHI

- The NHI will fundamentally change the way we deliver our services. It will provide many opportunities to enhance services. It is essential that the NHLS is well prepared for the implementation of NHI. A comprehensive business case will be developed to examine all aspects of both the provision of services as well as the financing of the NHI pathology services.

10.1.2. Financing Strategies for NHI

- Explore Alternative Reimbursement Mechanisms for the financing the NHLS to ensure the financial sustainability of the NHLS.
- Determine the funding of tests not covered by the NHI

10.1.3. Develop and implement a planning approach to:

- Position the NHLS as a provider of choice for services for the future.
- Identify opportunities to enhance both the provision of services as well as enhance the revenue.
- Develop a strategy to deliver competitive, cost-effective and sustainable solutions for the NHI.

10.2. Establish a high-level multi-disciplinary Business Intelligence Unit

10.2.1. Performance measures

The most common performance measure that is usually measured is turnaround time (the time it takes to process a test); that is the time from when the request is made until the result is received. The time taken to process tests, even urgent ones varies considerably. Added to this are also tests that get lost. Without an effective logistics system, more often the turnaround time (TAT) reflects the time it takes during the analytical stage and does not include the pre-analytical stage (drawing specimens from patients, collecting specimens from facilities and transporting them to the testing laboratories, receiving the specimens in the testing laboratories and registering them onto the laboratory information system before they are analysed) where most of the delays occur.

Other performance measures that are used are activity to cost (cost per test), activity to the workforce (productivity), service quality (error rates, patient's safety and timeliness).

For efficient and effective management of pathology services, there is a need for more and better performance information.

In the United Kingdom, a successful benchmarking exercise has been implemented. The programme uses an advanced peer grouping methodology to analyse data and present it in a user friendly format to benchmark the facility and discipline to other facilities. The programme analyses quality, workload, case-mix and complexity, turnaround times, demand optimisation, best practice, staffing and skills mix, productivity and cost-efficiency. The programme has proved to be extremely useful. The NHLS needs to analyse the available data to benchmark the departments within.

Business Intelligence System
♦ Increase the capacity to conduct an econometric and actuarial analysis of price and volumes ♦ Improve the capacity to enhance the billing systems to deal with complex reimbursement mechanisms. ♦ Increase the capacity for monitoring and evaluation of performance and utilisation. ♦ Increase the capacity for business intelligence and data analysis to inform policy decisions. ♦ Develop a strategy for collaboration with the private sector. ♦ Develop a process to allow for benchmarking and transparent pricing in the private and public sectors.

10.3. Increase operational efficiency

10.3.1. Streamline workflows through the development of the core laboratory service to meet future demand.

- Advances in automation allow for the integration of pre-analytic and post-analytic handling of specimens and analytic processing for high-volume tests for a number of pathology areas. The NHLS will invest in these technologies to develop a core laboratory service.

10.3.2. Increase utilisation of integrated technology platforms

- Technology has improved to such an extent that equipment and techniques can be used for testing across disciplines. There are a number of highly specialised integrated technology platforms (such as testing platforms for viral load, HBV, HPV, HCV) which may have unused capacity. The NHLS will investigate the optimal utilisation of these integrated platforms.

10.3.3. Increase utilisation of automation in test processing

- The NHLS will investigate through the expert committees where advances in automation can improve the delivery of diagnostic services through eliminating manual processing steps and reducing technical variation in testing.

Increase operational efficiency
Pre-Analytical and Post-Analytical Services
♦ Implement integrated barcode technology for specimen transfers between facilities. ♦ Implement technology specimens tracking and storage. ♦ Implement greater use of automation through order entry systems (electronic ordering). ♦ Work with the Department of Health to expand the use of point-of-care technology, where clinically appropriate

10.4. Promote new technology and innovation to improve service delivery

'The foundation of medicine, pathology, has not changed for over 150 years.
It's time to change"

10.4.1. Utilisation of digital pathology

Advances in new technologies such as digital imaging technology are well documented. Digital technologies could push the pathology into becoming more efficient and more scalable. It will change the role of pathologists while allowing patients to get results quicker and more accurately.

The NHLS will invest in digital technology to improve access to experts across the country to improve oversight and pathology in rural areas. The initial investment in digital technology will be in anatomical pathology, where challenges are currently being experienced with shortages of pathologists.

10.4.2. Use of precision medicine

Precision medicine is a new, rapidly evolving approach to improving the way diagnosis and treatment is provided. It helps increase our understanding of diseases and how they progress, which informs the development of evidence-based diagnostic tests and targeted therapies that take into account the patient's biological characteristics, health status, medications they are already prescribed, and environmental and lifestyle factors. It results in better outcomes for patients and more cost-effective services.

Precision medicine for personalised and preventive care is rapidly being advocated for. The NHLS will develop a policy and guidelines on the use of precision medicine particularly in the areas of genomics, proteomics, and metabolomics biomarkers, and develop protocols for its use in oncology and chronic diseases.

New Technology and Innovation
♦ Implement digital pathology particularly in the area of anatomical pathology.
♦ Develop a policy and guidelines on the use of precision medicine particularly in the areas of oncology and chronic diseases.
♦ Investigate the implementation of mHealth applications.

10.5. To be leaders in teaching, training, research, and innovation.

The NHLS is the sole provider of the training of pathologists and medical scientists in the country. The high failure rates in pathology registrar training limit the outputs of new pathologists thus compounding the shortage of pathologists. The NHLS being the sole training platform for pathologists in the country, means that the organisation becomes the pool for the private pathology sector as well. This has resulted in the current aggressive recruitment by the private sector of pathologists. The private sector has an advantage over the NHLS in that it is able to

attract pathologists at much higher salaries. Therefore, there is an urgent need to train and qualify more pathologists to be able to meet the demand. The NHLS will build strong collaborations with key stakeholders to support these core mandates.

Teaching, training, research, and innovation
♦ Implement the Framework for collaborative research. ♦ Develop services to support research projects. ♦ Increase pathology awareness amongst undergraduates. ♦ Contribute to the development of the curriculum. ♦ The NHLS will build strong collaborations with key stakeholders to support these core mandates.

PART C: MEASURING PERFORMANCE

Impact: Better clinical outcomes for patients.

Impact Statement: The NHLS will contribute to better health care for people of South Africa by providing a rapid, reliable and efficient service delivery at low cost.

Outcomes:

- Clinical Effectiveness and Efficiency
- High-Quality Services
- Cost-Effective Services
- Good Governance

Outcome Statement: Internationally, because of the importance of pathology and laboratory medicine in determining diagnoses and clinical outcomes, a large number of countries are conducting reviews of their pathology services. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) stated that whilst the reviews may differ there are essentially three components to most of the reviews:

- **Improving quality** across the spectrum from analytical quality, quality assurance to quality management to laboratory accreditation.
- **Improving clinical effectiveness** by targeting the use of laboratory medicine to improve clinical outcomes. This entails timeous results, clinical interpretation, and advisory service and patient-focused medicine.
- **Improving cost-effectiveness** by doing more at equal or higher quality for a lower total cost. This requires appropriate use of laboratory services and demonstrating value for money.

In the future delivery of pathology services, within the context of universal coverage and national health insurance, the NHLS will contribute towards better clinical outcomes for patients by improving quality, clinical and cost-effectiveness.

Table 11: Outcomes

Outcome	Outcome Indicator	Baseline (2018/19)	Five-year target (2024/25)
Clinical effectiveness and efficiency	Develop and implement a service delivery model	New	Implement 80% of the service delivery model
	Develop and implement the specimen tracking system	New	Implement 100% of the specimen tracking system.
	Percentage of TB Microscopy tests performed within 40 hours	94%	95%
	Percentage of TB GeneXpert tests performed within 40 hours	94%	95%
	Percentage of CD4 tests performed within 40 hours	91%	95%
	Percentage of HIV Viral Load tests performed within 96 hours	86%	90%
	Percentage of HIV PCR tests performed within 96 hours	76%	85%
	Percentage of cervical smear screening performed within 5weeks	84%	90%
	Percentage of laboratory tests (FBC) performed within eight (8) hours	95%	95%
	Percentage of laboratory tests (U&E) performed within eight (8) hours	94%	95%
	Develop and implement Point of Care Testing (POCT) plan	New	50% implementation of the Point of Care Testing (POCT) plan.

Outcome	Outcome Indicator	Baseline (2018/19)	Five-year target (2024/25)
	Develop and implement a real-time communication system with patients	New	Send SMS to 100% of patients who provided cellphone numbers and gave consent
	Implement the interface between NHLS LIS and the HPRS	New	80% implementation of the HPRS
	Develop and implement the order entry system	New	Implementation of the order entry system in 100% of facilities that have internet connectivity.
	Implement digital pathology	New	Roll out to 100% of anatomical pathology and haematology laboratories.
	Percentage System Uptime for Critical Systems at laboratory level	99%	99%
	Staff Turnover ratio	3%	5%
	Average staff recruitment turnaround within 90 days	89%	95%
	BBBEE compliance	Level 8	Level 2
	Percentage of employees with approved and evaluated performance agreements	94%	99%
	Number of pathology registrars admitted and trained in NHLS	57	30

Outcome	Outcome Indicator	Baseline (2018/19)	Five-year target (2024/25)
	Number of Intern Medical Scientists admitted and trained in NHLS.	36	50
	Number of intern medical technologists and student medical technicians admitted and trained in NHLS.	248	250
	Percentage of employees trained as per the approved training plan (WSP)	81%	95%
High-Quality Service	Percentage compliance achieved by laboratories during annual quality compliance audits	90%	95%
	Percentage of laboratories achieving proficiency testing scheme performance standards of 80%	96%	98%
	Number of National Central laboratories that are SANAS Accredited	50	53
	Number of Provincial Tertiary laboratories that are SANAS Accredited	12	17
	Number of Regional laboratories that are SANAS Accredited	17	44
	Number of District laboratories that are SANAS Accredited	11	50
	Percentage of NICD laboratories that are SANAS accredited	100%	100%

Outcome	Outcome Indicator	Baseline (2018/19)	Five-year target (2024/25)
	Percentage of NIOH laboratories that are SANAS accredited	New	100%
	Number of NICD laboratories with WHO reference status	7 laboratories with WHO reference status	7 laboratories with WHO reference status.
	Number of ISO 9001 certified departments	3 departments	8 departments
	Develop and implement the pathologists' national coverage plan	New	50% implementation of the pathologists' national coverage plan
	Number of articles published in the peer-reviewed journals	593	700
	Percentage of identified prioritised diseases under surveillance	89%	90%
	Percentage of outbreaks responded to within 24 hours after notification	100%	100%
	Annual report of population-based cancer surveillance	1	1
	Number of field epidemiologists qualified	9	10
	Percentage of occupational, and environmental health laboratory tests conducted within the predefined turn-around time	75%	90%

Outcome	Outcome Indicator	Baseline (2018/19)	Five-year target (2024/25)
	Number of occupational, environmental health and safety assessments completed	36	36
	Number of occupational health surveillance reports produced	4	4
Cost-Effective Service	Ratio of current assets to current liabilities	3.1 times	2:1
	Cash flow coverage ratio (Operating cash in-flows / total debt)	4.1 times	2:1
	Number of Creditor days	29 days	30 days
	Number of Debtors days	127 days	90 days
	Develop and implement revenue and costing strategy	New	Implement 100% of the revenue and costing strategy.
	Percentage turnaround time for awarding tenders within 90 days.	84%	90%
Governance	Audit Opinion of the Auditor General	Unqualified	Clean
	Percentage of allegations reported through NHLS tipoff platforms that are investigated within 180days.	New	90%

Key risks.

The risks detailed below are not specific to a specific outcome. Any of them can have an impact on the NHLS Strategic Plan.

Table 12: Key Risks

Outcome	Key Risk	Risk Mitigation
Clinical effectiveness and efficiency	Significant volume increases due to a change in the national department of health policies.	NHLS should be advocate for increased resources when volumes increases.
High-quality service	Adequacy and suitability of IT infrastructure.	Fully funded ICT governance plan.
Cost-effective services		Cost-effective Service level agreements with all service providers with clear deliverables and penalties.
Good governance	Building infrastructure	Development of priority capital expenditure plan.
	Attraction and retention of scarce skills.	The NHLS requires an effective recruitment and retention strategy.
	Adequate training and research funding.	
	Lack of 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.
	Liquidity and use of financial resources	

Outcome	Key Risk	Risk Mitigation
	Biosafety and Biosecurity relating to pathogenic organisms. Transition to NAPHISA Running on outdated Technologies	The NHLS will develop implement a revenue enhancement strategy Continue efforts to Effective audit committee to have oversight and encourage accountability within the NHLS financial management. Implement numerous internal controls to mitigate risk. There is a Biosafety and Biosecurity Committee in NICD with an action plan including appropriate training. Organisational development initiatives, steering committee and preparation of NAPHISA business case. Scanning mechanism of new technologies. Establishing innovative ways to support of new technologies.

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