





National Health Laboratory Service Annual Report 2018/19



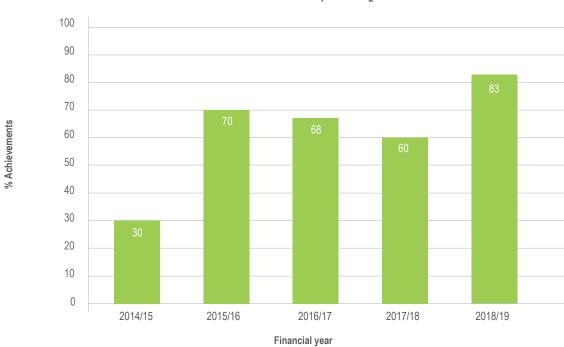
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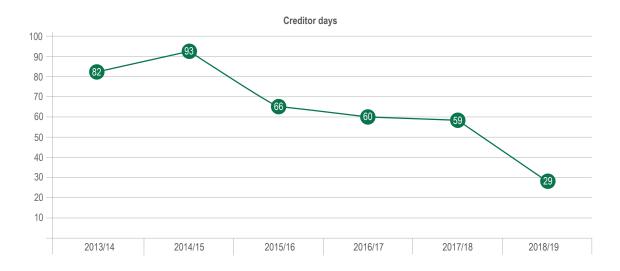
Performance Highlights

Overall performance achievements



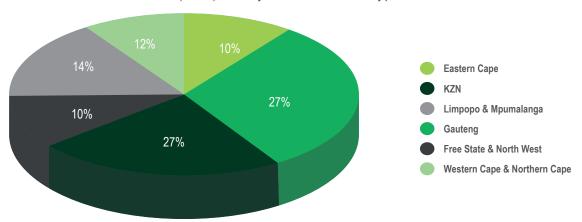


Creditors days

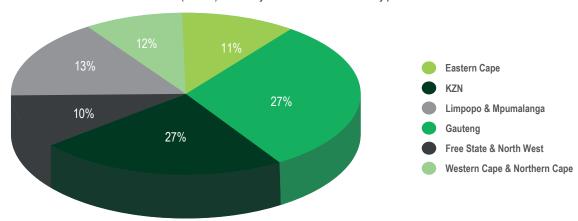


Financial year revenue distribution





(2018/19) Financial year revenue distribution % by province





1.PART A: GENERAL INFORMATION



1.1. National Health Laboratory Service General Information

Registered name of the public entity: National Health Laboratory Service (NHLS)

Legal form: Schedule 3A public entity

Practice number: PR5200296

Registered office address: 1 Modderfontein Road

Rietfontein

Sandringham

Johannesburg, 2000

Postal address: Private Bag X8

Johannesburg

2131

Contact telephone number: 011 386 6000

Email address: enquiries@nhls.ac.za

Website address: http://www.nhls.ac.za

Company Secretary: Adv Mpho Mphelo

External auditors: Sizwe Ntsaluba Gobodo Grant Thornton Inc.

Bankers: First National Bank Limited, Rand Merchant Bank

Limited, Investec Limited and Nedbank Limited

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1.2. Abbreviations and acronyms

AAR Academic Affairs and Research

AARMS Academic Affairs and Research Management System AARQA Academic Affairs, Research and Quality Assurance

ACTG AIDS Clinical Trials Group AFP Acute flaccid paralysis

WHO Regional Office for Africa **AFRO**

Auditor-General AG

AIDS Acquired Immune Deficiency Syndrome

AMAAnti-mitochondrial antibody

AMARA Times Media Annual Recruitment Awards Anti-LKM-1 Anti-liver/kidney microsomal antibody

APCA Anti-parietal cell antibody APP Annual performance plan aPTT Activated prothrombin ARC Audit and Risk Committee

ARMS-PCR Amplification refractory mutation system polymerase chain reaction

Antiretroviral therapy ART

ARV Antiretroviral

ASLM African Society for Laboratory Medicine

Anti-smooth muscle antibody ASMA Aspartate Transaminase AST

ΑU Africa Union

ВА Bilateral agreement

BLUC Blood and Laboratory User Committee

BPA Blanket purchase agreement

BRICS Brazil, Russia, India, China and South Africa

CANSA Cancer Association of South Africa

CAPRISA Centre for the AIDS Programme of Research in South Africa

CC Collaborating Centre

CCHF Crimean-Congo haemorrhagic fever

CCMT Comprehensive Care Management and Treatment CCPCP Cervical Cancer Prevention and Control Policy

CD4 Cluster of differentiation 4

CDC Centers for Disease Control and Prevention

CDW Central Data Warehouse CED Centre for Enteric Diseases CEO Chief Executive Officer

CEZPD Centre for Emerging Zoonotic and Parasitic Diseases

Centre for Healthcare-Associated Infections and Antimicrobial Resistance CHARM

CHBH Chris Hani Baragwanath Hospital Community Healthcare Centre CHC CHE Council on Higher Education CHIVSTI Centre for HIV and STI

CIPC Companies and Intellectual Property Commission

Cryptococcal Meningitis CM

CMJAH Charlotte Maxeke Johannesburg Academic Hospital

CMSA Colleges of Medicine of South Africa

CMVCytomegalovirus CNS Central nervous system

COBIT Control Objectives for Information and Related Technologies CPD Continuing professional development
CPP Comprehensive prevention package
CPUT Cape Peninsula University of Technology

CQI Continuous quality improvement

CrAg Cryptococcal antigen

CRDM Centre for Respiratory Diseases and Meningitis
CRE Carbapenem-resistant Enterobacteriaceae

CROI Conference on Retroviruses and Opportunistic Infections

CRP C-reactive protein
CSF Cerebrospinal fluid

CSIR Council for Scientific and Industrial Research

CTB Centre for Tuberculosis
CU Comprehensive university
CVD Cardiovascular disease

CVI Centre for Vaccine and Immunology

DAFF Department of Agriculture, Forestry and Fisheries

DBS Dried blood spot

DCS Department of Correctional Services

DCST District Clinical Support Team

DGGE Denaturing gradient gel electrophoresis

DGM Dr George Mukhari Hospital
DoH Department of Health
DoL Department of Labour
DMP Diagnostic Media Products
DNA Deoxyribonucleic acid

DRC Democratic republic of Congo dst Drug susceptibility testing

DST Department of Science and Technology
EAP Employee Assistance Programme

ECC Expert Chair Committee

ECHO Project Extension for Community Healthcare Outcomes

ECM Enterprise content management EDTA Ethylenediaminetetraacetic acid

EE Employment Equity

EFI European Federation of Immunology

EGK Electronic gatekeeping EID Early infant diagnosis

ELISA Enzyme-linked immunosorbent assay

EOC Emergency Operations Centre
EPTB Extra-pulmonary tuberculosis
EQA External quality assessment

ESBL Extended-spectrum beta-lactamase

ESF Education Service Fee
ET Ekurhuleni Tshwane
EU European Union
EV Enterovirus

EXCO Executive Management Committee

FA Fanconi anaemia
FinCom Financial Committee
FBC Full blood count

FIOH Finnish Institute of Occupational Health

FIND The Foundation for Innovative New Diagnostics

FISH Fluorescence in situ hybridisation

FNA Fine needle aspiration

FPD Foundation for Professional Development

FSASP Federation of South African Societies of Pathology

GC-MS Gas chromatography-mass spectrometry

GDD Global Diseases Detection GDH Glutamate dehydrogenase GDoH Gauteng Department of Health **GDSP** Global Data Services Platform

GEMP Graduate entry medical programme

GERMS-SA Group for Enteric, Respiratory and Meningeal Disease Surveillance in South Africa

GIS Geographic information system

GLASS Global Antimicrobial Resistance Surveillance System

GOARN Global Outbreak Alert and Response Network

GRAP Standards of Generally Recognised Accounting Practice

GSEC Governance and Social Ethics Committee

GSH Groote Schuur Hospital

GXP GeneXpert НΑ Haemophilia A

HAART Highly active antiretroviral therapy

HBV Hepatitis B virus **HBC** Hepatitis C virus

HIV counselling and testing HCT

HCW Healthcare workers HEU HIV-exposed uninfected HHVHuman herpesvirus HIVDR HIV drug resistance

HIV human immunodeficiency virus

HIV-PCR human immunodeficiency virus - Polymerase chain reaction

HIV VL HIV viral load

HLA Human leucocyte antigen hMPV Human metapneumovirus HOD Head of department

HPCSA Health Professions Council of South Africa

HPRS Health Patient Registration System

HPV Human papillomavirus

HRP Hospital Revitalisation Programme HSS Health systems strengthening HTA Health technology assessment HVTN HIV Vaccine Trials Network

IALCH Inkosi Albert Luthuli Central Hospital

IAPC Institutional Academic Pathology Committees IATA International Air Transport Association (IATA) ICOH International Commission on Occupational Health Information and communications technology ICT

ICU Intensive care unit

IHR International Health Regulations

ILDAC Integrated laboratory data analysis for care

iLEAD Innovation for Laboratory Engineered Accelerated Diagnostics

Influenza-like illness

International Labour Organization ILO IMD Inherited metabolic disease

IMDRF International Medical Devices Regulatory Forum

INR International normalized ratio

IP Intellectual Property

IPC Infection prevention and control IPR Intellectual property rights IQC Independent quality control IRMA Immunoradiometric assay

ISO International Organization for Standardization

IT Information technology

ITGC Information Technology Governance Committee
ITIL Information technology infrastructure library

JEE Joint External Evaluation

JSW Johannesburg Sedibeng West Rand

KEH King Edward VIII Hospital

King IV King Code of Governance Principles (King IV).

KPA Key performance area

KIDCRU Children's Infectious Diseases Clinical Research Unit

LAN Learning academy
LAN Local area network

LAB/IPC Laboratory and Infection Prevention and Control

LBC Liquid-based cytology LFT Liver function test

LIS Laboratory Information System

LPA Line probe assay

LSHTM London School of Hygiene and Tropical Medicine

LTI Laboratory for issue Immunology

MALDI-TOF Matrix Assisted Laser Desorption/Ionization
MBOD Medical Bureau for Occupational Diseases

MCDS Minimum Clinical Data Set MCH Maternal Child Health

MCWH Maternal child women's health MDO Missed diagnostic opportunity

MDR Multidrug-resistance

MDR-TB Multidrug-resistant tuberculosis

MGIT AST Mycobacterium Growth Indicator Tube-Antibiotic Susceptibility Test

MHSC Mine Health and Safety Council
MIC Minimum inhibitory concentration

MLPA Multiplex ligation-dependent probe amplification

MMed Master of Medicine

MOU Maternity Outpatient Unit
MoU Memorandum of understanding
MRC Medical Research Council

MRSA Methicillin-resistant Staphylococcus aureus
MSSA Methicillin-susceptible Staphylococcus aureus
MTB/RIF Mycobacterium tuberculosis/rifampicin

NAAT Nucleic acid amplification test

NAGI National Advisory Group on Immunisation
NAPC National Academic and Pathology Committee
NAPHISA National Public Health Institute of South Africa

NCD Non -communicable diseases

NCOH National Centre for Occupational Health

NCR National Cancer Registry
NDoH National Department of Health

NEHAWU National Education, Health and Allied Workers' Union

NEPAD New Partnership for Africa's Development

NGO Non-governmental organisation
NGS Next generation sequencing
NHA National Health Act, no. 61 of 2003

NHI National Health Insurance

NHLS National Health Laboratory Service
NHRC National Health Research Committee

NIAID National Institute of Allergy and Infectious Diseases
NICD National Institute for Communicable Diseases

NIH National Institutes of Health

NIOH National Institute for Occupational Health

NIOSH National Institute for Occupational Safety and Health NIPMO National Intellectual Property Management Office

NMC Notifiable medical condition

NMCSS Notifiable Medical Conditions Surveillance System
NNRTI Non-nucleoside reverse-transcriptase inhibitor

NPO Non-profit organisationNPP National Priority ProgrammesNPPU National Priority Programmes Unit

NPR National Priority Research

NQF National Qualifications Framework NRF National Research Foundation

NTT National task team

OECD Organisation for Economic Co-operation and Development

OEHS Occupational and Environmental Health and Safety
OHASIS Occupational Health and Safety Information System

OHS Occupational Health and Safety

O.P.D. Out Patient Department
ORU Outbreak Response Unit
OTT Office of Technology Transfer

PAHWP Pan African Harmonisation Working Party
PathRed Pathology Research and Development
PBMC Peripheral blood mononuclear cell

PCR Polymerase chain reaction
PCT Patent Cooperation Treaty

pct procalcitonin

PEPFAR United States President's Emergency Plan for AIDS Relief

PFGE Pulsed-field gel electrophoresis
PFMA Public Finance Management Act
PHC Primary healthcare facility

PI Protease inhibitor

PIVOTAL Professional, vocational, technical and academic learning

PLG Panleucogated

PMA Prioritised management area
PMC Peri-mining communities

PMTCT Prevention of Mother-to-Child Transmission

POCT Point-of-care testing

POPI Protection of personal information

PP Plasma preparation

PPC Parliamentary Portfolio Committee

PPO Serve Professional Provider Organisation Services

PRF Poliomyelitis Research Foundation

PSC Plasma Separation Card PTS Proficiency testing schemes

QA Quality assurance

QAD Quality Assurance Division

QC Quality control

QCA Quality compliance audit QCI Quality control initiative

QCMD Quality Control for Molecular Diagnostics

QF-PCR Quantitative fluorescent polymerase chain reaction

QIT Quality Improvement Tool
QMS Quality management system

RA Rheumatoid arthritis

RACL Relational algebraic capacitated location

RCCH Red Cross War Memorial Children's Hospital

RCE Regional Centre of Excellence
RDC Research Development Committee

RDT Rapid Diagnostic Test

RDTMP Research development training and mentorship programme

RfA Results for Action

RFLP Restriction fragment length polymorphism

RHRC Remuneration and Human Resources Committee

RIA Radioimmunoassay

RIC Research and Innovation Committee

RIF Rifampicin

RPR Rapid plasma reagin
RSV Respiratory syncytial virus

RT-PCR Real-time polymerase chain reaction
RTQII Rapid test quality improvement initiative

RXH Red Cross Academic

SAAVI South African AIDS Vaccine Initiative SABMR South African Bone Marrow Registry

SACOMD South African Committee of Deans of Medical Schools

SADC Southern African Development Community
SAHCS Southern African HIV Clinicians Society

SAIOH Southern African Institute for Occupational Hygiene

SAIMR South African Institute for Medical Research
SAMRC South African Medical Research Council
SANAS South African National Accreditation System

SANBS South African National Blood Services
SANDF South African National Defence Force
SANReN South African National Research Network

SAPHRA South African Health Products Regulatory Authorities

SAPS South African Police Service
SARI Severe acute respiratory infection

SASOHN South African Society of Occupational Health Nursing Practitioners

SASOM South African Society of Occupational Medicine

SAVP South African Vaccine Producers

SAVQA South African viral quality assessment

SBE Snakebite envenoming

SCC Staphylococcal cassette chromosome

SDG Sustainable development goal

SFLC Serum free light chains

SHE Safety, health and environment

SLA Service level agreement

SLE Systemic lupus erythematosus

SLIPTA Stepwise Laboratory Quality Improvement Process Towards Accreditation

SLMTA Strengthening Laboratory Management Towards Accreditation

SME Sub-acute measles encephalitis

SMS short message service

SNP Single nucleotide polymorphism

SOE State-owned enterprise SOP Standard operating procedure

SPF Specific-pathogen-free

SPI-RT Stepwise Process for Improving the Quality of HIV Rapid Testing

STEA Scientific travel and events attendance

STI Sexually transmitted infection

TAT Turnaround time TB Tuberculosis

TBH Tygerberg Hospital Tshwane District Hospital TDH

TENET Tertiary Education and Research Network of South Africa

TEPHINET Training Programs in Epidemiology and Public Health Interventions Network

TMS Tissue microarray analysis

ToR Terms of reference TOT Training of trainers

TQM Total Quality Management

T-RFLP Terminal restriction fragment length polymorphism TTAC Technologist and Technician Advisory Committee

TTO Technology Transfer Office **TWAS** The World Academy of Sciences

UCT University of Cape Town

UI user interface

U&E Urea and electrolytes

UFS University of the Free State UKZN University of KwaZulu-Natal

UN United Nations

UoT University of Technology US Stellenbosch University

USAID United States Agency for International Development

UTT Universal Test and Treat

Vaccine-derived polio virus type 2 VDPV2 VOIP Voice over Internet Protocol

 \vee L Viral Load

WCL Western Cape Laboratories WHO World Health Organization WIL Work integrated learning

University of the Witwatersrand Wits

WSP Workplace skills plan XDR Extensive drug resistance

1.3. Foreword by the Chairperson



The core
mandates of the
National Health
Laboratory
Service (NHLS)
are to provide
a pathology
and laboratory
service for public
sector users, as
well as to train
professionals for
and to research
in the field. To
meet its mandate
the NHLS has
approximately
268 laboratories
cross the
country, ranging
from highly
sophisticated

laboratories to laboratories in

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Introduction

South Africa's health system consists of a large public sector that serves the poorer majority of our people and a private sector that predominantly serves the 17% who have medical insurance. The core mandate of the National Health Laboratory Service (NHLS) is to provide laboratory services for public sector users, train professionals to deliver pathology and laboratory services and conduct research in the field.

The NHLS is equipped to meet its mandate through its 226 laboratories across the country, ranging from highly sophisticated central academic laboratories, to laboratories in the most distant rural hospitals. The NHLS makes a substantial contribution to the cutting edge HIV and tuberculosis (TB) services that our country is acclaimed for, thus making a significant contribution to reducing the burden of these diseases.

As a public entity that serves the public health sector the NHLS is expected to offer value for money. This is especially critical due to our national burden of disease and the associated requirement for suitable treatment and care in the public sector. In practise, the more efficient the NHLS is, the less provision the provinces have to make for use of laboratory services. The NHLS is proud of the fact that its repertoire of tests continues to be substantially more economical than that of the private sector, in spite of the additional costs involved in training, research and providing services in rural areas. The NHLS is also proud of the quality of its services and its turnaround times.

Not surprisingly, the NHLS is also by far the biggest provider of diagnostic laboratory services in the country. This annual report illustrates the volumes of tests we conduct to support clinicians, strategic planners and decision-makers in the public healthcare sector. As the Chairperson of the NHLS Board, I am honoured to have the opportunity to lead an organisation that serves the people of our country in such a valuable way.

Strategic overview

The NHLS has a mammoth task to perform, and is entrusted with far-reaching and life-saving responsibilities. This annual report presents a picture of the services provided in each province and the institutes and of the systems that support them. The NHLS operates under the umbrella of the five programmes which serve to meet the objectives of its strategic plan and annual performance plan (APP). These are: Laboratory Services; Academic Affairs, Research and Quality Assurance; Surveillance of Communicable Diseases; Occupational Health and Safety; and Administration.

Laboratory services

This is a core function and the largest component of the NHLS that serves to provide cost-effective and efficient health laboratory services to the country's public healthcare sector, as well as other stakeholders, on request. This can only be achieved if the NHLS' delivery machine - its network of laboratories - is effective in executing this mandate. The focus of this programme is therefore to ensure that the NHLS enhances its operational efficiency and renders its services in a timely manner, to ensure timeous diagnosis and treatment of patients. In spite of setting higher standards, the performance indicators of this service demonstrate that almost all of the targets were achieved. There is however room for future improvement.

Academic Affairs, Research and Quality Assurance

In addition to the ongoing quality assurance (QA) programme, many laboratories were assessed for SANAS accreditation throughout the year, and significant improvements were recorded, especially in our regional and district laboratories. Our partnerships with universities and Universities of Technology (UoTs), received considerable attention. The NHLS continued to support training of pathologists, medical scientists and laboratory technologists. The improved focus on the NHLS research mandate is starting to bear results. A number of publications and research reports were issued, which added to the global and national body of knowledge and supported our contribution to service provision.

Surveillance of Communicable Diseases

This vital national and continental function is performed by one of the Institutes of the NHLS, the National Institute for Communicable Diseases (NICD). Its specialised laboratory and public health capacity has attained global recognition and it serves as a reference laboratory for both the public and private sectors in South Africa and Africa.

The past financial year saw the end of the Listeria outbreak declared by the Minister of Health, Dr Aaron Motsoaledi, on 3 September 2018. The Listeria outbreak highlighted the role of the Emergency Operations Centre (EOC) in managing a public health crisis and the importance of the ability to use next-generation sequencing (NGS) for molecular epidemiology. The multi-governmental effort and extensive stakeholder collaboration enabled the detection of the source of the outbreak and its containment. For this, the NICD received the Alfred Nzo Environmental Health Excellence Award from the National Department of Health (NDoH).

The NICD supported the national DoH with a joint external evaluation (JEE) exercise of the International Health Regulations (IHR) and led the development of aspects of the JEE action plan. The NICD furthermore deployed a medical epidemiologist to the Butembo health zone of the Democratic Republic of Congo (DRC), under the Global Outbreak Alert and Response Network (GOARN), to assist in the Ebola outbreak relief efforts.

High profile activities such as these should not be allowed to mask the exceptional ongoing work of the institute's seven centres and other entities who met their targets in the year under review.

Occupational Health and Safety

The National Institute for Occupational Health (NIOH) continues to play a vital niche role in Occupational Health and Safety (OHS). A focus area of the past year was engaging directly with workplaces and with communities around workplaces to profile OHS prevention and health promotion and to implement the national strategic Plan on HIV, TB and sexually transmitted infections (STIs). As a World Health Organization Collaborating Centre, the NIOH collaborates with many of the 44 WHO Collaborating Centres, including those from the Brazil, Russia, India, and China (BRICS) countries. The NIOH is leading also as a coordinating centre for the global project on the informal economy and vulnerable workers". The NIOH also delivers a Gender@ Work Programme and a Workplace Ethics and Trust Project.

While delivering for South Africa, the NIOH also collaborates globally, including on nanotechnology research. Its specialised laboratories provide services throughout the continent. An occupational health and safety information system (OHASIS) was implemented, extensive OHS train-the-trainer courses were provided to several New Partnership for Africa's Development (NEPAD) countries, and health workforce training was delivered in Southern Africa through the WHO/International Labour Organization (ILO) HealthWISE programme. In South Africa, the NIOH supports the training of the next generation of OHS professionals through engagement with multiple academic and civil organisations. The NIOH met almost all its key targets, but there is still room for improvement going forward.



In spite of challenges, including those leading to the suspension and subsequent dismissal of the Chief Executive Officer (CEO) and other managers, the NHLS improved on all the functions and processes that enable it to execute its mandate more effectively and efficiently – Finance, Human Resources, Information Technology and Governance.

As becomes evident by this report, the financial position of the NHLS as at the end of the financial year under review was much stronger compared to the previous years. The NHLS also managed to improve its financial status quite significantly, placing the institute in a more liquid position than before. The longstanding issue of creditor days was reduced, and the organisation paid its suppliers on a regular basis. Our supplier relationships improved, except for those with whom we had contractual disputes.

Management has identified that procurement practices followed in the past were not always in line with national prescripts and legislation. The last year was therefore dedicated to identifying all these practices and the irregular expenditure generated by it. Although the amount is high, the NHLS confident that substantially all the irregular practices and expenditure have now been identified and that improved processes and controls are being put in place to prevent this from happening again. The NHLS remains committed to root out all corruption and bad practices in order to comply with fair and equitable procurement processes.

I am extremely pleased that management improved on the audit outcome from the previous year and that the entity achieved an unqualified audit opinion. At the same time, the Board acknowledges that a lot of hard work is still required to improve on the control environment of the NHLS. The Board has set management the objective of achieving a clean audit and, through its sub-committees, will carefully monitor progress towards this objective in the year ahead.

We continued to experience challenges in our information and communications technology (ICT) environment, but a number of improved policies and systems were implemented to radically modernise the NHLS ICT infrastructure to deliver integrated support to the business of the organisation.

Strategic Relationships

The value of strategic relationships for the NHLS in the public healthcare sector cannot be underestimated. Positive relationships and partnerships were fostered with the national and provincial departments of health, other government departments, universities and UoTs, research institutions, non-governmental organisations (NGOs), professional associations and industry bodies. Internationally, the NHLS retained its strong historical partnerships with the WHO, Centres for Disease Control (CDC) and the African Society of Laboratory Medicine (ASLM). All these partnerships continue to impact positively on the work of the NHLS, and its ability to execute its mandate. The NHLS leadership and management teams will continue to build and strengthen these relationships in the interest of enriching the public healthcare system and our other mandates.

The NHLS Board

The NHLS Board continued to deliver diligently on its governance mandate, setting the strategic direction, policies and budget; enabling delivery on the strategic plan and APP, improving the financial and human resource status, and providing oversight of and direction to the executives. During the year under review, the Board not only facilitated stability, but also enabled significant improvements. The Board will continue to perform its oversight and strategy function so that the NHLS is a well-oiled organisation, delivering optimally in the present, and ready to meet the challenges of the future.

The year ahead

The Board has much to attend to in the next financial year. It will commence with aiming to accomplish stability in the top echelons of the organisation. There is also still work ahead to achieve the financial position we aspire to, while mobilising resources to invest in equipment and infrastructure, and continuing to keep our annual tariff increases down. We did however make progress in preparations to change our financial model from a fee for service basis, to a modified capitated reimbursement model.

To offer even better value for money, we not only have to continue to improve the efficiency of our services, but we also have to determine the best national platform – the optimum configuration, size, service offering and opening hours of our different laboratories and services.

Accelerating laboratory quality accreditation is vital to offer users the assurance that our standards of service are guaranteed. The academic platform will continue to receive support for its critical role, with special attention to the retention of senior pathologists. The NHLS will continue to invest in the modernisation of the information technology (IT) system to ensure that we have a state-of-the-art system; strive for innovations with regard to the specimen tracking system to ensure improved turnaround times of results; enable real-time communication with patients through enhanced communication technology; and, implement enhancements in the logistics and procurement systems, for improved service delivery. In addition, improved grant management is essential to retain confidence of our funders.

The publication of the draft National Health Insurance (NHI) Bill heralds major changes for the NHLS of the future. Further work on operations and supporting the NHI to deliver will be undertaken.

Conclusion and acknowledgements

The year was marked by many challenges and successes. At the year end, the NHLS was in a stronger position than at the start of it. This would not have been achieved without the committed service of staff of the NHLS and the executive team. Particular thanks are due to Dr Kamy Chetty, for availing herself to act as the CEO and for the vital contributions she made. Thanks are also due to other staff who acted in executive positions during the year.

I would like to express my sincere gratitude and that of the entire Board to the former Minister of Health, Dr Aaron Motsoaledi, for his unwavering support of the NHLS, his commitment to a successful NHLS for the public healthcare system, and his dedication to unquestionable governance. I am thankful to the Director-General of Health, Ms Malebona Precious Matsoso, for being a pillar of support and wisdom. We would like to indicate our appreciation to the Members of the Executive Council (MECs) for Health and Heads of provincial health departments who recognised the fact that the NHLS is a national asset, and as such, prioritised payments to the NHLS, in spite of prevailing financial challenges.

In conclusion, I would like to thank my fellow Board Members for the expertise and strategic counsel they brought to the institution, and for serving with great dedication, including on the various sub-committees of the Board, to ensure that we provide a full strategy and oversight function over the NHLS. Many serve on the Board without remuneration and others for a fraction of what they would be able to receive in a comparable private sector organisation.

I am sure that the public, who depends on the NHLS for affordable and accessible laboratory and pathology services to support their healthcare, will join me in acknowledging their services.



Prof Eric BuchChairperson

1.4. Acting Chief Executive Officer's Overview



Acting Chief Executive Officer **Dr Kamy Chetty**

Although the NHLS is in a better financial position than the previous years, management continued to implement stringent cost containment measures to ensure that the production costs are managed optimally.

It is once again my pleasure to present the NHLS annual report for the 2018/2019 financial year, a reporting period that was underpinned by positive results. The institute has gone from strength to strength over the past years, in spite of experiencing various challenges. Over the past two years, the Board and the executive management team managed to turn the NHLS' financial position around and achieved adequate financial stability. As a result, the NHLS was able to achieve 83% of its predetermined strategic objectives, which is a remarkable improvement when compared to the achievement of 60% of the predetermined strategic objectives in the 2017/2018 financial year.

Financial overview

Over the years, the NHLS had encountered issues of underpayment by some of the Provincial Departments of Health. Because of our continued and extensive stakeholder engagement efforts, the provinces managed to finally reduce some of their historical debt, and paid for their current consumption. As at 31 March 2019, the provincial department of health debt payable to the NHLS amounted to R5.3 billion. The majority of the debt is owed by KwaZulu-Natal and Gauteng provinces, which constitutes approximately R4.3 billion or 82% of trade receivables. In the year 2018, the NHLS successfully negotiated a settlement agreement with the Gauteng Province. The NHLS continues to engage with KwaZulu-Natal Department of Health (DoH) to reach an amicable settlement regarding the historic debt, as well as with other provinces, to ensure regular payments.

The NHLS generated a surplus of R996 million in the 2018/2019 financial year, compared to a surplus of R1.4 billion in the previous financial year. The revenue increased from R7.9 billion to R8.5 billion. The revenue from provincial budgets amounted to 87% of the total revenue generated. This was largely due to increases of tests conducted for viral loads (VLs), cytology (gynae) by liquid based cytology (LBC), GeneXpert, procalcitonin (PCT), TB, creatinine automated, group 1 cresyl violet stains, C-reactive protein (CRP), profile discrete analyser urea and electrolytes (U&E), and HIV PCR.

The NHLS received a net cash inflow of R9.1 billion compared to R8.0 billion in the previous financial year. Of this R9.1 billion, R3.6 billion was utilised for personnel costs 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 increases in labour, test volume, 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 a R458 million increase in debt impairment and a R54 million increase in employee costs. The long outstanding accounts payable balances from the procurement of goods 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.

Although the NHLS is in a better financial position than the previous years, management continued to implement stringent cost containment measures to ensure that the production costs are managed optimally.

People management

The shortage of appropriately qualified professionals remains a challenge in the NHLS. The core issue is a shortage in qualified pathologists. This is compounded by a high staff turnover of pathologists and migration of pathologists to the private sector and internationally.

The overall vacancy rate in NHLS for the 2018/2019 financial year was at 9.4%, and the pathologists contributed 12.6% of the 9.4%.

In the year under review, we achieved a staff retention rate of 94.6%, which implies that we had a total staff turnover rate of only 5.4%. We remain committed to the development and support of our staff and a total of 5 905 staff members received various forms of training, which constitutes an achievement of 81% of the target as determined in our annual performance plan (APP).

The NHLS provides vocational training to registrars, intern medical scientists, intern medical technologists and student medical technicians in alignment with the requirements of the Health Professions Council of South Africa (HPCSA). During the 2018/2019 financial year, 57 registrars, 36 intern medical scientists and 248 intern medical technologists were trained in the NHLS.

The NHLS staff members serve as brand ambassadors for the organisation and they made us proud. Allow me to mention but a few who placed the organisation on the world map:

- Dr Sophia Kisting, Director of the National Institute for Occupational Health (NIOH) was awarded the President of Convocation Medal at the University of Cape Town (UCT);
- Prof Anna-Lise Williamson, who is heading up the Human Papillomavirus (HPV) Surveillance Section, received a gold medal for her internationally recognised work in vaccinology and the development of new vaccines, as well as for her research in the field of HPV;
- Prof Maureen Coetzee, a research professor at the University of the Witwatersrand (Wits) and an honorary researcher at the NICD, received a platinum award for a lifetime of outstanding endeavours in the field of
- Prof Penny Moore received a silver medal for the research that she has conducted over the past decade, which has provided a roadmap for the development of broadly neutralising antibodies required for an HIV vaccine:
- Prof Bavesh Kana, who is the Director of the Centre of Excellence for Biomedical TB Research, walked away with a silver medal. He was also awarded the CEO Titan Award for South Africa and the Southern African Development Communities (SADC) region and the African Continent; and the Wits Enterprise Innovators Award. In addition, he was appointed as a Howard Hughes Medical Institute International Early Career Scientist, and selected as one of the Top 200 Young South Africans by the Mail and Guardian; and
- A Special Award for Contribution to Public Health Surveillance and Research was conferred to Prof Lucille Blumberg, the Head of Public Health Surveillance and Response Division, and for her work as a medical consultant to the Emerging Pathogens Centre on Rabies and Viral Haemorrhagic Fever.
- Professor. Lynn Morris was awarded the World Academy of Sciences (TWAS) prize in Medical Sciences for 2018, in recognition of her pioneering studies on the neutralizing antibody response to HIV infection that has provided fundamental insights for HIV vaccine development.



Improving operational efficiency across the business was one of our core focus areas during the period under review. This is evidenced by implementing efficient recruitment processes which resulted in a staff recruitment turnaround time of 89% against an annual target of 80%. We managed to maintain a staff turnover of 5.4% of which 3% were voluntary resignations. This is an indication of a stable workforce which is committed to the organisation. The NHLS successfully piloted a specimen tracking system to identify gaps in the specimen value chain and develop an improvement plan.

Improvements in systems

The aim of Information Technology (IT) is to be a strategic enabler to the business operations of the NHLS and to ensure that the organisation transforms into a digital business. A strategy was therefore developed to articulate the vision and provide a roadmap on how IT will support the NHLS to achieve its business objectives, transform into a state-of-the-art laboratory service and become a sustainable digital healthcare business. The strategy also outlines strategic IT actions, which will be performed to enable the NHLS to strengthen its service delivery and improve operational- and cost efficiency.

The network infrastructure and connectivity remain a business challenge for the NHLS and projects aiming at upgrading the infrastructure commenced in the 2018/2019 financial year. This encompasses a local area network (LAN) upgrade project to refresh the following sites: Sandringham, Braamfontein, Chris Hani Baragwanath Hospital (CHBH) and Charlotte Maxeke Academic Hospital (CMAH).

The NHLS partnered with the Council for Scientific and Industrial Research (CSIR) to address network bandwidth challenges. To further improve business operations and increase productivity, network bandwidth was upgraded at several prioritised NHLS sites.

A number of projects were implemented in the 2018/2019 financial year, with the aim to ensure that the NHLS commences its journey to transform into a digital healthcare business. The following major projects were implemented in the period under review:

- Rollout of the web-based Academic Affairs and Research Management System (AARMS), to enable online research applications management;
- Upgrade of the Laboratory Information System (LIS) to the latest version, to improve user functionality;
- Integration of the LIS with the Health Patient Registration System (HPRS), which is a flagship project by the National Department of Health (NDoH) aimed at improving patient data management and establish a foundation for the successful rollout of the NHI;
- Development of interfaces with a number of healthcare facilities and other healthcare industry partners
 to deliver the replicable and context-appropriate implementation of a health information exchange model
 for clinical data;
- Continuous rollout of the Enterprise Content Management (ECM) solution, to digitise critical business documents and improve efficiency in the work flow of the business; and
- Implementation of a contract management system to monitor procurement expenditure and commitments.

Service delivery

The test volumes increased by 2%, from 92 486 362 in the 2017/2018 financial year, to 94 404 922 in the 2018/2019 financial year. The NHLS managed to provide high quality services within acceptable turnaround times (TATs) for almost all the national priority tests, including full blood count (FBC) and (U&E) tests. There was however, a challenge with the HIV PCR tests, due to a global short supply of test kits.

In 2017, South Africa transitioned from Xpert MTB/RIF to Xpert MTB/RIF Ultra (Xpert Ultra), due to its higher sensitivity in detecting Mycobacterium Tuberculosis (MTB) particularly amongst patients living with HIV. Since March 2011, 14 982 734 tests have been performed, including 2 655 078 Xpert Ultra tests. South Africa has the largest HIV treatment programme in the world, accounting for 20% of people on ART globally. The country also has one of the largest domestically funded programmes, with ~80% of the AIDS response funded by the government. The NHLS provides HIV VL testing services as part of this programme for the national DoH by means of 16 centralised HIV VL laboratories, that are located across eight provinces in South Africa (except Northern Cape).

Viral load tested volumes for 2018/2019 reached 5.22 million with KwaZulu-Natal processing 1.54 million specimens (29.4% of the annual test volume), followed by Gauteng with 1.39 million (26.7% of the annual test volume). Overall, there were 200 482 more viral load tests performed in 2018/2019, a 4% increase when compared to 2017/2018 financial year. As per the NHLS APP for 2018/2019, 75% of HIV VL should be tested within 96 hours. The target was exceeded with >86% of HIV VL processed within the required time period.

The year ahead

We expect the year ahead to be both interesting and challenging. We must continue to strengthen the NHLS' capability to deliver on its mandate, which will entail a holistic approach that considers our people, processes and systems, infrastructure and more importantly, our customer service. Exciting future opportunities are also in the pipeline for the NHLS, which will be realised as soon as the NHLS Amendment Bill is proclaimed and implemented. The NHLS must also continue to remain at the forefront of advancements in the field of laboratory medicine as it continues to develop high-technology laboratories of the future.

The impending implementation of the National Health Insurance (NHI), which is a financing system that will make sure that all South African citizens and legal long-term residents are provided with essential healthcare, regardless of their employment status and ability to make and direct monetary contribution to the NHI fund. This will necessitate the NHLS to be fully prepared to support the NHI in its delivery.

I am confident that the NHLS is ready for all the challenges and opportunities that will arise in the future.

Acknowledgments

In conclusion, I would like to thank the Board of the NHLS, and in particular the Chairperson Prof Eric Buch, for their support and guidance during the year under review. I would also like to express my gratitude to the executive and senior management teams for their commitment to continue focusing on our journey to renew and revitalise the NHLS to become a patient-centric organisation and execute its mandate with high levels of excellence. The employees of the NHLS also deserve commendation, as they are the foot soldiers who make things happen on the ground. Without them, their skills and expertise, the public healthcare system in South Africa would be incomplete. As we strive to improve on operational efficiency and effectiveness, I know that I can rely on the innovative ideas and outstanding expertise of NHLS employees. Lastly, my sincere thanks to organised labour, for their contributions towards creating a stable work environment.

The NHLS plays an important role in the country's public healthcare system, and that it will continue to do so for many years to come. With its network of laboratories country-wide, improved technology and the growing talent of its people, the NHLS is well-positioned to deliver on its mandate.

Dr Karmani Chetty Acting Chief Executive Officer (CEO)

1.5 Board Members



Prof Eric Buch (Chairperson)



Ms Nelisiwe Mkhize







Mr Ian Van der Merwe



Prof Mary Ross



(Acting CEO)















Mrs Nicolene

1.6. Statement of responsibility and confirmation of accuracy of National Health Laboratory Service annual report.

To the best of our knowledge and belief, we confirm the following:

- All information and amounts disclosed in the National Health Service (NHLS) annual report, are consistent with the annual financial statements audited by SNG Grant Thornton;
- The annual report is complete, accurate and free from any omissions;
- The annual report was prepared in accordance with the Annual Report Guidelines as issued by National Treasury:
- The annual financial statements (Part E), were prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP), as applicable to the NHLS;
- The Accounting Authority is responsible for the preparation of the annual financial statements and for the judgments made in this information;
- The Accounting Authority is responsible for establishing and implementing a system of internal control, designed to provide reasonable assurance as to the integrity and reliability of the performance information, the human resources information and the annual financial statements; and
- The external auditors are engaged to express an independent opinion on the annual financial statements.

In our opinion, the NHLS annual report fairly reflects the operations, performance information, human resources information and financial affairs of the NHLS for the financial year that ended 31 March 2019.

Yours faithfully

Acting Chief Executive Officer (CEO)

Chairperson of the Board

1.7 Overview



The National Health Laboratory Service (NHLS) is a national public entity, established in terms of the National Health Laboratory Service Act, no. 37 of 2000, to provide quality, affordable and sustainable health laboratory services, education and research. It has approximately 268 laboratories across the nine provinces of South Africa, excluding depots, and serves approximately 80% of the South African population.

The NHLS is the main provider of pathology services to the national, provincial and local departments of health, through its countrywide network of quality assured diagnostic laboratories. It also provides surveillance support for communicable diseases, occupational health and cancer.

The NHLS is managed according to the provisions of the National Health Laboratory Service Act; the NHLS Rules, gazetted in July 2007; and the Public Finance Management Act (PFMA), no. 1 of 1999. It is a state-owned enterprise (SOE), governed by a Board and a Chief Executive Officer (CEO).

It has a clear organisational structure consisting of a head office in Sandringham, Johannesburg, six regions (Mpumalanga and Limpopo; KwaZulu-Natal; Eastern Cape; Western and Northern Cape; Free State and North West; and Gauteng) and two institutes, namely: The National Institute for Communicable Diseases (NICD), incorporating the National Cancer Registry (NCR) and the National Institute for Occupational Health (NIOH). The six regions are purposefully designed to ensure that the NHLS plans, agrees on budgets and monitors laboratory services jointly with provincial health partners, with the intention for laboratory services to be clearly part of the public health delivery system.

The NHLS delivers services throughout the public sector, from academic, provincial tertiary, regional and district hospitals, to primary healthcare facilities. The level of complexity and sophistication of services increases from the peripheral laboratories to the central urban laboratories, (with specialised surveillance infrastructure existing at specific sites).

South African Vaccine Producer (SAVP), is a wholly owned subsidiary of the NHLS and the only South African manufacturers of antivenom for the treatment of snake, scorpion and spider evenomation.



Vision

To render efficient patient centred services and become a global centre of excellence for innovative laboratory medicine.

Mission

The mission of the NHLS is to:

- Provide quality, affordable and sustainable health laboratory services through an integrated network of laboratories;
- Provide training for health science education; and
- Execute innovative and relevant research with a focus on patient care.

Values

The following values form the guiding principles that govern and align the behaviour of all NHLS employees:

#	Value	Description
3.1	Care	Caring about the environment and society: This involves consideration of our impact on the environment and local communities, acting with concern and sensitivity. The NHLS is committed to behave ethically and contribute to the economic development of the workforce, community and society at large. It is about giving back to society and the environment, as well as capacity building for a sustainable future.
3.2	Unity of purpose	All working together towards a common goal: All employees are united by a common vision and support each other in contributing to a beneficial and safe working environment. Teamwork and cohesion are key, and collaboration includes pooling resources and communicating about each other's roles. We foster trust and honesty in all our interactions with colleagues and behave professionally at all times. We value all contributions, treat everyone consistently and fairly, and capitalise on diverse viewpoints. We address and resolve conflicts effectively. We listen to others to fully understand and give clear, concise information when communicating expectations and accountabilities and providing feedback during coaching. The NHLS goals are a priority, and we use NHLS resources wisely and effectively and take responsibility for our own work.
3.3	Service excellence	Valuing good work ethics and striving towards service excellence for customers: This speaks to being committed to working with customers and building good relationships with them by understanding their needs, responding quickly and providing appropriate solutions. We treat them with respect at all times; we are helpful, courteous, accessible, responsible and knowledgeable in our interactions. We understand that we have internal and external customers that we provide services and information to. We aim to present this information in a clear and concise manner, and the message is adapted to suit the audience.

#	Value	Description
3.4	Transformation	Looking forward to the future and growing together: This encompasses investing in professional growth of our staff by sharing knowledge and experience, peer networking, education through training, and seeking opportunities to develop. It covers creative problem solving, informed risk taking, learning from our mistakes and experiences, and behaving professionally. We aim to adapt to change timeously and positively, address setbacks and ambiguity and adapt our thinking and approach, as and when a situation changes. Ideas are shared and implemented effectively. Our leaders are committed to develop innovative approaches and drive continuous improvement, as well as effective and smooth change initiatives.
3.5	Innovation	Pioneering relevant research solutions and training: We identify needs to broad challenges that are present in our local society. We create space for research to be done and support new ideas by bringing them to the market. We pursue cost-effective solutions in research and training. We monitor the impact of solutions on the challenges faced. We support the application of new processes in the organisation, at senior management level. We encourage pioneering personalities to think and operate outside the research box. We reward and publish boundary-breaking initiatives. We giving credit where it is due.
3.6	Integrity	Working with integrity and responsibility: We set and achieve our goals to consistently deliver business results, while complying with standards and meeting deadlines. We display commitment to organisational success; proactively identify ways to contribute and take initiative to address issues or unlock opportunities. We build efficiency through the best use of public resources.

1.8. Legislative and other mandates

The legislative mandate of the NHLS is derived from the Constitution, the National Health Act, no. 61 of 2003 (NHA), the NHLS Act 37 of 2000, and several laws, regulations and policies issued by Parliament.

1.8.1 Constitutional mandate

In terms of the constitutional provisions, the NHLS is, amongst others, guided by the following sections and schedules:

- 1. The Constitution of the Republic of South Africa, 1996, places obligations on the state to progressively realise socio-economic rights, including access to healthcare;
- 2. Section 27 of the Constitution states the following with regards to healthcare, food, water, and social security:
 - a Everyone has the right to have access to:
 - (i) Healthcare services, including reproductive healthcare;
 - (ii) Sufficient food and water; and
 - (iii) Social security, including appropriate social assistance in instances where they are unable to support themselves and their dependents.
- 3. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights; and
- 4. No one may be refused emergency medical treatment.

1.8.2 The National Health Act, no. 61 of 2003

This act provides a framework for a structured and uniform health system within South Africa, taking into cognisance all the obligations imposed by the Constitution and other laws on the national, provincial and local governments regarding health services.

The objectives of the 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 cooperative governance and management of health services, within national guidelines, norms and standards to guide each province, municipality and health district to address questions of health policy and delivery of quality healthcare services;
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourages participation;
- Promote a spirit of cooperation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans;
- Create a foundation for the healthcare system, that must be interpreted and implemented alongside other laws and policies that relate to health.

1.8.3. The National Health Laboratory Service Act, no. 37 of 2000

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



Additional prescripts that create our governance context

The NHLS is required to comply, inter alia, with the following;

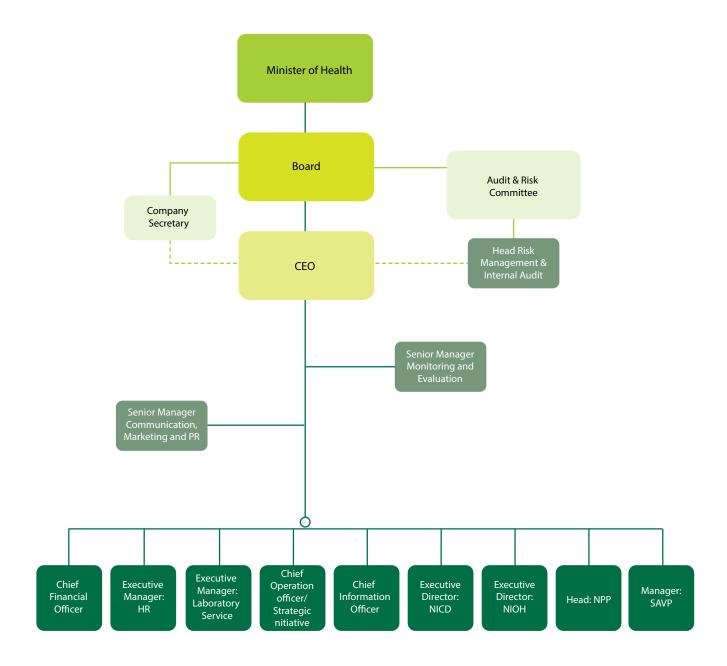
- Constitution of the Republic of South Africa, Act 108 of 1996 (as amended)
- Public Finance management Act, No 1 of 1999 (as amended)
- National Health Laboratory Service Act, No 37 of 2000
- National Health Act, no 61 of 2003
- Preferential Procurement Framework Act, No5 of 2000
- Companies Act, No 71 of 2008
- General rules established in terms of Section 27 of the NHS Act
- Protocol on Good Governance in the Public sector
- King IV Code of Corporate Governance
- Treasury Regulations issued in terms of PFMA
- All laws that are applicable to the health sector

1.8.5. Policy initiatives

As articulated in its Strategic Plan 2015/16-2019/20, the NHLS is committed to support the following:

- The National Health Insurance (NHI), which will cover a defined repertoire of pathology services that are aligned with the package of services required per level of care. The pathology services will be delivered at public healthcare level, as well as at higher levels of care as defined by the NHLS Act and in line with the NHA. The latter requires the establishing, monitoring and enforcing of quality control standards applicable to pathology services, to ensure patient safety.
- The National Public Health Institute of South Africa (NAPHISA), that has the following functions:
- Communicable diseases;
- The National Cancer Registry:
- Occupational health:
- Non-communicable diseases; and
- Injury and violence prevention.

The various departments that will form part pf NAPHISA are still being determined but it is anticipated that the NICD, including NCR and NIOH will be incorporated into NAPHISA.





2.PART B: PERFORMANCE INFORMATION



2.1. Auditor's report predetermined objectives

The independent auditor performed the necessary audit procedure on the performance information of the NHLS to provide reasonable assurance in the form of an audit conclusion. The audit conclusion on the performance of the NHLS against its predetermined objectives, is included in the report to management, with material findings being reported under the 'Predetermined objectives' heading in the report in the 'Other legal and regulatory requirements' section of the auditor's report on pages 187 - 192.

2.2. Situational analysis

2.2.1. Performance Environment

2.2.1.1. The Landscape in South Africa

Medical testing laboratories are distributed across the public and private health sector in South Africa. The NHLS was established in 2000 by an Act of Parliament to provide pathology services for the public health sector, servicing over 80% of the population across all nine provinces. The population of South Africa is growing rapidly with individuals who require healthcare. The demographics, geographic distribution and prevalence of disease contributes greatly to the type and capacity of laboratory services required.

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

The priority diseases in South Africa remain the HIV and TB epidemics, which require significant volumes of testing to support their management, the sheer burden of which is unparalleled globally. With the increased pressure of the HIV 90:90:90 targets and END TB strategies, this is likely to remain an important mandate of the NHLS. The prevalence of HIV is estimated at 12,6% for the general population and rises to 18% in the 15-49year age group. Over 7 million South Africans are HIV infected with approximately 4,3 million individuals on antiretroviral therapy. The recent WHO report confirms the unique nature of these epidemics in South Africa where high rates of co-infection occur, further challenging diagnostic assay algorithms and needs (WHO, Global Tuberculosis Report, 2017). At least 69% of TB cases are co-infected with HIV. Tuberculosis has showed signs of decline in South Africa, but a prevalence of 380/100 000 (210-590) and incidence of 450/100 000 (400-510) confirm that there is still much to be done. As treatment progress has been made, an inevitable consequence has been the development of both HIV drug resistance and multi/extremely drug-resistant (MDR/XDR) TB, requiring new technologic approaches to diagnosis and monitoring. The rapid acceleration plans for HIV and TB treatment access will have a knock- on effect on the NHLS that will require significant program review with the automation, modernization, consolidation and integration of laboratory platforms and services to ensure affordability. The accelerated HIV treatment initiation plan alone will impact heavily on the investment requirements of the NHLS, if the targets of 6 million on treatment by 2019/2020 are to be realised.

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

A wave of non-communicable diseases is likely to add further requirements to laboratory services with Cancer predicted to increase by at least 30% by 2030 with annual figures reaching an estimated 10 million cases (Lancet, 2017). In a recent survey in rural South Africa, high rates of stroke, cardiovascular disease,

hypertension and dyslipidemia was noted in addition to HIV, with at least 56% of individuals having two or more of these diseases (Hofman,2014: SAMJ). By 2030 it is predicted that non-communicable diseases (NCDs) will account for over 6-fold more morbidity than Communicable Diseases. Due to the high burden of communicable diseases, non-communicable diseases have not been the priority of the National Department of Health and have not received enough attention. This is changing as demonstrated by national public health policies released recently to facilitate national access to diagnosis and care for Cervical and Breast Cancers (NDoH Breast cancer, Prevention and control policy; Cervical cancer policy, August 2017). In addition, occupational, environmental and safety risk factors, including workplace exposures and injuries, are significant contributors to the global burden of diseases and to morbidity and mortality (The Lancet 2016 Vol 388, Issue 10053, p1659-1724).

These examples clearly demonstrate the increasing need and greater investment in precision laboratory medicine to facilitate greater prevention in public health. Much needs to be done on the laboratory front where there are only 230 pathologists serving the public sector and only 75 anatomical pathologists [1 per 750 000 of the population (NHLS, 2017)].

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

2.2.2. Organisational environment

2.2.2.1. Network of Laboratory Services

The National Health Laboratory Service (NHLS) is a national public entity established in terms of the National Health Laboratory Service Act 37 of 2000 to provide quality, affordable and sustainable health laboratory and related public health services to all public healthcare providers, other government institutions and any private healthcare provider in need of service. It was also mandated to support health research and provide training for health science education.

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

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

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

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

for the NHLS, which itself was facing financial concerns. However, the two Institutions (NICD and NIOH), currently receive funding from the Department of Health for teaching, training and research.

The NHLS laboratories are predominantly based in the health care facilities, in all nine provinces. The highest level of care is provided at the National Central Hospitals and the lowest level at Primary Health Care Facilities. The complexity of service requirements and the large number of health care facilities that require a pathology service means a renewed focus needs to be placed on innovation and new approaches to laboratory systems across the entire laboratory value chain. A multi-disciplinary approach to the service design and planning will need to be maintained. The increased demands mean appropriate workforce development with staff retention being an important focus as we move forward.

2.2.2.2. Linkages within the NHLS laboratories

There are ten National Central laboratories (Academic), that offers routine and highly specialised laboratory services and act as referral centre for lower level laboratories. The National Central laboratories also offer training for health professional in collaboration with the Medical Universities and the Universities of Technology.

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

2.3. Strategic outcome oriented goals

The goal statements and descriptions of each of the strategic outcome orientated goals are shown in the table below:

Goal	Goal Statement
Goal 1: Modernised and accessible laboratory service	Provide 100% of hospitals at regional or higher level with pathologist cover by 2020, and to offer a comprehensive, quality, cost-effective and timeous pathology service which subscribes to international standards. Accomplish this requires that all tests be carried out according to International Best Practice and that optimal use is made of technology to provide improved turnaround time.
Goal 2: Academic excellence in training and research	To produce highly competent pathology health professionals who spearhead service delivery and locally relevant research. It is the ultimate strategic intent of the NHLS to ensure that research ultimately strengthens laboratory systems and influences policy development for improvement of health outcomes.
Goal 3 Sound governance and improved stakeholder relations	The NHLS must show accountability and transparency through communicating more frequently with its stakeholder on its strategic initiatives and key decisions, both internally and externally. The NHLS will ensure sound corporate governance through strict adherence and compliance with all relevant legislation, financial regulations, directives, policies and procedures.
Goal 4 Effective and efficient organisation	Ensure effective management of the NHLS through efficient use of resources, integrated systems and improved monitoring and evaluation. With the introduction of National Health Insurance (NHI), it is essential that there is optimisation of resources. For these reasons, a comprehensive review of the NHLS in its entirety, including but not limited to governance, service model, financial and funding models and workforce planning models is being undertaken. The NHLS must be transformed into an even more dynamic, effective and efficient entity which meets the need of its patients, builds capacity and grow the NHLS footprint.
Goal 5 Efficient financial practices	NHLS must ensure effective financial management, policy and practice and strengthen the management of financial resources and procurement processes. The NHLS must generate sufficient revenue to ensure financial viability and sustainability.
Goal 6 Skilled, competent and motivated workforce	Competent and motivated staff plays a vital role in ensuring organisational success. It is the intended goal of the NHLS to have the right number of staff with the right skills mix at the right level available and employed in appropriate positions within the organisation.

2.4. Performance information by programme

2.4.1. Introduction

Performance information enables the organisation to track how well the organisation is progressing in meeting its planned strategic goals and strategic objectives. The performance information is key to effective management, including planning, budgeting, implementation, monitoring and reporting of information. It also facilitates accountability and enables stakeholders and interested parties to track progress and identify the scope of improvement plans and better understand the issues involved (Framework Performance of Information: National Treasury).

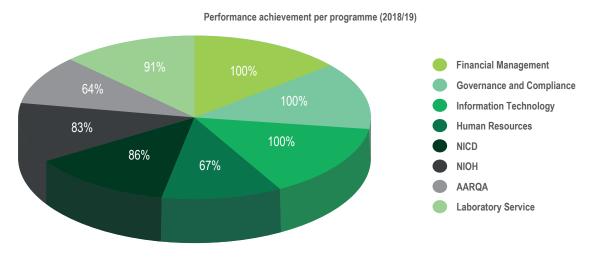
The National Health Laboratory Service managed to achieve 83% of its set targets. The performance has increased significantly when compared to the 60% reported in the previous financial year.

Table 1 below shows the overall performance of individual programmes.

Table 1: Summary achievement per programme for financial year 2018/19

Programme	Score	% Score
Financial Management	6/6	100%
Governance and Compliance	5/5	100%
Information Technology	5/5	100%
Human Resources	4/6	67%
NICD	6/7	86%
NIOH	5/6	83%
AARQA	9/14	64%
Laboratory Service	10/11	91%
NHLS Overall (2018/19)	50/60	83%
NHLS Overall (2017/18)		60%

Figure 1: Summary achievement per programme for the financial year 2018/19





Programme purpose

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

- Financial Management: The purpose of this sub-programme is to maintain and improve the cash flow of the NHLS;
- Governance and Compliance: The purpose of this sub-programme is to provide support services and ensure compliance with relevant legislation;
- Information Technology (IT): The purpose of sub-programme is to build a robust and agile IT infrastructure, and to innovative digital solutions that will enable state-of-the-art laboratory services at the NHLS, by 2020; and
- Human Resources Management: The purpose of this sub-programme is to provide effective services and enable operations through efficient processes and adequate human resources.

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

Key performance indicators

Pe	Performance indicator		Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
1.1.1	Develop and implement the financial management policy	New	New	Approved policy and plan implemented	Policy developed ,approved and implemented	0	©	On target
1.2.1	Ratio of current assets to current liabilities	1.3 times	1.9 times	2.6 times	3.1 times	0.5 times	☺	This was due to a 68% increase in the current ratio, which was driven by a 52% reduction in payables from exchange transactions.
1.2.2	Cash flow coverage ratio (Operating cash flows / total debt)	0.8 times	1.1 times	2.0 times	4.1 times	2.1 times	<u>:</u>	This was due to a significant reduction in payables from exchange transactions and R1,1bn increase in cash and cash
		(1.9 times)	(2.3 times)					equivalents
1.2.3	Percentage of material	44%	43%	41%	41%	0%	\odot	On target
1.2.3	cost to revenue	4470	43%	(38%)	4170		(
1.2.4	Number of creditor	60 days	59 days	60 days	29 days	31 days	\odot	The NHLS made extra payment to its suppliers towards the end of the financial
	days	(74 days)	(51 days)					year, and settled its April accounts.
1.2.5	Number of debtors days	164 days	114 days	150 days	127 days	23 days	\odot	The deviation of 23 days is due to collections exceeding annual billing which resulted in an overall
		(336 days)	(260 days)					decrease in the time taken to collect outstanding debt.
1.3.1	Contract management system implemented	New	New	100% implementation and loading of all contracts (existing and new) on the system	100% implementation and loading of all contract (existing and new) on the system	0%	☺	On target
1.3.2	Percentage turnaround time for awarding tenders within 90 days after closing date	New	New	80%	84%	4%	<u></u>	The over achievement is due to improved processes and productivity in the department.

NB: Historical figures (in brackets) were restated on the basis of revised ratio calculations, to align it with more accepted ratio standard calculations.



The strategic objectives contributed to the achievement of the "Efficient Financial Practices" strategic outcome-oriented goal. The cash position of the NHLS as at the end of March 2019, demonstrates stronger financial liquidity, which in turn constitutes greater financial stability.

Sub-programme - Governance and Compliance							
Strategic objective 1.4	Audit opinion of the Auditor General.						
Objective statement:	Clean audit outcome by ensuring continuous management practices through compliance with standards operating procedures and systems within the NHLS.						
Strategic objective 1.5	Strengthen oversight role of the Board						
Objective statement	The Board have a basic responsibility to ensure sustainable improvements in corporate valuations by providing strategic guidance and oversight.						
Strategic objective 1.6	Effective monitoring and evaluation system						
Objective statement	Effective monitoring and evaluation systems are necessary to gather information which will inform policies and decision making.						

Key performance indicators

ı	Performance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
1.4.1	Clean audit opinion of the Auditor General	Unqualified audit opinion	Qualified audit opinion	Unqualified	Unqualified	0	\odot	On target
1.5.1	Effective monitoring tool to measure compliance with Board's decisions and resolutions	New	New	Approved monitoring tool	Approved Monitoring tool	0	\odot	On target
1.5.2	Review and revise the code of conduct and ethics policy	New	New	Reviewed and revised code of conduct and ethics policy	Reviewed and revised code of conduct and ethics policy	0	©	On target
1.6.2	Develop and implement methodology to collect and collate information to establish an effective monitoring and evaluation system	New	New	Methodology developed and approved.	Methodology developed and approved	0	\odot	On target
1.6.3	Develop and implement an integrated reporting system to show compliance with key indicators and governance practices.	New	New	System developed and approved	System developed and approved	0	\odot	On target



Commentary on the contribution of the strategic objectives to the strategic outcome oriented goals

The strategic goals contributed to the achievement of the "Sound and Improved Stakeholder Relations" and "Effective, Efficient and Ethical Organisation for Improved Service Delivery and Implementation of the NHI" strategic outcome-oriented goals. The NHLS developed a monitoring and evaluation framework and procedures to establish an effective monitoring and evaluation system.

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

Key performance indicators

	Performance Indicator	Actual 2016/17	Actual 2017/18	Planned Target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
1.7.1	Development of IT Strategy Complete	New	75%	Approved IT strategy	Approved IT strategy	0	\odot	On target
1.7.2	Development of the IT roadmap in alignment with the IT strategy	New	0%	Approved IT roadmap	Approved IT roadmap	0	\odot	On target
1.7.3	Number of dashboard, analytics and customer channels projects implemented	New	4	4	4	0	\odot	On target
1.7.4	Percentage System Uptime for Critical Systems at facility level	99%	99%	99%	100%	1%	\odot	On target
1.7.5	Number of Modernisation Projects completed	New	5	10	10	0	\odot	On target

Commentary on the contribution of the strategic objectives to the strategic outcome oriented goals.

The strategic objective contributed to the achievement of the "Effective, Efficient and Ethical Organisation for Improved Service Delivery and Implementation of NHI" strategic outcome-oriented goal. The developed IT strategy and roadmap articulate how IT will enable the NHLS to achieve its business objectives, transform into a state-of-the-art laboratory service and become a sustainable digital healthcare business. The strategy also outlines strategic actions, which will be undertaken to enable the NHLS to strengthen its service delivery and improve operational and cost efficiency.

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

Key performance indicators

	Performance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
1.8.1	Staff Turnover ratio	5%	-	5%	3%	-2%	\odot	The NHLS has strong retention strategies and fulfils an integral role in its market.
1.8.2	Average staff recruitment turnaround within 90 days	62%	-	80%	89%	9%	\odot	This deviation was due to the implementation of efficient processes for filling of critical posts
1.8.3	Percentage of Employment Equity achieved across grade C,D & E relative to EAP	83%	88%	90%	70%	-20%		63.1% is the average of the three levels. A score of 70% represents an improvement when compared to the average score of 63.1% of all three levels.
1.8.4	Percentage of employees with approved and evaluated performance agreements	63%	80%	95%	94%	-1%	8	The target was not achieved because there were staff who were on maternity leave, study leave and temporary disability leave during the performance assessment period
1.8.5	Percentage of employees trained as per the approved training plan (WSP)	New	New	90%	81%	-9%	8	Some of the staff who requested professional, vocational, technical and academic learning (PIVOTAL) qualifications, were not enrolled.
1.9.1	Develop and Implement Human Resource plan and the workforce model	New	New	Approved Human Resource plan and pilot the model	Approved	0	\odot	On target
1.10.1	Develop and implement the integrated performance management system	New	New	Approved integrated management system	Approved integrated management system	0	\odot	On target

Commentary on the contribution of the strategic objectives to the strategic outcome orientated goals.

The strategic objectives contributed to the achievement of the "Skilled, Competent and Motivated Workforce" strategic outcome-oriented goal.

Changes to the planned targets.

There were no changes to the planned targets for Programme 1 in 2018/2019 financial year.

Linking performance to budget:

Programme 1	Budget 2018/19	Actual Expenditure 2018/19	Over/ Under Expenditure	Budget 2017/18	Actual Expenditure 2017/18	Over/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Administration	1,208,981	843,003	365,549	890,219	212,816	677,403

Reasons for deviations from the budget

Whilst the cash flow position improved when compared to the previous financial year, the executive remains cautious and continuously implemented stringent cost containment measures to ensure that the production costs are managed optimally.

2.2.1.2. Programme 2: Surveillance of Communicable Diseases

Programme purpose

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

Strategic objectives

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

Key performance indicators

F	Performance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
2.1.1	Percentage of identified prioritised diseases under surveillance	90%	90%	90%	89%	-1%	8	The deviation was due to challenges in tracking patients for follow up.
2.1.2	Percentage of outbreaks responded to within 24 hours after notification	100%	100%	100%	100%	0	\odot	On target
2.1.3	Percentage of SANAS accredited NICD laboratories	100%	100%	100%	100%	0	\odot	On target
2.1.4	Annual report of population based cancer surveillance	New	New	1	1	0	\odot	On target
2.1.5	Maintain WHO reference laboratories status	New	New	Maintenance	Maintenance	0	\odot	On target
2.2.1	Number of articles published in the peer reviewed journals	128	180	130	180	50	☺	Taking into account that publication is subject to the completion of research, the NICD will review this target going forward to assess whether it is realistic.
2.2.2	Number of field epidemiologists qualified	14	8	7	9 students	2	©	More students from previous years' cohort graduated in the year under review.



The strategic objectives contributed to the achievement of the "Modernised and Accessible Laboratory Service" and the "Academic Excellence in Training and Research" strategic outcome- oriented goals.

Changes to target

There were no changes to the targets of Programme 2 in the 2018/2019 financial year.

Programme 2	Budget 2018/19 R'000	Actual expenditure 2018/19 R'000	Over/under expenditure R'000	Budget 2017/18 R'000	Actual expenditure 2017/18 R'000	Over/under expenditure R'000
Surveillance and Communicable Diseases	384,502	404,961	-20,459	367,008	309,431	57,576

Reasons for deviations from the budget

Funds for Good and Services and mainly on Repairs and Maintenance to buildings was not capitalised, but allocated to the operational budget and expensed.

2.4.1.3. Programme 3: Occupational and Environmental Health and Safety

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

Programme purpose

The National Institute for Occupational Health (NIOH) is a National Public Health Institute that provides occupational and environmental health and safety support across all sectors of the economy to improve and promote workers' health and safety. National and provincial government departments and public entities are important clients, including the Medical Bureau for Occupational Diseases (MBOD) of the National Department of Health (NDoH). The institute achieves its objectives by:

- i) Providing occupational medicine, hygiene, advisory, statutory pathology and laboratory services;
- ii) Conducting research and
- iii) Providing teaching and training in occupational and environmental health and safety.

Strategic objectives

Programme - Occupational and Environmental Health Services							
Strategic objective 3.1	Robust and efficient occupational and environmental health services.						
Objective statement:	Provide and improve occupational and environmental health services including laboratory testing, hazard and health assessments surveillance reports, and NHLS OHS audits.						
Strategic objective 3.2.	Research and training in occupational and environmental health and safety.						
Objective statement	Promote and conduct research on occupational and environmental health, including gender issues, in South Africa; and advance capacity building to strengthen human resources in occupational and environmental health and safety.						

Key performance indicators

Pe	erformance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
3.1.1	Percentage of occupational and environmental health laboratory tests conducted within predefined turn-around time	85%	86%	90%	75%	-15%	8	The deviation was due to high work volumes, impacted negatively on turnaround times.
3.1.2	Number of occupational, environmental health and safety assessments completed	22	29	30	36	6	©	The Occupational Hygiene Section has a Service Level Agreement (SLA), with the Department of Correctional Services (DCS), which increased the number of reported exposure assessment. The Occupational Hygiene, Immunology and Microbiology sections were also requested to assist the NDoH (Civitas Building) with exposure assessments in response to the contravention notices raised by the Department of Labour (DoL).
3.1.3	Number of surveillance reports produced	New	2	3	4	1	☺	An additional report has been introduced in this financial year to test feasibility for continued reporting in the future, i.e. ensure alignment with the National Public Health Institutes of South Africa Bill (NAPHISA).
3.1.4	Percentage of NHLS laboratories audited which were below targeted compliance in 2017/18	New	98%	95%	98%	3%	©	SHE officer managed to complete 285 audits in this financial year thus exceeding the annual target.
3.2.1	Number of articles published in the peer reviewed journals	24	25	27	34	7	©	This deviation was due to increased capacity in the Toxicology, Biochemistry and Immunology departments, which resulted in the increased research output.
3.2.2	Number of students, interns, registrars under supervision	20	28	26	29	3	©	This reflects our response to the ongoing demand for capacity building and supervision of postgraduate students. External bursaries were also available in the reporting period, which led to an increase in the number of students who were able to register.

Commentary on the contribution of the strategic objectives to the strategic outcome orientated goals

The strategic objectives contributed to the achievement of the "Modernised and Accessible Laboratory Service" and the "Academic Excellence in Training and Research" strategic outcome- oriented goals.



There were changes to the targets for Programme 3 in 2018/2019

Linking performance to budget:

Programme 3	Budget 2018/19 R'000	Actual expenditure 2018/19 R'000	Over/under expenditure R'000	Budget 2017/18 R'000	Actual expenditure 2017/18 R'000	Over/under expenditure R'000
Occupational Health	142,431	126,823	-15,608	129,355	93,478	35,877

Reasons for deviations from the budget

There is negligible amount overspend on labour cost, due to payment made for proficiency and performance pay progression.

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

Programme Purpose

The main purpose of this programme is to strengthen the mandate of the NHLS of maintaining and providing quality assured and accredited laboratory medicine and the academic platform. Two of the focus areas within this programme are to:

- Ensure that research is conducted to contribute to service delivery improvement and quality and
- Ensure national coverage by NHLS pathologists.

The overall aim is to oversee and collaborate with various training institutions that contribute to the development of qualified and skilled people who operate within the scientific field of pathology services.

The programme has three sub- programmes namely:

Quality Assurance

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

Academic Affairs

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

Research and Innovation

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



Strategic objectives

Sub-Programme - Quality Assurance						
Strategic objective 4.1	Improved quality management systems (QMS)					
Objective statement:	Improve total quality management (TQM) systems within laboratories and support departments to increase certification of support departments and accreditation of laboratories.					

Key performance indicators

Per	Performance indicator		Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
4.1.1	Percentage compliance achieved by laboratories during annual quality compliance audits	90%	90%	85%	79%	-6%	8	The checklist was thoroughly reviewed to improve its alignment to ISO 15189, which may have impacted negatively on the other laboratories' performance. Laboratories that were performing high in previous years were accredited thus not audited using this tool. The vacant QA Coordinator positions may have led to limited support to some laboratories
4.1.2	Percentage of National Central laboratories that are SANAS Accredited	90%	92%	97%	94%	-3%	8	Inkosi Albert Luthuli Central Hospital (IALCH) Haematology was assessed in March 2019. The SANAS certificate is still awaited.
4.1.3	Percentage of Provincial Tertiary laboratories that are SANAS Accredited	47%	71%	75%	70%	-5%	8	There were no new laboratories accredited during Q4, Nelspruit pre SANAS audit was not successful, and Rustenburg's second pre SANAS audit was successful in March 2019
4.1.4	Number of Regional laboratories with SANAS Accreditation status	11%	27%	8	17	9	©	The over achievement is due to improved implementation of strategies, which contributed to the accreditation of more laboratories.
4.1.5	Number of District laboratories with SANAS Accreditation status	New	3%	5	11	6	©	The over achievement is due to improved implementation of strategies which contributed to more laboratories accredited.
4.1.6	Percentage of laboratories achieving proficiency testing scheme performance standards of 80%	New	92%	90%	96%	6%	☺	The over achievement is due to improved implementation of strategies which contributed to improved quality management systems.
4.1.7	Prepare gap analysis and work plan to support service departments and laboratories for certification and accreditation processes in preparation for the NHI.	New	New	Approved work plan	Approved work plan	0	☺	On target

Sub-Programme -Academic Affairs							
Strategic objective 4.2	Increase pool of available pathology health professionals and pathologist national coverage.						
Strategic objective 4.3	Improved Training platform						
Objective statement	Promote capacity building of health professionals to strengthen a business case for sustained development for the NHLS through the development of pathologists, medical scientists, medical technologists and medical technicians. Ensure adequate and relevant contribution to diagnose laboratory services outside Academic centres, access by and clinical interaction with clinicians outside academic centres and contribution to the improvement of service delivery across the NHLS platform by pathologists.						

Key performance indicators

Pe	Performance indicator		Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
4.2.1	Number of pathology registrars admitted and trained in the NHLS.	243*	63	30	57	27	☺	The intake was determined by the number of registrars and the available funds. There is currently a shortage of pathologists in the pathology service sector and NHLS is the only institution mandated to train the registrars.
4.2.2	Number of medical scientists admitted and trained in the NHLS.	New	New	50	36	-14	8	The other cohort of medical scientist interns was taken in the previous financial year and more intake will be in the 2019/20 financial year.
4.3.1	Number of student medical technologists admitted and trained in the NHLS.	New	New	100	248	148	☺	The intake was determined by the number of students who qualified from the universities of technology. NHLS has the mandate to train the health practitioners, as a result cannot turn the students away.
4.3.2	Number of student medical technicians admitted and trained in the NHLS.	New	New	30	0	-30	8	The business priority shifted towards medical technologists. Student technicians will be appointed in 2019/20.
4.3.3	Number of bilateral agreements signed with universities and the universities of technology	New	New	16	5	-11	8	Most universities (medical) have requested the review of the ESF before signing. UoTs could not sign as the BAs are still being finalised.

^{*}The number of registrars admitted in 2016/17 was reported as all the registrars in the training platform as per the definition of the KPI in that year.

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

Key performance indicators

P	erformance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation
4.4.1	Number of articles published in the peer reviewed journals	570	588	590	593	3	☺	The number of publications in a given period is determined by the timing between the submission of the article and the approval thereof. More articles were approved within the financial year.
4.4.2	Develop and implement a proposal on research priorities	New	New	Proposal approved by the Board and two research priorities implemented	Proposal approved by Board and two research priorities implemented.	0	☺	On target

Commentary on the contribution of the strategic objectives to the strategic outcome orientated goals.

The strategic objectives contributed to the achievement of the "Modernised and Accessible Laboratory Service" and the "Academic Excellence in Training and Research" strategic oriented goals. The NHLS improved significantly in strengthening its quality management systems in the regional and district laboratories. It also exceeded its expectations in the publication of research based articles.

Changes to target

There were no changes to the targets for Programme 4 in 2018/19 financial year.

Linking performance to budget:

Programme 4	Budget 2018/19 R'000	Actual expenditure 2018/19 R'000	Over/under expenditure R'000	Budget 2017/18 R'000	Actual expenditure 2017/18 R'000	Over/under expenditure R'000
Academic Affairs, Research and Quality Assurance	59,892	71,157	-11,265	-	221,475	-221,475

Reasons for variation from the budget.

On the other hand, there was an underspend on direct material due to improved operational efficiency.



Programme purpose

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

Sub-Programme - Operational efficiency

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

Strategic objectives

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

Key performance indicators

I	Performance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation	
5.1.1	Percentage TB Microscopy tests performed within 40hours	96%	94%	90%	94%	4%	☺	Over achievement	
5.1.2	Percentage TB GeneXpert tests performed within 40 hours	97%	9.%	90%	94%	4%	©	resulted from improved operational efficiencies and effective	
5.1.3	Percentage CD4 tests performed within 40 hours	94%	Q10	90%	91%	1%	©	management of working hours.	
5.1.4	Percentage Viral Load tests performed within 96 hours	87%	82%	75%	86%	9%	©		
5.1.5	Percentage HIV PCR tests performed within 96 hours	82%	77%	80%	76%	-4%	8	Some of the laboratories experienced challenges with frequent instrument down time which necessitated referral to other testing sites. This created bottlenecks and resulted in delayed TATs	



	Performance indicator	Actual 2016/17	Actual 2017/18	Planned target 2018/19	Actual 2018/19	Actual deviation	Dash board	Comment on deviation	
5.1.6	Percentage Cervical Smear tests performed within 5 weeks	97%	90%	80%	84%	4%	☺	Over achievement	
5.1.7	Percentage of laboratory tests (FBC) performed within 8 hours	80%	94%	90%	95%	5%	©	resulted from improved operational efficiency and effective management of	
5.1.8	Percentage of laboratory tests (U&E) performed within 8 hours	80%	91%	90%	94%	4%	©	working hours.	
5.2.1	Review all laboratory facilities to determine infrastructure and equipment needs.	New	New	Approved Plan by the Board	Approved plan by the Board	0	☺	On target	
5.2.2	Implementation of the pilot specimen tracking system	New	New	Pilot the system	System piloted	0	\odot	On target	
5.3.1	Develop the laboratory structure per level of care (organogram)	New	New	Approved laboratory organogram per level of care	Laboratory organogram approved	0	☺	On target	

Commentary on the contribution of the strategic objectives to the strategic outcome oriented goals

The strategic objectives contributed to the achievement of the "Modernised and Accessible Laboratory Service" and the Effective and Ethical Organisation for the improved service delivery and implementation of NHI" strategic oriented goals. NHLS continues to offer laboratory service of high quality within the TATs.

Changes to target

There were no changes to the targets for Programme 5 in 2018/19 financial year.

Linking performance to budget:

Programme 5	Budget 2018/19	Actual expenditure 2018/19	Over/under expenditure	Budget 2017/18	Actual expenditure 2017/18	Over/under expenditure
Laboratory Services	6,482,693	6,309,519	173,174	6,080,474	5,928,534	151,940

Reasons for deviations from the budget

The NHLS executives continued to implement stringent cost containment measures to ensure that production costs are optimised. The laboratories have also improved and strengthened the operational efficiencies resulting in minimal wastage of direct materials.

Linkage to budget for all programmes

Programmes	Budget 2018/19	Actual Expenditure 2018/19	Over/Under Expenditure	Comments	Budget 2017/18	Actual Expenditure 2017/18	Over/Under Expenditure	Comments
	R"000	R"000	R"000		R"000	R"000	R"000	
Administration	1,208,981	843,003	365,549	Whilst the cash flow position improved, the executive remained cautious and continuously implemented stringent cost containment measures to ensure that production costs are managed optimally	890,219	212,816	677,403	Underspent on labour and bad debt write off
Surveillance and Communicable Diseases	384,502	404,961	-20,459	Funds for goods and services and mainly on repairs and maintenance to building was not capitalised but allocated to the operational budget and expensed.	367,008	309,431	57,576	Underspent on capital expenditure
Occupational and Environmental Health and Safety	142,431	126,823	-15,608	There is negligible amount overspent on labour cost due to payment made for the proficiency and performance pay progression	129,355	93,478	35,877	Underspent on labour
Academic Affairs. Research and Quality Assurance	59,892	71,157	-11,265	There is negligible overspent on labour costs due to payment made for proficiency and performance pay progression	1	221,475	-221,475	
Laboratory Services	6,482,693	6,309,519	173,174	The executive continued to implement stringent cost containment measures to ensure that production costs are optimised.	6,080,474	5,928,534	151,940	Underspent on labour
TOTAL	8,278,499	7,684,306	491,391		6,809,850	6,950,895	-141,045	

2.4.2. Business Unit Performance

2.4.2.1. Introduction

The NHLS has five business units that serve to execute its core mandate as follows:

- Support the national DoH in delivering laboratory services to South Africans;
- Provide training in health sciences in partnership with universities and UoTs, and
- Promote and undertake relevant and innovative health-related research.

The business units are classified as follows:

- · Laboratory Services, which is further classified into six regions, namely: Eastern Cape, Free State and North West, Gauteng, KwaZulu-Natal, Limpopo and Mpumalanga and Northern and Western Cape;
- Academic Affairs, Research and Quality Assurance (AARQA)
- National Priority Programme (NPP)
- The NICD; and
- The NIOH.

We furthermore have the following support services departments:

- Human Resources:
- Finance:
- Information Technology and
- Communication; and Marketing and Public Relations.

Lastly, the NHLS also has a subsidiary namely the South African Vaccine Producers (SAVP).

2.4.2.2. Laboratory Services

2.4.2.2.1. Eastern Cape



Introduction

The NHLS in the Eastern Cape offers pathology services to all the public health facilities with different tiers of laboratories. The region maintained the same number of laboratories as per the previous year, which is 38 laboratories and seven depots.

The pathology services are offered from five business units: Nelson Mandela Bay and Sarah Baartman; Buffalo City and Amathole; Nelson Mandela Academic Laboratory; OR Tambo and Chris Hani and Alfred Nzo and Joe Gqabi, which covers all eight districts.

The Eastern Cape continued to offer excellent service to the DoH to improve patient outcomes.

Table EC1: Eastern Cape laboratories per health district

Health District	Nelson Mandela Metropolitan	Sarah Baartman	Buffalo City Metropolitan	Amathole	OR Tar	nbo	Chris Hani	Alfred Nzo	Joe Gqabi
Business Unit	Nelson Mandela Baartman	& Sarah	Buffalo City and	Amathole	Nelson Mandela Academic Lab	OR Tambo	& Chris Hani	Alfred Nzo	& Joe Gqabi
Laboratory	Port Elizabeth Provincial Tertiary	Graaff Reinet	East London (Frere) Tertiary	Butterworth	Chemical Pathology	Zitulele	Queenstown Regional	Matatiele	Empilisweni
	Livingstone Tertiary	Somerset East	Cecilia Makiwane Regional	Madwaleni	Haematology	Canzibe	Glen Grey	Mt Ayliff	Aliwal North
	Dora Nginza Regional	Humansdorp	Bisho	Willowvale	Microbiology	St Barnabas	Hewu	St Patricks	Mt Fletcher
	Uitenhage	Grahamstown		SS Gida	ТВ		Cradock	Madzikane KaZulu	
		Port Alfred		Victoria	Cytology		Cofimvaba	*St Elizabeth Regional	
					Histology		All Saints	*Holy cross	
					Virology		Cala	*Dr Malizo Mpehle Memorial	
					Lab Support Services				
Number of laboratories, per business unit	9 laboratories		8 labora	atories	1 laboratory with 8 departments	10 lab	poratories	10 labo	pratories

^{*}Laboratories in OR Tambo which were grouped under Alfred Nzo and Joe Gqabi business units due to their geographic location.

Table EC2: Depots per health district

OR Tambo	Amathole	Alfred Nzo
Isilimela	Tafalofefe	Greenville
Qumbu Health Centre		Maluti
Nessie Knight		
Bambisana		

Diagnostic services and new developments

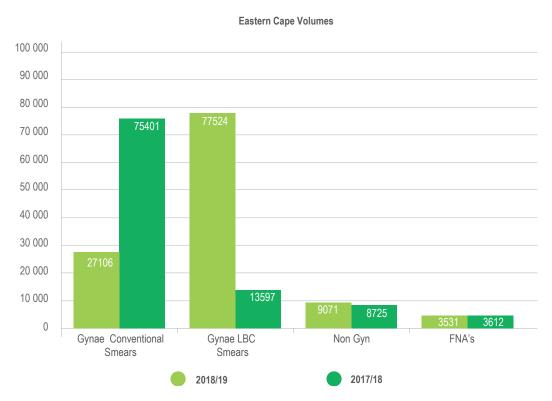
An increase of 7% year-on-year from 9,158,007 to 9,792,273 was noted in the total number of tests performed in the year under review.

Table EC3: NPP test volumes

Test	2017/2018	2018/2019	% Difference
GeneXpert	388 915	410 666	5.30%
CD4	326 166	308 732	-5.65%
HIV PCR	67 412	71 557	5.79%
VL	533 380	552 457	3.45%

The gynaecological volumes in the Eastern Cape increased by 18% comparing to the previous year (2017/2018). This increase was influenced by the roll-out of liquid-based cytology (LBC) to the province, as 74% of the total cases were LBC.

Figure EC1: Cervical smear volumes



New tests

New tests were added to the scope in different laboratories to improve TAT and meet customer demand, as well as to reduce tests sent to private laboratories and referrals outside the region.

Table EC4: New tests per laboratory

Business Unit	Laboratory	New Test	
Nelson Mandela Academic Lab	Cytology	Liquid-based cytology	
Nelson Mandela & Sarah Baartman	Virology/Serology Molecular	Xpert Flu/RSV	
		TP Syphilis	

Business Unit	Laboratory	New Test		
Alfred Nzo & Joe Gqabi	Aliwal North	RPR; CRP		
	Empilisweni	RPR		
	Matatiele	D-Dimer; Troponin-T		
	Dr Malizo Mpehle Memorial; Holy Cross; St Elizabeth & St Patricks	Arterial Blood gas		
OR Tambo & Chris Hani	Cofimvaba	HBA1c		
	Queenstown, Cradock, Hewu, Glen Grey, St Barnabas	Hepatitis B Surface antigen rapid		
	Canzibe	Hepatitis B Surface antigen rapid, CRP and cholesterol		
	All Saints & St Barnabas	Arterial Blood gas		

Service delivery and coverage

The laboratories at each of the five business units offer services to provide for the different levels of care across all eight health districts. Couriers are collecting specimens on a daily basis from hospitals and PHCs that have no onsite laboratory services. The couriers collect twice a day from the health facilities in the metropolitan municipalities and within close proximity to the laboratories. The services are extended to the Department of Correctional Services and the South African National Defence Force.

Central, tertiary, regional and large district laboratories offer a 24-hour service; and the medium and small district laboratories are on call after hours and weekends.

In the year under review, Nelson Mandela Academic Laboratory/ Walter Sisulu University migrated from conventional smears to LBC, to support the National Cervical Screening Programme uptake. LBC was implemented throughout the province and all the health facilities in the Eastern Cape districts received training on it. Even though LBC was fully implemented throughout the province, the conversion rate from conventional smears to LBC is currently at 95%, as at March 2019.

The provincial adequacy rate increased by 4% from the previous year and by 8% since the implementation of LBC in the 2016/2017 financial year.

Table EC5: Adequacy rate per health district

	2016	2017	2018	% Increase/Decrease
Alfred Nzo	49%	51%	50%	-1%
Amathole	42%	49%	55%	6%
Buffalo City Metro	49%	59%	61%	2%
Chris Hani	43%	46%	49%	3%
Joe Gqabi	44%	52%	51%	-1%
Nelson Mandela Bay Metro	63%	62%	68%	6%
OR Tambo	59%	63%	63%	0%
Sarah Baartman	55%	57%	62%	5%

Turnaround Times

The region met all the TAT targets, but Nelson Mandela Academic laboratory, as well as Buffalo City and Amathole business units did not meet the TAT target for cervical smears and CD4. The Nelson Mandela and Sarah Baartman business units did not achieve the targets for GeneXpert and TB microscopy. This was due to referred specimens with shared tests between microbiology and TB laboratories.



Table EC6: Turnaround times for measured tests (TAT measures when the specmen is registered in the laboratory until the results

Business Unit	TB Microscopy in 40 hours	GXP in 40 hours	CD4 in 40 hours	Viral Load in 96 hours	HIV PCR in 96 hours	Cervical smear within 5 weeks	UE & FBC within 8 hours
Target	90%	90%	90%	75%	80%	80%	90%
Nelson Mandela Academic Lab	98%	96%	72%	75%	90%	43%	95%
Nelson Mandela & Sarah Baartman	85%	83%	96%	89%	81%	92%	93%
Buffalo City & Amathole	96%	98%	88%	86%	N/A	75%	93%
OR Tambo & Chris Hani	97%	96%	90%	98%	N/A	N/A	92%
Alfred Nzo & Joe Gqabi	98%	97%	90%	97%	N/A	N/A	84%
EC Region	92%	92%	87%	81%	86%	85%	92%

New laboratories and upgrades

Eastern Cape maintained the same number of laboratories than the previous year, and no new laboratories were opened.

East London (Frere) laboratory, the chemistry and serology laboratories with departments were upgraded to an open plan, to improve workflow.

Major renovations were done at the Port Elizabeth microbiology laboratory, which is one of the few microbiology laboratories that test public health samples.

To improve compliance to the Occupational Health and Safety Act, the Cofimvaba; All Saints and Queenstown laboratories underwent minor renovations.

Previously, operations at the laboratories were slow due to downtimes as a result of inadequate bandwidth. In the year under review, a bandwidth upgrade was completed at 50% of the laboratories and two of the depots. This caused a major boost in staff morale, and improved laboratory operations and service delivery.

TATs for CD4 was negatively affected by ageing equipment at St Elizabeth and Nelson Mandela Academic laboratories. In September 2018, both laboratories received new equipment, which resulted in a significant improvement in TATs.



Accreditation of laboratories

It is worth noting that the Eastern Cape maintained SANAS accreditation in all of its laboratories that are already accredited.

One of the strategic objectives of the NHLS for the year under review, was to increase the percentage of SANAS-accredited laboratories to improve quality of services. The Eastern Cape contributed to this overall objective through the initial accreditation of four district and two regional laboratories.

Table EC7: Accredited laboratories

The second secon		SANAS	Lab Tier
	Chemical Pathology	Accredited	
	Histopathology	Accredited	
	Cytology	Accredited	
Notes a Mandala Asadomia Lab	Haematology	Accredited	National Central (NHI
Nelson Mandela Academic Lab	Microbiology	Accredited	district)
	ТВ	Accredited	
	Virology	Accredited	
	LSS	Accredited	
	PE - Histopathology	Accredited	
	PE - Cytopathology	Accredited	
	PE - Haematology P2	Accredited	
	PE - Microbiology	Accredited	
	PE - Media/ Grassware	ISO 9001	
Notes a Mandala Pay 0 Cayala Pasytunan	PE - Tuberculosis	Accredited	Provincial Tertiary
Nelson Mandela Bay & Sarah Baartman	PE - Serology & Virology	Accredited	
	PE - LSS	Accredited	
	Livingstone - Chemical Pathology	Accredited	
	Livingstone - Haematology	Accredited	
	Livingstone - LSS	Accredited	
	Dora Nginza - Clin Path & LSS		Regional
	EL - Chemical Pathology	Accredited	
	EL - Cytopathology	Accredited	
	EL - Haematology	Accredited	Dravingial Tartiary
Duffelo City and Ametholo	EL - Microbiology	Accredited	Provincial Tertiary
Buffalo City and Amathole	EL - Serology	Accredited	
	EL - LSS	Accredited	
	Cecilia Makiwane*	Accredited	Regional
	Willowvale*	Accredited	CHC
	Dr Malizo Mpehle Memorial Hospital (DRMMM)	Accredited	District (NHI district)
Afred Nzo & Joe Ggadi	Aliwal North	Accredited	District
Alled N20 & Joe Gqddi	Mt Ayliff*	Accredited	District
	Madzikane kaZulu*	Accredited	District
OR Tambo & Chris Hani	Queenstown*	Accredited	Regional
OR Tallipo & Cliris Halli	St Barnabas*	Accredited	District (NHI district)

^{*} Laboratories that achieved initial SANAS accreditation in 2018/2019

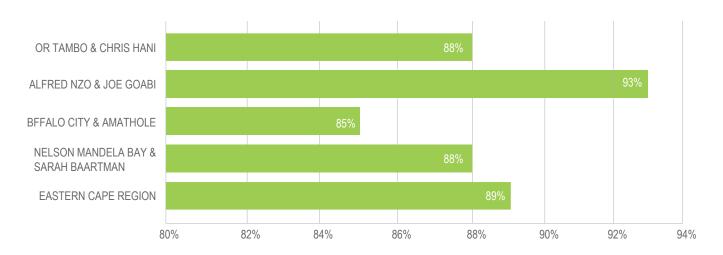
Laboratory staff celebrated their SANAS accreditation with their area and business managers, as well as their QA coordinators and manager. St Elizabeth laboratory was enrolled in the SLIPTA programme as a means to ensure that systems and processes are in place in preparation for SANAS accreditation.

Table EC8: SLIPTA audit results

Laboratory Name	Baseline audit	2018/2019
St Elizabeth	72% (2-Star rating)	79% (3-Star rating

NHLS laboratories that are non-accredited are subjected to QCAs to assess the laboratories' compliance to the ISO 15189 standard. The region achieved an average of 89% compliance. Figure EC9: Quality compliance audits per business unit

QCA Audits % Compliance



Stakeholder relations

The Cytology laboratory coordinator trained HCWs in all the districts to finalise the implementation of the LBC. The HCWs specifically received training on the correct method of specimen collection to improve adequacy rate and management of consumables used for LBC.

The region maintained constant interaction with clients to strengthen stakeholder relations, including attendance of provincial events. Our laboratory managers attended clinical governance meetings at hospitals and PHCs and conducted clinic visits. Our business managers also attended the district management team meetings.

The NHLS in Eastern Cape has been instrumental in supporting the provincial DoH's Thuma Mina campaign events that were held in the Buffalo City and Amathole districts. The NHLS provided onsite TB testing in both districts.

The Eastern Cape DoH hosted their National World TB day commemoration on 28 March 2019, under the theme: "It's TIME! For Religious Leaders and Parliamentarians to lead the fight to end TB in South Africa." The NHLS once again provided onsite TB testing; as well as courier services to transport samples to the laboratory for immediate testing.









The business units also conducted a customer satisfaction survey to identify service delivery gaps and understand how the clients perceive our service. The region achieved an average of 86%. The results of the survey were analysed to inform the development of an action plan for improvement. The laboratory managers also visited the clinics to close the gaps.

Holy Cross laboratory in OR Tambo district hosted an open day event on 31 January 2019, with the aim to increase customer awareness on the services offered by the NHLS, as well as to expose school leaners to the core business of the organisation and help them consider pathology as a career path. The event invite was extended to local high schools; Tabazi; Zwelibongile and Mpingana. Based on the feedback from the grade 12 learners who attended, the day was highly informative. One of the leaners said that the she found the profession very interesting although they didn't know much about it before.

Conclusion

The NHLS in Eastern Cape once again demonstrated its commitment to offering a patient-centred laboratory service to the Eastern Cape community. Stakeholder relations grew from strength to strength through constant engagement. The region's outstanding performance was only possible because of the dedication and enthusiasm of every one of the NHLS Eastern Cape employees, who prove be an asset to the organisation.



2.4.2.2.2. Free State and North West

Introduction

The Free State and North West delivers laboratory services at various levels, from PHCs to tertiary level care to all districts within the two provinces. The region operates a wide specimen collection and results delivery service to a large number of PHCs in all the districts, thus assisting the provincial DoH in providing health services to all communities.

The diagnostic pathology services rendered in the region, range from basic clinical pathology tests, to highly specialised tests. This includes: Chemical pathology, haematology, microbiology, virology, anatomical pathology (histopathology and cytopathology), genetics, and tissue typing.

The Free State and North West has three (3) business units, namely, Free State, Universitas Academic and North West. As at March 2019, the region had a total staff complement of 643, including 62 students. The region's performance per province is outlined below.

North West Province

The North West Business Unit is responsible for providing all the provincial districts with laboratory services through a total of ten (10) laboratories and three (3) depots.

Tshepong and Rustenburg are provincial tertiary laboratories linked to Wits and Sefako Makgatho Academic Centres respectively. As a result, the two laboratories are the main referral centres in the business unit and the province, providing more complex tests. The distribution of the laboratories per district is as indicated in table F1 below.

Table F1: Laboratories per district

North West Province							
Bojanala Dr Kenneth Kaunda Ngaka Modiri Molema Ruth S Mompati							
Rustenburg	Tshepong	Mafikeng/Bophelong	Joe Morolong				
Moses Kotane	Potchefstroom	Lehurutshe	Taung				
Brits	Wolmaransstad (depot)	Volmaransstad (depot) Gelukspan Ganyes					
Thusong (depot)							
Total = 3	3	4	3				

Diagnostic services and new developments

As indicated, Tshepong and Rustenburg are referral laboratories in the province with Tshepong being the main centre. In addition to routine testing, Tshepong also conducts LPA, TB culture, CD4 and VL testing. However, due to proximity and by association, the laboratories in Bojanala district are referring their specialised tests to Sefako Makgatho Academic Unit.

The North West Business Unit had an increase of 3.5% in VL tests compared to the previous period. There was also a significant decrease in CD4 and TB GeneXpert tests. The volume changes are indicated in table F2 below.

Table F2: Comparison of NPP volumes between 2017/2018 and 2018/2019

Test	Test Volumes 2017/2018		% Difference
CD4	154 171	145 966	-5.3%
HIV VL	138 223	143 092	3.5%
TB GeneXpert	138 726	114 353	-17.6%

Service delivery

The North West NHLS laboratories provide service to 19 hospitals, 331 clinics, three SANDF area health military units and 15 correctional centres. Five (5) of the laboratories, Tshepong, Mafikeng, Potchefstroom, Joe Morolong and Rustenburg operate a 24-hour service, and the remainder provide call out services. The business unit met >90% TAT for routine- and NPP tests, except VL and HIV PCR, which was mainly due to aging instrument breakdowns. The actual performance is indicated in table F3 below.

Table F3: Percentage TAT performance for NPP tests 2018/2019 (TAT measures when the specmen is registered in the laboratory until the results are authorised)

Test	Target	Actual
CD4 (within 40 hours)	95%	95%
HIV PCR (within 96 hours)	75%	66%
HIV VL (within 96 hours)	70%	52%
Cervical Smear (within 5 weeks)	70%	84%
GeneXpert (within 40 hours)	95%	98%
TB Microscopy (within 40hours)	95%	96%
U&E (within 8 hours)	90%	95%
LFT (within 8 hours)	90%	94%
FBC (within 8 hours)	90%	95%

Notable achievements

Tshepong laboratory maintained its SANAS accreditation status for the third consecutive year and increased its scope of accredited departments to include microbiology, TB and virology. Rustenburg and Mafikeng laboratories passed the pre-SANAS assessments and were recommended to apply for accreditation. Mafikeng and Rustenburg laboratories also achieved a 5-Star SLIPTA rating.

Mafikeng, Tshepong and Job Shimankana Tabane (Rustenburg) achieved a 100% students pass rate for their medical technology interns.

New laboratories and laboratory upgrades

Tshepong and Taung laboratories were allocated new space to allow for growth and expansion as their current laboratory spaces were too small. Phase 1 for both laboratory renovations were completed in this financial year. Phase I of the renovations at Mafikeng and Rustenburg laboratories were also completed to improve the workflow as well as working conditions, to be compliant with health and safety requirements.



Rustenburg phase 1: New recieving office



Taung phase 1: Flooring and painting

Stakeholder relations

The NHLS and the North West DoH are negotiating a revised SLA. A formal SLA is of the utmost importance to promote a high work ethic at administrative, organisational, research and financial levels between the two organisations.

As part of the two-year Global Funded NPP, the business unit increased TB diagnostic campaign activities in the peri-mining communities, utilising a GeneXpert TB mobile laboratory. The unit also supported the World Aids Day in Rustenburg, by making one of the GeneXpert TB mobile units available for onsite testing.

Free State Province

The Free State Province is serviced by two NHLS business units, namely; Universitas Academic Unit and Free State Business Unit. Universitas is servicing the academic hospital, including the national district hospital, while the Free State Business Unit is servicing the Pelonomi Provincial Tertiary Hospital and the rest of the hospitals in the province.

Pelonomi and Universitas laboratories are the pathology training platforms associated with the University of Free State Medical School. These two laboratories are also the main referral centres, that provide full pathology services, including paternity testing. The distribution of the laboratories per district is indicated in table F6 below.

Table F6: Free State laboratories per district

Free State Province						
Fezile Dabi Lejweleputswa Motheo Thabo Mofutsanyano						
Sasolburg	Welkom (Bongani)	Universitas	Bethlehem (Dihlabeng)			
Kroonstad		National District	Manapo			
		Pelonomi				
		Botshabelo				
Total = 2	1	4	2			

Diagnostic services and new developments

As the tertiary laboratory in the province, Universitas is conducting almost all of the specialised tests, except for CD4 testing, which is done at Pelonomi laboratory. However, CD4 testing is also done at Welkom and Manapo regional laboratories. The total provincial statistics are in line with the 90-90-90 policy and are indicated in table F7 below.

Table F7: Comparison of NPP volumes between 2017/18 and 2018/2019

Test	Volumes 2017/2018	Volumes 2018/2019	% Difference	
Cytology	81 977	157 808	92.5%	
CD4	164 650	143 098	-13.1%	
HIV DNA PCR	43 389	44 351	2.0%	
HIV VL	351 449	375 312	6.8%	
TB GeneXpert	103 293	103 513	0.2%	

Service delivery

The Free State Business Unit has seven (7) laboratories which provide services to 225 PHC facilities and 10 CHCs. These laboratories also service 15 other district hospitals and 18 correctional services facilities. Universitas laboratory is also responsible for servicing the national district hospital, as well as 3 Military Hospital. The NHLS has an outsourced transport service provider that is responsible for the collection of specimen and delivery of results and consumables. The routes are covered 100% and collection takes place daily on week days. TAT results are indicated in table F8 below.

Table F8: Percentage TAT performance for NPP tests 2018/19 (TAT measures when the specmen is registered in the laboratory until the results are authorised)

Test	Target	Actual
CD4 (within 40 hours)	95%	90%
HIV PCR (within 96 hours)	75%	74%
HIV VL (within 96 hours)	70%	88%
Cervical smear (within 5 weeks)	70%	96%
GeneXpert (within 40 hours)	95%	98%
TB microscopy (within 40 hours)	95%	95%
U&E (within 8 hours)	90%	97%
LFT (within 8 hours)	90%	96%
FBC (within 8 hours)	90%	92%

Notable achievements

Welkom achieved a 5-star rating during the ASLM exit audit. Kroonstad laboratory maintained its SANAS its SLIPTA star rating from 1 to 3. Universitas introduced LBC and the uptake was very good in the province. New CD4 analysers were installed in Pelonomi. Welkom and Manapo laboratories improved their TATs for CD4.

New laboratories and upgrades

Pelonomi laboratory is in the process of being renovated and Phase 1 was completed during this financial reporting period. This includes renovations to the CD4 room, the consolidation of Haematology, the INR clinic, doctor's office and boardroom, as well as swapping Microbiology and TB around to optimise space. Phase 2 of the renovation will improve the workflow at the receiving office and was almost complete by the end of the financial year.

Some renovations were also done at Botshabelo and Manapo laboratories during this period. The renovations are also contributing to uplifting the staff morale, as their working environment is being improved in compliance with health and safety requirements. In addition, an access control system was installed at all the laboratories, to improve the security at the workplace.



Pelonomi renovations phase 1

Stakeholder relations

Blood and laboratory user committees are functional at all hospitals in the province. Relations with the University of the Free State remained excellent and amicably cooperative, as experienced at informal and formal meetings with the Dean at Institutional Academic Pathology Committee meetings.

The relationship with the Free State DoH, our major stakeholder, remained positive, and various meetings and training sessions were conducted with clients. The business unit also maintained an excellent working relationship with the Free State DoH laboratory services manager, enabling positive results for interventions and communications on use of laboratory services, in line with the SLA and provincial DoH requirements for EGK and MCDS

Arrangements were made for the microbiology pathologist from Universitas to visit the Dihlabeng Regional Hospital to provide the doctors with support regarding microbiology testing and proper use of antibiotics.

Universitas Academic also conducted an outreach visit to Welkom, Kroonstad and Botshabelo hospitals and laboratories, to engage both clinicians and laboratory technical staff.



2.4.2.2.3. Gauteng

Introduction

The NHLS Gauteng provides laboratory services to three metropolitan municipalities (City of Johannesburg, City of Tshwane and Ekurhuleni) and two district municipalities (West Rand and Sedibeng). In addition, the region provides services to other provinces and other areas on the African continent.

The network of services is strategically provided via six business units: Charlotte Maxeke Academic (CMAH), Chris Hani Baragwanath Hospital (CHBH), Tshwane Academic Division (TAD), Dr George Mukhari Hospital (DGM), Ekurhuleni Tshwane (ET), and Johannesburg Sedibeng West Rand (JSW).

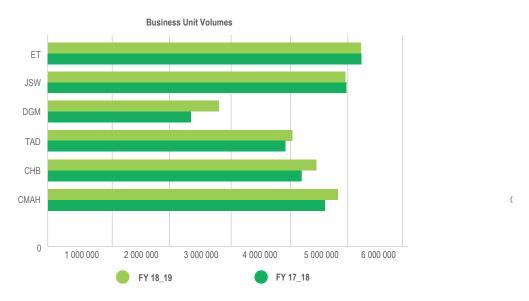
Laboratory distribution

		Laboratories per district		
Tshwane	Ekurhuleni	City of Johannesburg	Sedibeng	West Rand
TAD	Tembisa Provincial Tertiary	СМАН	Sebokeng Regional	Leratong Regional
DGM	Tambo Memorial Regional	СНВН	Kopanong District	Dr Yusuf Dadoo District
Kalafong Provincial Tertiary	Pholosong Regional	Helen Joseph Provincial Tertiary		Carletonville District
Mamelodi Regional	Far East Rand Regional	Edenvale Regional		
Jubilee District	Thelle Mogoerane Regional	South Rand District		
Odi District	Bertha Gxowa District	Braamfontein Complex		
6	6	6	2	3

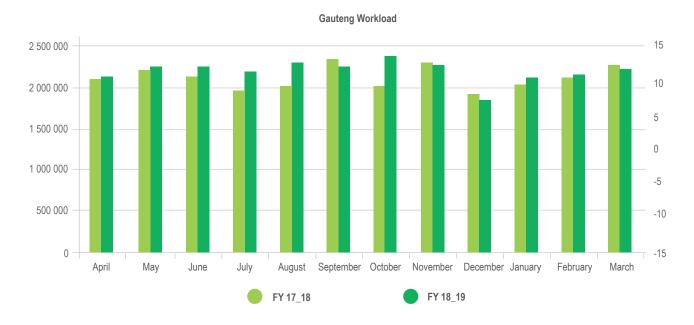
Diagnostic services and new developments

A total of 26 402 746 tests were done in this reporting period, which constitutes an increase of 3.5% when compared with the previous financial year (2017/2018). The Gauteng region's volumes continue to increase as most of the population is moving towards more urbanised areas.

	FY 17_18	FY18_19
Charlotte Maxeke Academic (CMAH)	4 741 059	4 860 301
Chris Hani Baragwanath Academic (CHB)	4 154 455	4 373 234
Tshwane Academic Division (TAD)	3 912 317	4 045 061
Dr George Mukhari Academic (DGM)	2 382 819	2 850 852
Johannesburg, Sedibeng and West Rand (JSW)	4 970 994	4 947 312
Ekurhuleni Tshwane (ET)	5 349 478	5 325 986
TOTAL	25,511,122	26,402,746



	APR	MAY	JUN	JUL	AUG	SEPT	ост	NOV	DEC	JAN	FEB	MAR
FY 17_18	2054256	2184738	2124199	1967553	2046782	2323440	2071982	2261040	1912420	2056430	2171785	2336497
FY 18_19	2101646	2275879	2270867	2193082	2298368	2216952	2345277	2219372	1809902	2167446	2225123	2278832



The Gauteng is actively involved with the Gauteng DoH and supports all the priority programmes including: TB, cervical screening and HIV/AIDS. The data below demonstrates the volumes of tests performed by the NHLS Gauteng laboratories in the 2018/2019 financial year.

Tests	2017/2018	2018/2019	Difference	% Increase	Comment
VL	1,348,740	1,368,749	20,009	1.46%	Increased
HIV PCR (EID)	273,845	275,474	1,629	0.59%	Increased
CD4	661,337	621,910	-39,427	-6.34%	Decreased
GeneXpert	332,478	308,498	-23,980	-7.77%	Decreased

Cervical screening volumes					
Tests	2017/2018	2018/2019	Difference	% Increase	Comment
Gynaecological	306 999	350 461	43 462	14%	Increase
Non-Gynaecological	17 425	16 473	-952	-6%	Decrease
FNA - Fine Needle Aspiration	14 491	13 760	-731	-5%	Decrease

Service delivery and coverage

Services are delivered through a total staff compliment of 1991, which includes pathologists, scientists, medical technologists, and medical technicians, as well as trainees (registrars, intern technologists, technicians and scientists), including staff for other support functions as well.

We consistently maintained 100% clinic-laboratory specimen collection coverage, and the optimisation of routes allowed for increased frequency of collection, especially from the CHCs.

A concerted effort was made to improve interaction between the NHLS and the Gauteng HCWs, to address challenges as they are identified and to also strengthen working relationships between the two organisations.

Turnaround times

The Gauteng's performance in comparison to that of the previous financial year is demonstrated below. We continue to strive for excellence and the majority of our targets for the 2018/2019 financial year was achieved, with non-performance on only two of the parameters, due to varying factors. The new technology that was introduced, coupled with the additional resources provided, will assist in an improvement on the achievement of our targets.

(TAT measures when the specmen is registered in the laboratory until the results are authorised)

Turnaround times for Gauteng Region		
Data source: CDW	Annual target 2018/2019	Actual performance 2018/2019
Percentage TB microscopy tests performed within 40 hours	90%	97%
Percentage TB GeneXpert tests performed within 40 hours	90%	95%
Percentage CD4 tests performed within 40 hours	90%	94%
Percentage VL tests performed within 96 hours	75%	87%
Percentage HIV PCR tests performed within 96 hours	80%	75%
Percentage cervical smear tests performed within 5 weeks	80%	73%
Percentage FBC tests performed within 8 hours	90%	96%
Percentage U&E tests performed within 8 hours	90%	93%
Percentage LFT tests performed within 8 hours	90%	92%

Notable achievements

Accreditation: The following laboratories maintained their ISO 15189 accreditation in all their divisions: CMAH, DGM, CHBH, TAD (Steve Biko) and Braamfontein Complex (TB laboratory, immunology and cytology) and Helen Joseph.

Tambo Memorial and Thelle Mogoerane regional laboratories achieved SANAS accreditation in June and December 2018, respectively.

To increase the number of accredited laboratories will continue to be a focus area of the region.

Upgrading of laboratories



Tembisa laboratory: Beckman Coulter - AU 680 + Unicel DXI 800 Analyser and Pre-Analytics System

Stakeholder relations

The Gauteng maintained very good relationships with its stakeholders, including the DoH partners. These relations are strengthened through participation in several committees and meetings, as well as through our clinic laboratory interface coordinator.



Provincial World Aids Day (December 2018) - Held in Soweto (Dobsonville Stadium)

Conclusion

The NHLS Gauteng is committed to a patient-centric approach and for this reason our organisational strategy is aligned to the relevant South African health policies and mandate. We are continuously reviewing and upgrading our resources (equipment and staff) to meet the challenges that the public health sector is faced with.



2.4.2.2.4. KwaZulu-Natal

Introduction

The NHLS KwaZulu-Natal plays an important role to the DoH by providing essential clinical and medical laboratory services that serve as a foundation for clinical decisions as well as an objective means to measure and monitor biological and environmental markers.

KwaZulu-Natal also fulfils a unique strategic function for the country through the provision of public health laboratory services to ensure safe food and water to prevent foodborne illness and environmental threats. This includes testing of imported meats for human consumption. In the year under review, the KwaZulu-Natal public health laboratory received ISO:17025 accreditation, a standard that was specifically designed for food and public health laboratories, and an accomplishment that is unprecedented within the NHLS.

KwaZulu-Natal also provides laboratory services to the DCS, as well as a number of NGOs and NPOs. In addition, KwaZulu-Natal prides itself in 100% provincial pathologist coverage to clinicians throughout the province, either telephonically, or through face-to-face assistance, as and when required and where possible.

As captured by our regional slogan, "Quality now and everything else will follow," a key priority of the region is to deploy several strategies to consistently provide high quality services. This ethos is firmly embedded in all aspects of our operational DNA, including customer services, finances and corporate image which in turn leads to high performance which amongst other becomes evident from the fact that a total of 17 KwaZulu-Natal laboratories are SANAS-accredited.

Apart from this strong focus on quality, KwaZulu-Natal also continues to achieve financial excellence, as indicated by the fact the region, and even its academic complex, has managed to post a surplus for no less than four consecutive years.

NHLS KwaZulu-Natal comprise seven business units with a total of 64 laboratories that are located in public hospitals, as indicated by Table K1 below:

Table K1: KwaZulu-Natal business units and laboratories

NHLS - Business units		DoH - District Health	
Academic Complex		eThekwini	
eThekwini			
Harry Gwala-Ugu	Harry Gwala	Ugu	
Lembe-Thungulu	uThungulu	iLembe	
Mgungundlovu-Thukela	uMgungundlovu	uThukela	
Maju-Mzinyathi	Amajuba	uMzinyathi	
Mkhanya-Zulu	uMkhanyakude	Zululand	

Diagnostic services and new developments

During the 2018/2019 financial year, a total of 28 253 764 tests were performed and billed in the region. This reflects an increase of 19% in test volumes, compared to the previous financial year, mainly due to an increase in requests for GeneXpert and HIV tests.

Table K2: KwaZulu-Natal billed volumes 2018/2019

Business Unit	1Q1	2Q2	3Q3	4Q4	2018/2019 year- to-date
Academic Complex	1 219 308	1 196 699	1 216 038	1 207 878	4 839 923
eThekwini	1 745 515	1 853 245	1 732 620	1 882 117	7 213 497
Harry Gwala-Ugu	446 410	454 222	423 189	461 350	1 785 171
Lembe-Thungulu	747 888	779 744	755 755	832 535	3 115 922
Mgungundlovu-Thukela	1 054 042	1 085 172	1 087 189	1 160 279	4 386 682
Maju-Mzinyathi	432 781	442 863	383 737	416 185	1 675 566
Mkhanya-Zulu	543 506	561 508	537 904	594 085	2 237 003
Grand total	6 189 450	6 373 453	6 136 432	6 554 429	25 253 764

Service delivery and access coverage

Health facilities in KwaZulu-Natal enjoy 100% onsite services by the NHLS through 64 laboratories and 10 TB microscopy sites. The specimen collection coverage of PHCs is also 100%. Routes are continuously optimised and reviewed to ensure effectiveness and cost efficiency.

KwaZulu-Natal's Academic Complex provides specialised and routine diagnostic pathology services to Inkosi Albert Luthuli Central Hospital (IALCH), King Edward VIII Hospital (KEH) and their clinics, and are the referral laboratories for tests from other NHLS laboratories in the province. The laboratories perform testing on request for research units such as the University of KwaZulu-Natal School of Laboratory Medicine and Medical Science and the Medical Research Council, KwaZulu-Natal Research Institute for TB and HIV, as well as the private sector.

Figure K1: List of laboratories at the two national central hospitals:

National Central Hospital	KwaZulu-Natal Academic Complex Laboratories
Inkosi Albert Luthuli Central Hospital (IALCH)	IALCH Chemical Pathology
	IALCH Cytology
	IALCH Haematology
	IALCH Microbiology
	IALCH Virology
	IALCH Anatomical Pathology
King Edward VIII Hospital (KEH)	KEH Chemical Pathology
	KEH Haematology
	KEH Microbiology
	KEH laboratory Support Services Unit

The floor repair project at the IALCH continued into the 2018/2019 financial year. Despite the consequent relocation of laboratories to temporary facilities, the laboratories continued to provide diagnostic services to the province and to meet accreditation standards and TATs.

Due to cost efficiency measures and national procurement challenges, the introduction of new tests and technology was limited, and efforts were primarily focused on ensuring sustainability as a business unit, by maximising productivity and optimising processes.

The Cytology Laboratory, which introduced LBC testing in November 2017, processed a total of 135,636 gynaecological samples, which constitutes an 18% increase from 2017/2018 and a 7.5% overall increase in workload. The increased workload is due to the LBC uptake and the DoH Umdlavuza Campaign in April 2018, which involved the collection of more than 2000 samples in a single day. The acquisition of equipment such as an automated slide stainer and a cover slipper in November 2018, also contributed to enhancing the efficiency of the laboratory.

No new tests were introduced at the IALCH Chemical Pathology Laboratory, as there was a shortage of medical technologists to initiate a DNA laboratory in the Chromatography Section, and a shortage of medical technicians in the Electrophoresis Section. The KEH Chemical Pathology Laboratory introduced BnP as part of its scope in June 2018.

The Abbott Architect i4000 was validated to test five additional hepatitis markers, which in turn improved the workflow and TATs in the Virology Section.

The Mycobacterium Growth Indicator Tube-Antibiotic Susceptibility Test (MGIT AST) will replace the plate proportion method for TB susceptibility testing and is currently being validated in the IALCH Microbiology TB Laboratory.

Aging analysers in the IALCH Haematology Laboratory could not be successfully repaired or replaced, due to Impilo Consortium's budgetary constraints and delays in procurement processes by the NHLS Procurement Department.

A Regional Technical Expect Committee was formed for all disciplines that are chaired by the HODs (excluding the virology discipline). The HODs remain permanent members of the Regional Management Committee to encourage collective decision-making by technical experts and improve accountability. Pathologists ensure consultative service delivery coverage to all the laboratories in the region and perform regular visits to specific sites.

The uMgungundlovu-uThukela Business Unit supports two districts via seven laboratories and three microscopic centres. The unit caters for the diagnostic needs of 10 hospitals, 123 clinics and four prisons, as well as referrals from nine peripheral hospitals in KwaZulu-Natal.

uMgungundlovu- uThukela Business Unit		
Names of business units	uMgungundlovu-uThukela	
Number of laboratories in BU	7	
Number of accredited laboratories	3 (Edendale, Greys, Northdale)	
Laboratories earmarked for accreditation by March 2019	Estcourt, Emmaus	
Number of provincial tertiary laboratories	1 (Greys)	
Number of regional laboratories	2 (Edendale, Ladysmith)	
Number of district laboratories	4 (Appelsbosch, Emmaus, Estcourt, Northdale)	

These diagnostic services are pivotal to the success of the DoH's initiatives to improve the general health of the relevant population. The programmes are dynamic and include complex and specialised clinical interventions which in turn calls for a suitable diagnostic laboratory response from the business unit. To help ensure optimum patient care, the clinicians' diagnostic requirements are supported through 24-hour and callout laboratories.

The continuous training of both internal and external pre-analytical staff both was a critical factor to ensure more effective and efficient diagnostic services for the period under review.

The first human case of Melioidosis in South Africa was detected by the staff of the Microbiology Section at Northdale Laboratory in Pietermaritzburg. This was confirmed by the NICD via further testing on the organism, including Matrix Assisted Laser Desorption/Ionisation-Time of Flight (MALDI-TOF), electron microscopy and whole genome sequencing. The melioidosis was caused by the bacterium Burkholderia pseudomallei which the laboratory isolated through a blood culture test of a patient.

The business unit was instrumental in the launch of the National Cancer Campaign in Edendale, Pietermaritzburg, on 30 October 2018. Since then, various cancer campaigns were held in Pietermaritzburg and surrounding areas.

Figure 2: National Cancer Campaign launch at Caluza Stadium



The Majuba Mzinyathi Business Unit consists of six laboratories and one microscopic centre. The unit supports two districts, namely Amajuba and uMzinyathi. NHLS laboratories also support two CHCs in these two districts, namely Dannhauser and Pomoroy.

There are two regional laboratories, four district laboratories and 81 clinics in this business unit, of which 54 clinics are located in uMzinyathi District and 27 clinics in Amajuba District. The regional laboratories provide 24-hour services, while the district laboratories provide callout services to ensure uninterrupted services to hospitals and clients.

The business unit is characterised by a deep rural population where diseases such as TB and HIV are prevalent.

Majuba Mzinyathi Business Unit laboratories

Laboratory name	Level of healthcare
Charles Johnson Memorial Laboratory	District
Church of Scotland Laboratory	District
Dundee Laboratory	District
Greytown Laboratory	District
Madadeni Laboratory	Regional
Newcastle Laboratory	Regional
Niemeyer Microscopic Centre	Microscopic Centre

The Mkhanya-Zulu Business Unit is situated in the deep rural parts of Northern KwaZulu-Natal and consists of 11 laboratories, five of which are located in the uMkhanyakude District and six of which are located in Zululand District.

Zululand district laboratories	Level of healthcare
Vryheid	District
Itshelejuba	District
Dumbe (CHC)	District
Ceza	District
Nkonjeni	District
Benedictine	District
uMkhanyakude district laboratories	Level of healthcare
Hlabisa	District
Bethesda	District
Mosvold	District
Manguzi	District
Mseleni	District

The Lembe-Thungulu Business Unit has a total of 12 Laboratories, which includes one provincial tertiary laboratory, two regional laboratories and nine district laboratories. In accordance with the TATs agreed upon in each SLA, the national priority programmes are either supported through onsite or off-site laboratory services in the two districts, ILembe and King Cetshwayo.

Laboratory name	Level of healthcare
Ngwelezane	Provincial tertiary
Stanger	Regional
Queen Nandi (Empangeni)	Regional
Montebello	District
UMphumulo	District
Untunjambili	District
Catherine Booth	District
Empangeni	District
Eshowe	District
Kwa- Magwaza (St'Marys)	District
Mbongolwane	District
Nkandla	District
Ekhombe	District

Accessibility and improved service delivery is achieved through provision of daily courier specimen collection and delivery of results (100% coverage), use of SMS printers in certain PHCs and the use of Webview at hospital level. In addition to 100% coverage, the business unit ensures optimal collection of specimen through maximised routes and by doubling collections from clinics with high workloads.

In an endeavour to ensure quality service, reduce the rejection rates and accelerate TATs, the nursing staff and doctors were trained on phlebotomy techniques. The training was conducted by the NHLS phlebotomist, in collaboration with BD.

Ongoing engagement with clients strengthened the business unit's relationship with KwaZulu-Natal DoH. This engagement occurs at PHC, hospital and district level. Pathology service coverage is also provided to all provincial tertiary hospitals, regional hospitals and district hospitals, with the aim to improve the quality of tests.

Turnaround times

TAT targets were consistently achieved for all NPP tests, except for HIV-PCR. .

Table K5: Turnaround times (TAT measures when the specmen is registered in the laboratory until the results are authorised)

Test type	TAT target	Test count	Volume within target TAT	% Within target TAT
CD4	80%	987,052	911,056	92.30%
Cervical smear	50%	178,945	153,352	85.70%
FBC	80%	1,747,216	1,667,473	95.44%
GeneXpert	90%	519,468	487,030	93.76%
HIV PCR	70%	153,165	96,662	63.11%
LFT	80%	5,898,776	5,560,904	94.27%
Microscopy	90%	217,363	204,620	94.14%
U&E	80%	6,084,702	5,774,021	94.89%
VL	65%	1,437,503	1,151,102	80.08%



Notable achievements

A total of six laboratories at various levels of care achieved SANAS accreditation based on the ISO:15189 international standard.

Some of the performance highlights include:

- 100% SANAS accreditation of public health laboratories (SANAS:17025 accreditation was achieved in May 2018 and ISO:15189 accreditation was accomplished in the previous financial year);
- 100% SANAS accreditation of both the national central hospitals, IACLH and KEH;
- 100% SANAS accreditation of both provincial tertiary hospitals, Greys and Ngwelezane;
- Seven out of twelve (58%) regional hospitals received SANAS ISO: 15189 accreditation;
- Four laboratories passed the pre-SANAS assessment, and
- Ten laboratories passed SANAS surveillance assessments and maintained their SANAS accreditation.

Table K6: KwaZulu-Natal SANAS-accredited laboratories

SANAS accreditation status				
KPI	Regional target	Regional Actual	Comment	
National central laboratories	77.7% (7/9)	100% (8/8)	Target achieved and exceeded	
Provincial Tertiary laboratories	50% (1/2)	100% (2/2)	Target achieved and exceeded	
Regional laboratories	42% (5/12)	58% (7/12)	Target achieved and exceeded	
District laboratories	11% (1/37)	10.5% (4/38)	Not achieved, as it was not realistic	
Total accredited laboratories	17	12	Including the Public Health Laboratory	

Table K7: KwaZulu-Natal accredited laboratories

Accredited laboratories	Laboratories that passed the pre-SANAS audit
Addington laboratory	Edendale laboratory
IALCH Virology	RK Khan laboratory
IALCH Chemical Pathology	Stanger laboratory
KEH Chemical Pathology	King Dinizulu laboratory
KEH Haematology	Public Health laboratory ISO 17025
KEH Microbiology	Kokstad laboratory
Northdale laboratory	Catherine Booth laboratory
Public Health laboratory ISO 15189	
IALCH Microbiology	
Mahatma Gandhi laboratory	

King Dinizulu Laboratory received SANAS accreditation. Addington Laboratory maintained its accreditation status, which implies that it has now been accredited for five consecutive years. RK Khan passed its initial accreditation. The Public Health Laboratory passed the initial ISO: 15189 accreditation, as well as the ISO: 17025 SANAS audit. Mahatma Gandhi Laboratory maintained its SANAS accreditation. The National PTS targets for year-to-date averages were met. 91% of the laboratories achieved > 80%.

Table K8: NHLS KwaZulu-Natal proficiency testing schemes results

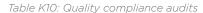
National targets	C2017/2018	C2018/2019
Target: 80%	89%	80%

The NHLS KwaZulu-Natal laboratories are audited annually by a SHE officer and the results of the audit for the year under review are indicated in table K9 below:

Table K9: Health and safety audits

Regional targets > 85%	C2017/2018 (Regional)	C2018/2019
Year-to-date average	91.4%	95.3%

QCAs are conducted annually on non-accredited laboratories and the results of the audit for the year under review are indicated in table K10 below.



National targets > 80%	C2017/2018	C2018/2019
Year-to-date average	90.7%	88.0%

Northdale, Edendale and Greys maintained their SANAS accreditation status during the period under review. Emmaus and Estcourt were recommended for application for SANAS accreditation after successful pre-SANAS audits. Edendale and Greys received certificates of achievement from ASLM Nigeria for ISO:15189 implementation. Intern orientation was conducted for new doctors within the GEN complex.

New laboratories and upgrades laboratory

The floor repair project at IALCH ensured the structural repair and reinforcement of floors in the Level 4 TB Culture Laboratory. All the IALCH laboratories were redesigned for improved layout and optimal use of space. Negative air pressure and a streamlined workflow was established in the TB Culture Laboratory, ensuring a safer working environment. Some of the smaller sections were also redesigned and restructured for optimal use. An additional air conditioning unit and humidifier was installed in the Transmission Electron Microscopy Unit in Anatomical Pathology and additional space for LBC sample filing was created in Cytopathology.

The IALCH bulk storage area is utilised for storage of blocks and slides by Histopathology, Cytopathology and Forensics. It was discovered that the area was contaminated with mould and that the slides were damaged as a result. During the 2018/2019 financial year, the slide cabinets were removed to a temporary container, whilst the basement was cleared, fumigated and air conditioned. Upon completion of this exercise, the contaminated slides were discarded and only the slides that were intact, were returned to the basement for storage.

Infrastructural challenges still exist at KEH laboratories. Floor repairs were budgeted for, but are still pending, due to delays in the procurement processes. The issue of the non-functional lift at KEH was escalated to the DoH in 2011. It was stated that a tender will be issued to obtain a service provider to repair the lift, but to date, this issue has not yet been resolved.

The Virology and CD4 departments at Madadeni Laboratory were successfully upgraded during the financial year under review. Rationalisation of GeneXpert instruments from Newcastle to Madadeni Laboratory and from Dundee to CJM laboratory was introduced. The renovations at Bethesda were completed and the renovations in Hlabisa are in progress. Jozini CHC also commenced operations in May 2018, although its official opening is only due in April 2019.

Stakeholder relations

Ongoing engagement ensured strengthened relationships with clients and partners such as the DoH, DAFF, SANDF, and DCS, as well as the municipalities and DoH partners. Interaction occurs at all levels and include attendance of meetings by our area and business managers, as well as the regional coordinators and laboratory managers. We also participate in client campaigns and roadshows.

Meetings and training sessions are frequently conducted with the PHCs and CHCs. Webview access was provided to the clinics and hospitals, to enable new doctors and clinic sisters to view results online. Training was conducted on the new PHC request forms.

An intern induction workshop was conducted at KEH in January 2019, to orientate new medical interns on good specimen taking practices, MCDS, EGK and protocols. The medical interns were also provided with Webview access to enable viewing of laboratory results via the internet. The NHLS laboratories were invited to participate in the induction workshops for new employees at KEH, on a quarterly basis.

Meetings between NHLS management, NHLS IT and AME Afrika focused on the optimisation of the newly introduced Meditech Hospital Information System (HIS) and its interface with TrakCare Lab. Apart from integrating these two systems, one of the main issues that is currently experienced, is a lack of sufficient bandwidth for use of the IALCH analyser middleware.

Meetings between NHLS and Impilo Consortium focused on day-to-day operational issues such as ensuring adherence to the regulations of the DoL and the municipality, as well as compliance with the PPP agreement pertaining to issues such as the equipment placement cycle, power outages, floor repairs, transitional changes, infrastructural changes, security, waste disposal and health and safety, to name but a few. The NHLS also conducted several meetings with the relevant subcontractors to address some of these issues.

In November 2018, an open day was hosted at Imbalenhle Clinic in Edendale, in collaboration with all other hospital departments as part of the DoH's Commemoration of Quality Month. The DoH awarded the NHLS exhibition with a certificate for its "Well displayed and organised open day stall."

NHLS staff supported the DoH with screening for the Umdlavuza Campaign which was held at IALCH on 21 April 2018. The DoH made it into the Guinness Book of World Records for conducting more than 1000 pap smears in an eight-hour day. The NHLS received and processed a total of 2049 pap smear specimens for this campaign.



Conclusion

Overall, NHLS KwaZulu-Natal demonstrated excellent performance against its targets, with marked improvements noted in service delivery, internal operations and quality, as well as financial sustainability, when compared to the previous financial year. This is despite continued challenges pertaining to critical skills shortage both on the training and service platforms.

Underpinned by its regional slogan: "Quality now and everything else will follow," the consistent quality of region's services becomes evident from the fact that KwaZulu-Natal has a total of 17 laboratories that are SANAS-accredited, an accomplishment that is unprecedented within the NHLS.



2.4.2.2.5. Limpopo and Mpumalanga

Introduction

NHLS in Limpopo comprises three business units, namely: Vhembe-Mopani Business Unit, Capricorn Business Unit and Sekhukhune-Waterberg Business Unit. There is a total of 37 laboratories that service all the general hospitals of the DoH in the province. These laboratories provide a 24-hour service, seven days a week.

Diagnostic services and new developments

Diagnostic services in Limpopo are offered through a network of laboratories across the entire province that are each associated with a general hospital of the provincial DoH. Several laboratories acquired new analysers to improve efficiency and quality of diagnostic services. Letaba received three new Beckman Coulter Aquios CL for CD4 testing.

Several district laboratories also acquired new analysers for Biochemistry and Haematology testing, which replaced the aging analysers. This resulted in reduced service disruptions due to breakdowns.

Mankweng laboratory acquired a state-of-the-art laboratory automation which includes the a pre analytical analyser that connects VL analysers with chemistry and immunology via a track, which ensures a fully automated testing platform. To achieve this, the laboratory underwent major renovation towards the end of the 2017/2018 financial year.



Mankweng Laboratory Automation

The introduction of the rapid strip test for detection of rotavirus and adenovirus from diarrhoea stool in the Polokwane Microbiology Laboratory improved the diagnosis and management of childhood diarrheal diseases. The laboratory continues to make a valuable contribution to reduce TB transmission in the province. The laboratory successfully completed the verification and, has implemented testing for second line TB drugs since 2017, and continues to support multi-drug resistance (MDR) and extensive drug resistance (XDR) initiation sites in Limpopo.

Service delivery and coverage

The Vhembe-Mopani Business Unit delivers these services with a total staff compliment of 103 as at end of March 2019, which includes medical technologists, medical technicians and other support functions. The Capricorn Business Unit delivers these services with a total staff compliment of 115 as at end of March 2019, which includes pathologists, medical technologists, medical technicians, laboratory assistants and other support functions.

The Sekhukhune-Waterberg Business Unit delivers these services with a total staff compliment of 85 as at end of March 2019, which includes medical technologists, medical technicians and other support functions.

The business units were able to offer daily clinic-to-laboratory specimen collection to over 500 clinics within the province.

A total of 244 non-functional SMS results printers were collected from across the Limpopo Province and were sent for repairs. These were upgraded with roaming SIM cards and bi-directional printers that enable clinics to query and print results locally. There is also a dashboard function to monitor the SMS printer activity remotely and intervene, as necessary.

Turnaround times

The TAT target set for all NPP routine hospital tests were achieved in the year under review, despite service interruptions caused by analyser and network downtime, which affected the CD4 count and TB testing in Capricorn. CD4 analysers are in the process of being upgraded.

Table 1: Turnaround times (TAT measures when the specmen is registered in the laboratory until the results are authorised)

		Vhembe - Mopani	Capricorn	Sekhukhune - Waterberg
Test type	Target	% Within target TAT	% Within target TAT	% Within target TAT
VL	75%	99.48%	89.0%	75%
LFT	90%	93.58%	92.4%	99.3%
U&E	90%	94.45%	93.9%	90%
FBC	90%	95.07%	95.2%	95.8%
GeneXpert	90%	95.88%	77.9%	95.2%
Microscopy	90%	94.47%	70.9%	94.3%
CD4	90%		81.2%	90%
Cervical Smear	85%		99.7%	

Notable achievements

The following laboratories in Vhembe-Mopani achieved SANAS accreditation: Letaba Regional- and Sekororo District laboratories.

In Sekhukhune-Waterberg, Matlala and Ellisras district laboratories achieved SANAS accreditation.

Mankweng Laboratory in Capricorn business unit maintained its SANAS accreditation due to continuous compliance with ISO 5189:2012 standards.

The following laboratories in Sekhukhune-Waterberg performed well on SLIPTA audits: Mokopane and St Ritas with ratings of 3 and 4 stars respectively. Subsequently, in March 2019, St Ritas laboratory underwent a pre-SANAS audit, and was recommended for SANAS audit application.

Two new pathologists (haematologist and chemical pathologist) were appointed in Polokwane to improve pathology coverage and quality of service in Limpopo laboratories and support the University of Limpopo's Medical School academic programme.

Our virologist presented a poster at the following congresses:

- PathCape 2018 Conference, which took place from 16 18 August 2018 at Spier Wine Farm in Cape Town;
 and
- South African HIV Clinician Society Conference 2018 which took place from 24 27 October 2018, at the Gallagher Convention Centre in Johannesburg.

Laboratory upgrades

A total of six laboratories in the province were upgraded to the value of R744 347. The laboratories are: Polokwane Microbiology, Sekororo, Ellisras, Donald Fraser, Siloam and Jane Furse. The upgrades aimed to improve the laboratory space and working conditions and ensure compliance to safety standards.

Stakeholder relations

Relations with stakeholders were maintained through different types and levels of engagements throughout the year.

Provincial SLA meetings were held in June and December 2018 where service delivery, TATs, quality, outbreak response, and payment of services and utilities were discussed.

The provincial World AIDS Day commemoration was held at Mankweng Sports Centre in Capricorn District and was attended by the NHLS business manager from Sekhukhune-Waterberg. Onsite TB testing was offered at the event, through our mobile laboratory.



Limpopo Worls Alds Day Commemoration

Between April and May 2018, the NHLS management, DoH and DoH partners conducted training on the new PHC handbook and rollout of the new NHLS requests forms (N1, N2, N3 and N4) for the districts and subdistricts.

The Microbiology Unit of the Polokwane laboratory is involved in various committees at facility, district and provincial levels. This includes: The Pharmacy and Therapeutics Committees and the Antibiotic Stewardship and Infection Control Committee. The department remains actively involved in the IPC programmes at the hospitals and partners with provincial and district managers, to strengthen IPC and outbreak response initiatives. We also participated in various workshops aimed at improving healthcare services.



Conclusion

The NHLS in Limpopo demonstrated overall good performance against its objectives for the financial year. There were marked improvements in TATS and QA. This was accomplished despite numerous challenges such as staff constraints, IT network instability and supply chain inefficiency. Lessons learnt from the reporting period, will be leveraged for continuous improvement in the financial year that lies ahead.

Mpumalanga

Introduction

The NHLS in Mpumalanga comprises two business units, namely Ehlanzeni Business Unit and Gert Sibande-Nkangala Business Unit. These business units are aligned to health districts.

The laboratory service is provided to the Mpumalanga province through a network of 21 laboratories managed in these business units.

Ehlanzeni Business Unit

The NHLS Ehlanzeni Business Unit offers laboratory services to about 13 general hospitals, 121 PHCs and CHCs, as well as three DCS facilities in the Ehlanzeni District.

The service is provided through nine NHLS laboratories spread throughout five sub-districts, viz; Mbombela, Nkomazi, Umjindi, Bushbuckridge and Thaba Chweu. Out of the nine laboratories, there is one provincial tertiary laboratory, two regional laboratories and six district laboratories. All hospitals in the Ehlanzeni Business Unit have laboratories, with the exception of two district hospitals, Matibidi and Sabie. Two laboratories, Rob Ferreira and Themba, render a 24-hour service, with one laboratory, Lydenburg, operating an eight-hour service. The remaining six laboratories also operating an eight- hour service, as well as a callout service.

Gert Sibande-Nkangala Business Unit

The NHLS Gert Sibande-Nkangala Business Unit comprises 10 fully functional laboratories, and two depots. The unit offers services to 161 PHCs and CHCs, and three DCS facilities within the Gert Sibande and Nkangala health districts. Two of these laboratories are provincial tertiary and regional institutions that are accredited by the SANAS and the HPCSA to train students in biomedical technology. These two sites offer 24-hour services, and the remaining eight laboratories that offer district level services use different shift- and callout systems to cover emergency services.

Diagnostic services and new developments

The number of tests performed by NHLS laboratories in Mpumalanga province dropped by 5%, when compared to the last reporting period. About 4.7 million tests were performed in 2018/2019 versus five million in the previous financial year.

The diagnostic services offered continued to support the NPP of the DoH through relevant tests performed within the province. The table below depicts the type and volumes of NPP tests received and tested on behalf of the province.

Table 1: Comparison of National Priority Programme volumes between 2017/18 and 2018/19

Test type	Volumes 2017/2018	Volumes 2018/2019	% Difference
CD 4	256 338	222 925	-13%
HIV VL	455 998	475 965	4%
Cervical cancer screening	69 139	40 751	-41%
TB GeneXpert	103 523	101 325	-2%
TB microscopy	67 440	56 961	-16%
HIV PCR (referrals)	56 590	56 617	0%

New developments

The Gert Sibande-Nkangala Business Unit offered 100% coverage of the GDSP bi-directional results printers at the Nkangala Health district PHCs. This helped to improve the rapid delivery of HIV and TB diagnostic results of patients throughout the health district; where previous coverage was less than 5%. All SMS printers within the province were furthermore upgraded to be on par with the above latest technology. The printers were handed over in a function attended by NHLS and provincial DoH representatives.

The Rob Ferreira laboratory acquired a new state-of-the-art chemistry analyser in October 2018 called AU680 and UniCel Dxl 800, to replace the old chemistry analyser of which the contract ended.

In order to improve sample handling and workflow in the chemistry laboratory, an AutoMate 2550 was installed.



Rob Ferreira pre- analytical and analytical systems.

The analysers in the provincial tertiary laboratory (Witbank) and the regional laboratory (Ermelo) in the Gert Sibande and Nkangala Districts, were replaced with new state-of-the-art and reliable analysers. This resulted in an immediate improvement in quality of tests and TATs.

As recommended by the national Cervical Cancer Prevention and Control Policy (CCPCP), a new cervical screening technique named LBC was rolled out in all sub-districts of Mpumalanga. The HCWs were trained to perform pap smears using LBC collection material. Test volumes on this method increased by 24% in 2018/2019 compared to 2017/2018. This also resulted in improved quality of pap smears and better patient management.

Service delivery and coverage

The NHLS Gert Sibande-Nkangala Business Unit ensured 100% access coverage of pathology services to the PHCs and CHCs through its network of specimen collection services. The NHLS Ehlanzeni Business Unit ensured 100% access coverage of pathology services to 121 PHCs and CHCs through its specimen collection services. Some smaller district hospitals without onsite NHLS services, such as Matibidi and Sabie hospitals, were covered through specimen collection twice a day.

The resident microbiologist contributed towards an improvement in liaison with the clinicians. In the 2018/2019 financial period, the microbiologist conducted a number of outreaches to the hospitals in the province, including: Themba, Lydenburg, Ermelo and Witbank. These visits served to discuss the antimicrobial stewardship programme and present data on local patterns of antimicrobial resistance. Through these visits, knowledge and expertise were shared to ensure efficient laboratory service utilisation and customer satisfaction.

The microbiologist also serves as a committee member on the provincial and district DoH's Antimicrobial Stewardship Committee.

Turnaround time

The table below show the tests performed, and the volumes and TATs achieved during the financial period in the two provincial business units. Acquisition of new analysers and filling of vacant positions anticipated in the new financial year are some of the interventions geared towards improvement of TAT.

Table 4: Mpumalanga turnaround times (TAT measures when the specmen is registered in the laboratory until the results are authorised)

Unit	Test method	Target	Test count	Volume within target TAT	TAT achievement
	TB Microscopy	90%	18 417	17 774	96.1%
Business	TB GeneXpert	90%	53 574	51 910	95.5%
	CD4	90%	110 455	102 180	93.9%
Sibande	FBC	90%	144 791	131 774	92.3%
ö	U&E	90%	509 119	452 911	90%
t.	HIV/PCR	90%	164 179	107 896	65.7%
Gert	Cervical Smears	70%	92 856	66 856	72.1%
	TB microscopy	90%	18 864	17 928	95%
Unit	TB GeneXpert	90%	45 040	43 474	97%
Business	HIV VL	75%	476 055	447 418	94%
usin	HIV PCR	80%	167 083	109 540	66%
	CD4	90%	109 111	91 979	84%
zen	FBC	90%	154 203	135 837	88%
Ehlanzeni	U&E	90%	504 021	433 536	86%
並	Cervical smears	80%	136 443	90 443	66%

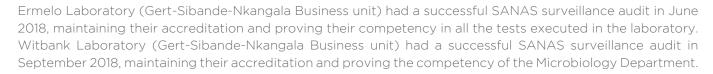
Notable achievements

Dr Ntuli, the Microbiologist at Rob Ferreira, presented a poster at the 5th South African TB Conference that took place from 12-15 June 2018. The abstract title was: "The Public Health Benefits of Setting-up a Tuberculosis Culture and PCR laboratory in a Limited Resource Setting." This was a descriptive analysis of the LPA results obtained from the Ermelo TB culture laboratory from January 2012 to March 2017. The findings of the analysis indicated that setting-up a TB culture and PCR laboratory in a low resource setting, can benefit the community by detecting TB in cases, which could have otherwise been missed by the GeneXpert tests.

Rob Ferreira Laboratory achieved a 5-star rating (>95%) in the May 2018 ASLM audit. The results demonstrated that the laboratory is ready for SANAS accreditation.

Accreditation

South African National Accreditation System



Stepwise Laboratory Quality Improvement Towards Accreditation

SLIPTA audits were conducted at three of the laboratories, using the 2015 WHO checklist with the aim to assess their readiness for accreditation and improve their performance and QMS. The Laboratories enrolled were Standerton and Mmamethlake, which received 3-star rating, and Shongwe which received 4-star rating.

Laboratories upgrade

An access control system was installed at a number of the laboratories to secure the facilities and ensure safety of the NHLS personnel and assets. These laboratories are: Tonga, Shongwe, Lydenburg, Themba, Tintswalo and the Ehlanzeni Business Unit office.

Stakeholder relations

Stakeholder relations in the province were continuously managed through engagements at different levels and through different programmes.

SLA review meetings were conducted on a quarterly basis with the provincial DoH.

Laboratory and blood transfusion meetings were attended, where input was rendered to improve the management of costs and sample rejections in laboratory services in the hospitals.

There were also engagements with the DCS to address any operational issues and identify gaps in service delivery.

PMTCT Quarterly Meetings were held with the Mpumalanga DoH, during which the performance of the HIV Mother-To-Child Transmission Programme was presented and discussed. Challenges experienced by laboratories with regard to high rejection rates were presented to the department and ways to minimise rejections were explored.

A total of 31 LBC training sessions were conducted in the respective districts and sub-districts in the province, by the NHLS and DoH programme managers for Maternal Child and Women's Health (MCWH).

HCWs and laboratory staff members were retrained on the PHC Laboratory Handbook, the Clinic-Laboratory Interface and the Ideal Clinic Initiative. The aim of this training was to eliminate operational challenges that exist at pre- and post-analytical phase and to close the gaps that compromise service delivery, through the use of the PHC Laboratory Handbook and the new forms that were designed to improve efficiency at PHC level.

Non-governmental organisations

- A joint partnership was established between the DoH, the NHLS and BroadReach, to drive collaboration on addressing the operational challenges that exist at PHC level; and
- · Right to Care was engaged on service delivery issues in partnership with the Mpumalanga DoH.

Conclusion

The NHLS in Mpumalanga strived to deliver a continuously improving service and client experience in line with the NHLS mandate within the province.

2.4.2.2.6. Western and Northern Cape



Western Cape

Introduction

The Western Cape province of South Africa, is situated at the southern extremity of the African continent. The provincial capital, Cape Town, is also the country's legislative capital. It is the fourth largest of the nine provinces and the third most populated. About two-thirds of the inhabitants live in the metropolitan area of Cape Town. The Western Cape is bordered on the north by the Northern Cape and on the east by the Eastern Cape.

The 40 NHLS laboratories in the region are divided into three business units spread across six health districts of the Western Cape province.

These business units are:

- Groote Schuur (GSH) and Red Cross Academic (RXH) Business Unit
- Tygerberg (TBH) Academic Business Unit and
- Green Point Complex (GPC) and Western Cape Regional Laboratories (WCL)

The table below summarises the Western Cape business units and laboratories:

Table WC1: Western Cape laboratories

National central laboratories	Tertiary laboratories	Regional laboratories	District laboratories
GSH Chemical Pathology	RXH Chemical Pathology	GPC Chemical Pathology	Vredendal
GSH Haematology	RXH Haematology	GPC Haematology	West Coast District
GSH Microbiology	RXH Anatomical Pathology	GPC TB laboratory	Karl Bremer
GSH Virology		GPC Media laboratory	Mitchell's Plain
GSH Cytology		Somerset	Helderberg
GSH Anatomical Pathology		George	Mossel Bay
GSH Immunology		Paarl	Oudtshoorn
GSH Tissue Immunology		Worcester	Knysna
GSH Genetics			Beaufort West
TBH Chemical Pathology			Khayelitsha
TBH Haematology			Hermanus
TBH Microbiology			Pollsmoor
TBH Virology			
TBH Immunology			
TBH Cytology			
TBH Anatomical Pathology			
TBH Genetics			
17 Laboratories	3 Laboratories	8 Laboratories	12 Laboratories

The academic business units in association with the University of Cape Town and Stellenbosch together with the regional laboratories provide diagnostic pathology services to national central, tertiary, regional and district hospitals within the Western Cape and surrounding provinces.



Diagnostic services and new developments

The laboratories are well resourced with state-of-the-art equipment and highly competent staff that are dedicated to deliver quality and patient-focused service.

Several instrument upgrades were implemented in the region including ten new AQUIOS instruments and two Sysmex XN1000 FBC analysers at GPC Haematology. The latter was required to improve the TAT for FBC and reticulocytes tests.

The TBH immunology laboratory received an "open" system robotic diluter at the end of March 2019. This system is able to process different enzyme-linked immunosorbent assay (ELISA) based tests, including pure immunology, infectious disease and autoimmune tests. This will enable the laboratory to continue to provide excellent service and support to the Rheumatology section of TBH hospital and patients with autoimmune disease in the Western Cape.

Several new tests were introduced in the business units in an effort to improve our service delivery and patient management. Improvements in TAT's were achieved through implementation of these tests at laboratories, which in turn helped to reduce the number and frequency of referrals of samples.

GSH Histology added Fluorescence in-situ hybridisation(FISH) to the diagnostic platform in November 2018

Table WC2: FISH tests added to diagnostic platform

Fish test	Application
MYC	
BCL2	B-cell lymphoma classification
BCL6	

The GSH Chemistry laboratory upgraded to the latest generation free T4 and Acetaminophen reagents.

RXH Chemistry and Haematology

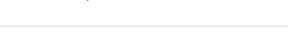
The RXH Clinical laboratory introduced three new tests at the facility:

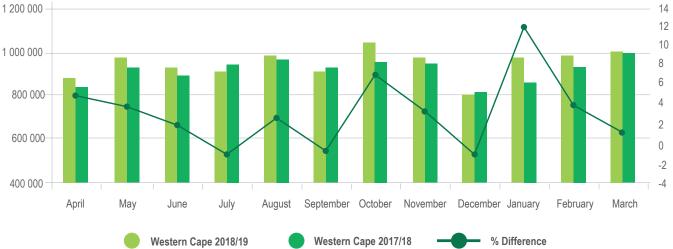
- Chromogranin A
- Galactossaemia
- HbA1c POC testing

The TBH Chemistry Department added serum free light chains (SFLC) to their test repertoire. The laboratory receives referrals for these tests from WCLs as well as from other provinces.

The Western Cape achieved a 3% increase in volumes for the year under review.

Table WC3: Western Cape test volumes comparison 2017/18 vs 2018/19





Test Volumes Camparison 2017/18 vs 2018/19

Service delivery and coverage

The collection of samples in the Western Cape maintain a 100% sample collection rate for all health facilities, due to amendments on certain routes and adjustment of courier collection times to improve courier efficiency. There were several challenges that impacted the courier services such as, Public protests in the region. However, contingency plans were implemented rapidly to ensure that samples are collected where possible, with minimal risk to couriers and laboratory staff.

Annual phlebotomy services are provided to the SANDF to monitor occupational health and safety for the military. Support for the Military laboratory at 2 Military Hospital to ensure continuity of service to the patients was achieved and a memorandum of understanding (MoU) was signed to guide future support.

Part of the dedicated team of histotechnologists assist with the histology sample processing and analysis. On average, 800 blocks are processed each day. Tygerberg histopathology experienced a huge increase in the workload due to receiving specimens from the Eden District, as well as an increasing number of specimens from surrounding facilities and clinics.

The diagnostic NHLS Microbiology laboratory at TBH experienced a substantial increase in the number of samples submitted for screening for carbapenem-resistant Enterobacteriaceae (CRE) in the 2018/2019 financial year. Samples increased from an average of 7 per month in 2017/2018 to an average of 121 samples per month in 201/2019. The primary driver was an increase in CRE cases from the neonatal platform in December 2018. Failure to identify a clear source, necessitated wide-scale screening across the entire neonatal platform in January 2019, together with other interventions. This, combined with a moderate elevation in CRE cases on the adult platform at TBH and sporadic cases at peripheral hospitals, resulted in more disciplined adherence to IPC recommendations for screening of contacts of these cases. As a result, regular screening has recently been implemented in the adult and paediatric intensive care units at TBH.

The laboratory also receives samples for methicillin-resistant Staphylococcus aureus (MRSA) screening, particularly preoperatively for orthopaedic procedures and during admission at the Tygerberg Hospital Burns admission O.P.D. Sample volumes increased by 59% in 2018/2019 when compared with the previous year, with the laboratory processing 81 samples per month on average for MRSA colonisation.

The Western Cape and Eastern Cape provinces experienced an unusual seasonal peak in the number of laboratory confirmed enterovirus (EV), aseptic meningitis cases during the 2018-2019 season. In South Africa, EV infections usually peak during the summer season. Community, intrafamilial and nosocomial clusters of EV aseptic meningitis are frequently described. Multiple serotypes usually co-circulate during an EV season with predominance of a single EV serotype. Cyclical epidemic patterns of circulation are also described.

More than 2930 samples were received for EV testing by TBH and GSH virology laboratories. The initial cases were reported in the Khayelitsha Health District of the Western Cape Metro region, with subsequent cases seen in the private sector, the Eastern Cape province and the Mitchell's Plain Health District of the Western Cape Metro region.

The molecular EV screening was performed using a PCR targeting the 5'UTR of the EV genome. Molecular serotyping using EV pan- and species- specific primers revealed echovirus 4 to be the predominant serotype. Efficient diagnostic services, with a particular emphasis on molecular diagnostics, have an important role in disease surveillance, assessing the epidemiology of diseases of public health importance, elucidating patterns of spread within the community and viral evolution or recombination events.

The successful testing of these samples would not have been possible without the dedication and commitment of all levels of laboratory staff.

Involvement of clinicians in the Western and Eastern Cape provinces, public health staff in the Western Cape Provincial CDC office, scientists and pathologists in the NHLS virology laboratories in the two provinces, the private healthcare sector (PathCare N1 City, Goodwood) and involvement of the NICD provides evidence to the diagnostic footprint of the NHLS, fostering improved service delivery, laboratory capacity building and stakeholder involvement.

Turnaround times

NPP targets were all met and maintained in the period under review. U&E, FBC and LFT targets were all also consistently achieved during this period.

NPP test volumes and turnaround time

The Western Cape business units achieved a 3% increase in NPP test volumes for the year under review.

Table WC5: Western Cape NPP TATs 2018/19 (TAT measures when the specmen is registered in the laboratory until the results are authorised)

		Fiscal Month	Total		
Area	Business Unit	Test Type	Test Count	Volume Within Target TAT	% Within Target TAT
Western Cape	Western Cape	CD4	162,143	154,530	95.30%
Western Cape	Western Cape	HIV PCR	42,131	39,357	93.42%
Western Cape	Western Cape	VL	315,247	267,945	85.00%
Western Cape	Western Cape	LFT	1,102,822	1,036,498	93.99%
Western Cape	Western Cape	U+E	1,825,936	1,763,681	96.59%
Western Cape	Western Cape	Cervical Smear	261,344	230,090	88.04%
Western Cape	Western Cape	FBC	651,910	628,804	96.46%
Western Cape	Western Cape	GeneXpert	235,691	226,059	95.91%
Western Cape	Western Cape	Microscopy	131,637	124,872	94.86%

Notable achievements

Dr Natalie Beylis, microbiology pathologist at the Green Point TB laboratory successfully completed the Fundamentals in Infection Prevention and Control Course during the period under review and the knowledge obtained has been implemented especially for the training of future professionals.

WHO site visit

The Green Light Committee and WHO, AFRO sent a delegation to perform a drug resistant TB programme review of the TB testing facilities and processes at Khayelitsha and Green Point laboratories during November 2018. The delegation, chaired by Dr Norbert Ndjeka - Director Drug-Resistant TB, TB and HIV at the national DoH, reviewed the SA DR-TB programme (covering clinical, laboratory, data etc. The group consisted of three laboratory consultants as well as members from the WHO and other participants from Uganda and Belgium.

The review was very well received by all participants and discussions regarding the laboratory workflow and patient data management systems were insightful The delegation also provided recommendations for the reporting of the TB statistics to the health facilities. The data is currently available on the NHLS CDW repository and the reports will be sent to the facilities in due course.



Figure WC4: Green Light Committee delegates with Dr Natalie Beylis representing GPC TB laboratory



Figure WC5: Delegates from the Joint Data Use Projects Learning Experience

Joint Data Use Projects Learning Exchange

Another highlight was the Joint Data Use Projects Learning Exchange.

The purpose of the site visit was for delegates to gain an appreciation of the value of centrally consolidating all laboratory data in one LIS. Elements discussed during the visit include:

- The opportunity for high throughput, efficient processes where the specimens can be centralised, as in urban areas:
- The specimen registration process, the way in which the UI is used, the sharing of UI updates on the LIS:
- The web-based results-viewing platform, and uptake of it by clinicians;
- The challenges and successes in rolling out a single country-wide online LIS, following a previous solution where each laboratory ran its own server;
- Plans for the increasing availability of point-of-care testing;
- GeneXpert, viral load and CD4 count availability to meet programme needs

The NHLS in Western Cape has provided support for the rollout of usage of Pre Exposure Prophylaxis (PrEP). The national DoH made the medication available to young women and adolescent girls and sex workers as well as men who have sex with men (MSM).



Western Cape laboratories maintained their SANAS and EFI accreditation, as well as their SABS certification for the laboratories that are assessed annually. In the WCL Business Unit, two district laboratories were accredited during the period under review. The Karl Bremer and West Coast District laboratories received excellent accolades from the audit teams, who were highly impressed by the quality standards at both these facilities. The lead assessor for the Karl Bremer assessment indicated that it was the best laboratory she had audited in many years. by The four regional laboratories maintained their SANAS accreditation, with improvements in quality noted as a feature by all the audit teams. The Hermanus and Helderberg district laboratories had successful pre-SANAS audits during the period under review, and both were recommended for SANAS accreditation.

Table WC6: Accreditation

Tier	Laboratory	Total number of laboratories	Number of laboratories accredited	% Accredited	
		SANAS Accreditation (ISO 15189:2012)			
National central	GSH	10	10	100%	
National central	TBH	7	7	100%	
Provincial tertiary	RXH	1	1	100%	
Regional	GPC	4	4	100%	
Regional	George	3	3	100%	
District	West Coast District (WCD), Karl Bremer	11	2	18%	
EFI Accreditation					
National central	GSH-Tissue Immunology	1	1	100%	
SABS Certification (ISO 9001:2015)					
Regional laboratory	GPC - DMP	1	1	100%	

Groote Schuur Hospital Histology

• The GSH Histology laboratory maintained an average TAT of 79% within seven days, despite having a significantly reduced consultant staff complement (5/11).

Groote Schuur Hospital Cytology

• The GSH Cytology laboratory experienced significant setbacks during the period under review, which impacted on TATs. The laboratory, however managed to recover and maintain a TAT of >95% for the last six months of the period.

Groote Schuur Hospital Virology laboratory

The GSH Virology laboratory conducted a study on HIV VL sample transport in plasma preparation (PP) and Ethylenediaminetetraacetic acid (EDTA) tubes. In conclusion it was found that unspun PP and EDTA samples were stable up to and beyond seven days between a temperature range of 4°C to 30°C. In practice, this means that the current process and time periods in bringing HIV VL samples to our laboratories have a minimum negative impact on HIV VL patient management. The aim is to publish this article during 2019/2020.

GSH Tissue Immunology laboratory

• The GSH Tissue Immunology laboratory underwent its biennial European Federation of Immunology (EFI) audit and was once again recommended for accreditation. We remain the only laboratory on the African continent to be EFI accredited.

- The following tests were recommended for SANAS accreditation:
- Human leucocyte antigen (HLA) 1 and 2 single antibody/antigen;
- HLA Class II antibody identification
- Anti-smooth muscle antibody (ASMA) immunofluorescence
- Anti-parietal cell antibody (APCA) immunofluorescence
- Anti-mitochondrial antibody (AMA) immunofluorescence
- Anti- liver/kidney microsomal antibody (anti-LKM-1) immunofluorescence

Groote Schuur Hospital Genetics laboratory

- The GSH Genetics laboratory established microarray service as a routine diagnostic test, which has since been recommended for SANAS accreditation; and
- The laboratory conducted a feasibility study to acquire an automated Karyotyping platform. This is currently in the procurement stage and should transform the laboratory in terms of TATs, quality and volumes of tests.

Groote Schuur Hospital Laboratory Support Service

- The GSH Laboratory Support Service (LSS) department designed and implemented a new uniform and phlebotomy bag for phlebotomy staff. This improved the NHLS brand within the academic business unit.
- The LSS department also redesigned the downtime labels to improve workflow during recovery periods. The new label incorporates LIS, middleware and instruments, which ensure that results are seamlessly linked to the correct episode number and downloaded for access.

The new, more sensitive GeneXpert Ultra tests are now performed at 13 of the Western Cape laboratories.

Quality assurance

All Western Cape Regional laboratories achieved an average of 97% for external PTS.

New laboratories and upgrades

The WCL Business unit appointed a laboratory manager for the Public Health laboratory with the intention to perform public health tests in the Western Cape starting in Quarter 3 of the 2019/2020 financial year. The manager is developing and preparing the laboratory according to the ISO 17025 standard. The implementation of the Public Health laboratory will improve our service as tests are currently referred to NHLS Public Health laboratories in Gauteng or KwaZulu-Natal.

Stakeholder relations

The NHLS management and staff provide an orientation programme for the medical interns in the region on an annual basis. Additional advisory and training sessions are conducted at numerous hospital forums Meetings were conducted at different facilities to discuss ways to reduce the number of rejections of samples. The NHLS, in collaboration with the University of Cape Town Medical School, facilitated a workshop on International Pathology Day, to demonstrate how research improves patient care and forensic investigations The TBH NHLS also hosted phlebotomy training sessions in key wards at Tygerberg hospital and participated in end user meetings.

The Western Cape managers also participated in meetings with the provincial DoH, as well as substructure meetings.

GSH business unit had a fine needle aspirate (FNA) stall (organised by Dr Heloise Buys). The stall was run by Dr Michelle Alisio from the Department of Paediatrics and the NHLS (A/Prof Komala Pillay, Dr Alessandro Aldera, Ruzeena Andrews and Xolelwa Mbutho). This initiative formed part of the Paediatric Skills Market Place at the 2019 University of Cape Town Paediatric Annual Refresher course, which was held at RXH on 12February 2019. Participants were shown how to perform an FNA, using chicken meat. The aspirates were collected and fixed by Ruzeena Andrews, stained by Xolelwa Mbutho and examined for adequacy by Prof Komala Pillay and Dr Alessandro Aldera.







Figure WC 14: Prof K Pillay at microscope examining slides for adequacy

Conclusion

The Western Cape NHLS continues to provide a high quality diagnostic service to stakeholders in the Western Cape and other provinces. Western Cape laboratories have improved their services to clients and 25 laboratories continued to maintain their SANAS accreditation while an additional four laboratories were accredited.

Western Cape regional laboratories will expand its service with the implementation of the Public Health laboratory and instrument replacements will further expand the test repertoire, improve the quality of the results and provide improvements in TATs for all facilities. Most district laboratories were earmarked for accreditation in the financial year that lies ahead.

Northern Cape

Introduction

Northern Cape is the largest, yet most sparsely populated province in South Africa. It has a surface area of 372 889km with a total population of approximately 1.23 million (2018), which forms 2.1% of the total South African population. The NHLS has a laboratory within each of the five districts.

Northern Cape districts and laboratories					
District	Laboratory name	Location			
Frances Baardt	Kimberley laboratory	Robert Mangaliso Sobukwe Hospital			
John Taolo Gaetsewe	Tshwaragano laboratory	Tshwaragano Hospital			
ZF Mgcawu	Upington laboratory	Dr Harry Surtie Hospital			
Pixley Ka Seme	De Aar laboratory	Central Karoo Hospital			
Namakwa	Springbok laboratory	Dr Izak van Niekerk Hospital			

Table NC1: Districts and laboratories

Diagnostic services and new developments

The Northern Cape's volume of tests for the 2018/2019 financial year increased to a total of 1 597 238 tests, which constitutes a growth of 0.1% when compared to 2017/2018. A quarterly comparison indicates an increase in quarter 1 and 4 and a decrease in quarter 2 and 3. National EGK rules were fully implemented for the period under review, with a monthly rejection rate of between 0.3% and 0.4%. De Aar laboratory recorded the highest increase in volume (13.6%) followed by Tshwaragano laboratory (5.8%). The increase at Tshwaragano was due to increasing the scope of tests.

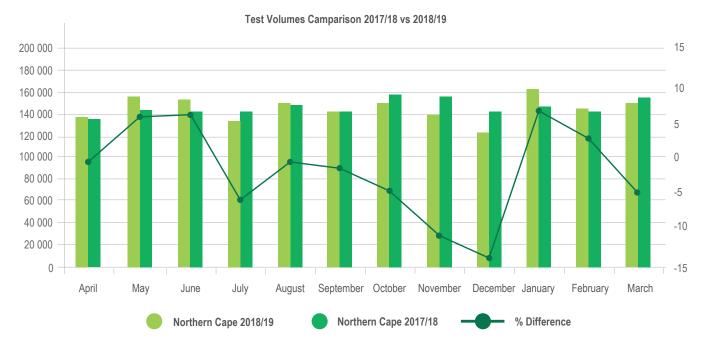


Table NC2: Volume comparison

Two laboratories increased their scope of tests to address customer needs. The number of CD4 testing sites were increased to four with the addition of Tshwaragano to the existing laboratories, namely, Kimberley, Upington and De Aar laboratories. Serum Rheumatoid factor and urine drugs of abuse tests were verified in the De Aar laboratory for implementation in April 2019.



Service delivery and coverage

Specimen collection in this vast province is maintained with 24 courier routes for daily collection of specimens from 212 facilities, as well as referring and referral laboratories within the North West, Northern Cape and Free State business units. Mines, mobile and satellite clinics are also serviced by these. Bidirectional SMS printers and Webview are utilised by the facilities.

Pathologist advisory services and support is received from the Universitas laboratory as the three pathologist posts in Kimberley remains vacant.

Turnaround times

The business unit performed well against the APP targets, by not only achieving the targets but also markedly improving the TATs when compared to the previous financial year. This was achieved by improving internal processes.

Table NC3: Average turnaround time full year (TAT measures when the specmen is registered in the laboratory until the results are authorised)

Area	Business Unit	Fiscal Month	Total			
Area	Business Unit	Test Type	Test Count	Volume Within Target TAT	% Within Target TAT	
Northern Cape	Northern Cape	CD4	56,758	54,440	95.92%	
Northern Cape	Northern Cape	VL	7,325	7,265	99.18%	
Northern Cape	Northern Cape	LFT	390,901	375,710	96.11%	
Northern Cape	Northern Cape	U+E	376,865	364,673	96.76%	
Northern Cape	Northern Cape	FBC	122,930	120,060	97.67%	
Northern Cape	Northern Cape	GeneXpert	63,569	63,259	99.51%	
Northern Cape	Northern Cape	Microscopy	19,142	19,046	99.50%	

Notable achievements

The Northern Cape Business Unit reduced its direct material expenditure with 4% compared to 2017/2018 and reduced the total expenditure with 6.4% compared to budget. A total number of 974 HCWs were trained on numerous laboratory related issues. An average score of 94% in the local customer satisfaction, which was conducted in 97 facilities in all five districts, which shows an average improvement of 5% when compared to the previous year. De Aar laboratory, the first district laboratory in the Northern Cape to achieve SANAS accreditation status.

Accreditation

Kimberley laboratory, a provincial tertiary laboratory, maintained its SANAS accreditation status after a successful surveillance audit. De Aar District laboratory obtained SANAS accreditation status after a successful initial assessment. The business unit is working towards accreditation of Upington, Springbok and Tshwaragano laboratories.

New laboratories and upgrades

Kimberley laboratory commenced with a renovation process. The objectives of the renovations are to:

- is to increase the capacity of the phlebotomy service;
- increase the available space within the specimen reception area; and
- improve workflow to prepare for full automation of the chemistry and haematology laboratories inclusive of a pre-analytical automation.

This is in line with a strategy to improve service delivery. Two Aquios CD4 instruments replaced the older MPL instruments in this laboratory, which in turn improved the workflow.

Stakeholder relations

The client liaison officer actively engages clients at all levels. Her duties include training of clients on elements such as MCDS, SMS printers, blood collection techniques, LBC procedures, EID collection techniques, use of Webview and changes in testing methodology. The strategy of being visible and available proved to be effective, with a marked improvement in customer satisfaction.

Table NC3: Client interaction

Clients Perspective	Q1	Q2	Q3	Q4	Total
Training (Health Care Workers)	227	238	382	127	974
Facilities Visited	39	50	37	38	164
Meetings	7	8	3	4	22

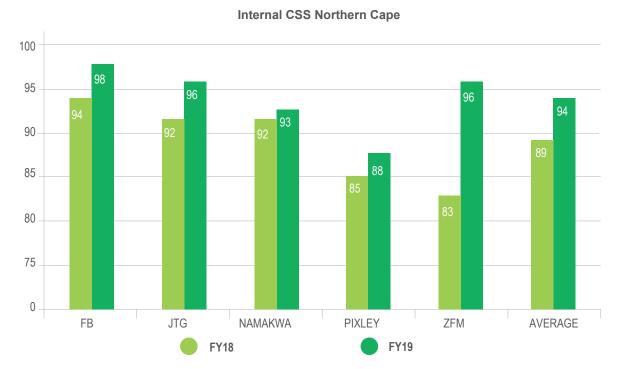


Table NC4: Internal customer satisfaction survey per district

Information technology

Bandwidth at the De Aar laboratory was upgraded in February, which resolved the slow network issues. The other four laboratories within the business unit are pending an upgrade. The TrakCare LIS was upgraded at a national level in November 2018. In general, the IT system and hardware is stable and well-maintained within the business unit, with an IT engineer situated in Kimberley to support the laboratories.

Conclusion

With this knowledge that Information Technology is a critical and a strategic enabler of the NHLS' current and future success, we will continue to fulfil our role to ensure that the environment is fit for purpose and designed for agility and efficiency. Furthermore, we will continue to enable business to achieve its mandate among others, laboratory test TATs, workforce modelling and customer billing as part of our plan to enhance the capabilities of our Technologies. We will improve the business operations by continuing to upgrade our network infrastructure and bandwidth to the rest of the NHLS sites.

2.4.2.3. National Priority Programmes



Prof. Wendy Stevens



Operations Manager Dr. Pedro Da Silva

Director: Professor Wendy Stevens Operations Manager: Dr Pedro da Silva

Overview

The National Priority Programmes (NPP), was established in 2010 to address the national DoH's need to provide increased access to patient testing to enhance treatment and care programmes. The NPP has been responsible for the implementation of several national laboratory programmes such as diagnosis of pulmonary and extra-pulmonary tuberculosis (EPTB) by molecular testing, cluster of differentiation 4 (CD4) count testing, reflexing cryptococcal antigen (CrAg) testing following CD4 determination, early infant HIV diagnosis, HIV viral load (HIV VL) testing, and HIV drug-resistance testing.

With Global Fund support, implementation was extended to the specific diagnostic needs of key populations in South Africa such as the mining- and peri-mining communities, and offenders in the Department of Correctional Services (DCS).

The NPP comprises a multidisciplinary team with members representing both the NHLS and the University of the Witwatersrand (Wits) Health Consortium. The multidisciplinary team allows for a holistic systems approach in supporting the implementation process through:

- Determining diagnostic needs;
- Research and development of diagnostic platforms and exploring innovations across the laboratory diagnostic chain for programmatic improvements;
- Offering technical assistance and training during and subsequent to implementation;
- Overseeing QA aspects of the programmes;
- Ongoing monitoring and evaluation to ensure programme maturation; and
- Expansion of the implementation science to further expand and guide surveillance, highlighting disease transmission hot-spots, improving linkage-to-care needs, identifying service delivery gaps, and integrating management at all levels of a tiered laboratory structure.

Programme implementation and development would not be possible without private-public partnerships, working closely with national and international stakeholders and funders, particularly, the Global Fund, CDC, the United States Agency for International Development (USAID) through Right-to-Care, Bill and Melinda Gates Foundation, the WHO and diagnostic suppliers, to name a few.

Activities of the respective projects and programmes conducted in 2018/2019 are detailed below.

National testing services for tuberculosis

National Xpert Ultra Testing Programme

Overview

The NPP is responsible for the implementation and programmatic monitoring of the Xpert MTB/RIF testing nationally. In 2017, South Africa transitioned from Xpert MTB/RIF to Xpert MTB/RIF Ultra (Xpert Ultra), due to its higher sensitivity in detecting MTB, particularly amongst patients living with HIV. Just like the earlier assay version, Xpert Ultra identifies the causative agent of TB, *Mycobacterium tuberculosis* MTB, and its susceptibility to rifampicin, a core-drug used in its treatment, utilising the same instrumentation and laboratory procedures. The switch to Xpert Ultra was performed across 203 existing testing laboratories on 325 Xpert instruments of varying capacity (GX4: 127; GX16:189; GX48: 1; and GX80: 8).

Operations

From April 2018 to March 2019, 2 199 375 Xpert Ultra tests have been performed, with the average national TB positivity rate being 9.7%. Average rifampicin resistance detection rates remained at 6%. The number of unsuccessful tests reported, remained below 2%.

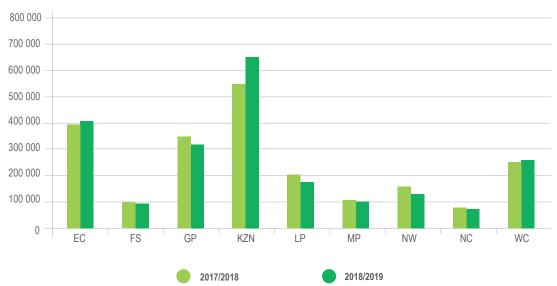


Figure NPP1: Xpert MTB/RIF and Xpert Ultra volumes by province for 2017/2018 and 2018/2019

Programmatic monitoring and evaluation

All Xpert Ultra laboratories are monitored in terms of test volumes, instrument utilisation, in-laboratory TATs, positivity rate, resistance rate, and error rates by data extraction from the CDW and the Cepheid C360 real time monitoring dashboard. Summary reports on laboratory performance are compiled and distributed monthly to area and business managers to facilitate continuous programme monitoring.

Quality assurance

To monitor testing quality, all Xpert Ultra testing laboratories are enrolled in Smartspot® EQA programmes, using dried culture spots. Three EQA panels, containing four samples each, were distributed to all Xpert Ultra testing sites with results submitted and analysed online. Laboratory participation in EQA increased to 98% in 2018/2019.

Laboratory and clinical training

The NPP training team is responsible for the provision of technical training on Xpert Ultra instrumentation and laboratory procedures and supports the national DoH with training of healthcare workers (HCWs) on the national algorithm for TB diagnosis and TB clinical management guidelines. Technical training comprises both onsite (individualised) and Basic/Advanced Xpert Workshops (groups), conducted in collaboration with the supplier, Cepheid.

Table NPP1: Healthcare workers trained on Xpert-related topics in 2018/2019

Province	Number trained
Eastern Cape	206
Free State	397
Gauteng	305
KwaZulu-Natal	301
Limpopo	213
Mpumalanga	499
Northern Cape	5
North West	212
Western Cape	29
Total	2167



Figure NPP2: laboratory staff attending the Advanced Xpert Ultra Training Course, Durban, KwaZulu-Natal

Output

Training and support

In 2018/2019, 333 laboratory staff received technical training with 145 certified as super-users through Advanced Training. Seventy-two laboratory support visits were conducted to address troubleshooting and other issues. Ninety-four healthcare facilities were visited with onsite mentoring related to specimen collection provided and 2167 HCWs trained.

The improved sensitivity with Xpert Ultra is largely due to the detection of 'trace' amounts of MTB, representing the lowest measurable level of genetic material due to amplification of specific insertion sequences. The increased sensitivity comes at a slight reduction in specificity, due to the detection of remnant bacilli (non-viable by culture-based diagnostic methods), particularly in patients with histories of previous TB. Clinical management of patients with 'trace' results is challenging and the clinical training programme incorporated guidance on this, in the interim, while awaiting updates to the national TB management guidelines. Of all Xpert Ultra reported results, 1.97% detect 'trace'.

Training and support activities for visiting delegations

The NPP and the NICD jointly hosted a high-level delegation from the Philippines from 21 - 25 January 2019. The visit was facilitated by the WHO. The visit aimed to draw lessons from South Africa's experience with respect to its National TB Control Programme and the supporting laboratory network and services. Of keen interest was the NHLS' robust specimen transportation and logistics framework, particularly for specimens received for TB diagnostic investigations, and the lessons learnt from national implementation of the Xpert Ultra programme.

The Philippines, like South Arica, shares a high incidence of TB, although with a low HIV/TB co-infection rate. The Philippines comprises an archipelago of 7100 islands and is challenged logistically and geographically in the provision of laboratory services. Drawing from South Africa's logistic network, key aspects will be implemented within the Philippines National TB Control Programme and supporting laboratory services.

Laboratory operations

The programme maintained a <2% rate of unsuccessful tests.

Granularity of specimen rejection rate monitoring improved by segregating these by technical and clinical reason, allowing targeting interventions by the training team to minimise further rejections. Rejected specimens not only aggravate delays in linkage to care, but also contribute to those lost to follow-up.

Standard operating procedures (SOPs) were developed to assist laboratory managers in monitoring their site-specific data through the Cepheid C360 monitoring dashboard. Following the laboratory verification of Xpert Ultra for diagnosis of EPTB, non-sputum specimen types were included and updated in the SOPs.

With the introduction of Xpert Ultra, an initial conservative approach was taken to confirm 'trace' results, and repeated specimens for TB culture were requested. In discussion with the national DoH, this strategy was modified due to concerns over delays in clinical management, while awaiting culture results. Updates to the reporting of Xpert Ultra results on the LIS were implemented on 28 October 2018, to simplify the clinical management guidance related to 'trace' detection.

NATIONAL TESTING SERVICES FOR HIV

National CD4 count and reflex cryptococcal antigen testing programmes

Overview

The CD4 count has been the principal basis for assessing an HIV-infected [person's level of immunosuppression] for timing initiation of antiretroviral therapy (ART). The WHO recommended starting ART at any CD4 in 2015, regardless of clinical symptomatology or underlying disease. Some work has argued for reduced frequency of CD4 counting when HIV VL testing is available. The move to UTT has therefore called into question the requirement for CD4 testing. Despite this, the continued important role has been reiterated in several recent publications, taking into cognisance the worldwide burden of advanced disease, especially in SA,^{1,2} the need to screen for underlying opportunistic infection and fast track very ill patients into care.

In this respect, continued monitoring of CD4 counts has enabled a world-first extensive national screening CrAg initiative³ whereby all patients with reported CD4 counts of <100 cells/Ql are reflexively screened for early cryptococcal disease (by screening for CrAg in plasma of routinely submitted CD4 specimens).

Monitoring of CD4 data is also important for surveillance of HIV, useful to monitor programmatic effectiveness, and indicate linkage to care. 4.5,6,7 Data about the burden of advanced disease has been used at international level to enable guideline development at the WHO,8 with updates on guidelines including special reference to cryptococcal management and testing³. CD4 data has been used for estimating incidence and/or prevalence of HIV disease and related opportunistic disease^{1,7,9}. Although the UTT strategy has slightly impacted a reduction in national CD4 test volumes, these remain >3million per annum, a testament to clinicians' confidence in the value of CD4 counts in monitoring patients who enter care.

CD4 servicing is decentralised across 49 testing facilities in South Africa and supported by the NPP CD4 unit that facilitates all training, site visits, onsite audits, and preparation for SANAS accreditation. The NPP CD4 unit further reviews and evaluates new and prototype CD4 testing platforms. National SOPs and standardised workflow systems are distributed for both CD4 and CrAg testing, to ensure standardisation across all testing facilities. Laboratory performance on the NHLS EQA programme and the Beckman Coulter inter-laboratory QA programme is monitored to assess laboratory performance. Test volumes and TATs are monitored weekly and monthly to identify laboratories with challenges in receiving, testing, or reviewing results for timeous operational interventions and strengthening of the national laboratory network. Laboratory capacity is monitored to ensure adequate testing platforms for continued quality of testing.

The placement of instruments is regulated through a tender process that was last adjudicated to Beckman Coulter in March 2018. The tender is up for review by 2020. The CD4 unit continues to train and support testing laboratories, assist other NPP activities with costing, best placement of equipment, and conduct operational research and instrument validations as required.

During 2018, the NPP CD4 unit facilitated a broad TAT review, initially describing the concept just for the

⁷ Carmona, S., et al. Persistent High Burden of Advanced HIV Disease Among Patients Seeking Care in South Africa's National HIV Program: Data from a Nationwide Laboratory Cohort. Clin Infect Dis 66, S111-S117 (2018).

² Coetzee, L.M., Cassim, N. & Glencross, D.K. Analysis of HIV disease burden by calculating the percentages of patients with CD4 counts <100 cells/microL across 52 districts reveals hot spots for intensified commitment to programmatic support. S Afr Med J 107, 507-513 (2017).

³ Govender, N.P. & Glencross, D.K. National coverage of reflex cryptococcal antigen screening: A milestone achievement in the care of persons with advanced HIV disease. S Afr Med J 108, 534-535 (2018).

⁴ Cassim, N., Coetzee, L.M., Schnippel, K. & Glencross, D.K. Compliance to HIV treatment monitoring guidelines can reduce laboratory costs. Southern African Journal of HIV Medicine 17, 1-5 (2016).

⁵ Larson, B.A., et al. Screening HIV-Infected Patients with Low CD4 Counts for Cryptococcal Antigenemia prior to Initiation of Antiretroviral Therapy: Cost Effectiveness of Alternative Screening Strategies in South Africa. Plos One 11, 24 (2016).

⁶ Cassim, N., Smith, H., Coetzee, L.M. & Glencross, D.K. Programmatic implications of implementing the relational algebraic capacitated location (RACL) algorithm outcomes on the allocation of laboratoryoratory sites, test volumes, platform distribution and space requirements. African Journal of Laboratoryoratory Medicine 6, 8 (2017).

⁷ Cassim, N., Coetzee, L.M., Stevens, W.S. & Glencross, D.K. Addressing antiretroviral therapy-related diagnostic coverage gaps across South Africa using a programmatic approach. Afr J Laboratory Med 7, 681 (2018).

⁸ World Health Organisation, W. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. Policy brief. (WHO, Geneva, 2017).

⁹ Song, R., Hall, H.I., Green, T.A., Szwarcwald, C.L. & Pantazis, N. Using CD4 Data to Estimate HIV Incidence, Prevalence, and Percent of Undiagnosed Infections in the United States. J Acquir Immune Defic Syndr 74, 3-9 (2017).

CD4 laboratories,^{10,11} and extending this to include a basket of the top volume diagnostic tests. The data is formatted weekly and visible via a micro-strategy dashboard in collaboration with Manfred Tepper from CDW and made available to all area-, business- and laboratory managers. Drilling capacity facilitates analysis of TAT data from national through to individual laboratory level, by test. This allows management at various levels to identify which provinces and/or laboratories contribute to poor performance. Tests included in the basket are: Haematology FBC, differential testing, international normalized ratio (INR), activated prothrombin test (aPTT), D-dimers and CD4 testing, chemical pathology U&E, liver function tests (LFTs), glucose- and cholesterol tests, amongst others, as well as microbiology (HIV VL, HIV DNA PCR, Xpert Ultra, rapid plasma reagin (RPR), and *Treponema pallidum* antibody tests).

Operations

CD4 volumes for 2018/2019 reached 2.803 million, compared to 3.057 million in 2017/2018, which constitutes a decrease of 9%. The monthly test volumes varied between 159 437 to 255 858 (mean of 233 626) (figure NPP3). Regional test volumes demonstrated that KwaZulu-Natal continued to process 27% of tests (763 481), followed by Gauteng (23%) and Western- and Northern Cape with the least number of tests at 220 824 (7.8%). The regional volumes decreased across all provinces/regions (figure NPP4).

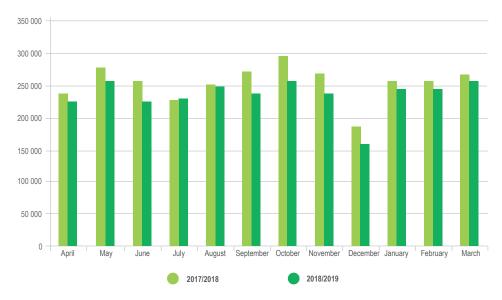


Figure NPP3: Annual CD4 volumes per month comparing 2017/2018 to 2018/2019

¹⁰ Cassim, N., Coetzee, L.M., Tepper, M., Motlonye, B. & Glencross, D.K. TAT as a risk model for operational services. in PathRed 2017 (2017).

11 Coetzee, L.M., Cassim, N. & Glencross, D.K. Using laboratoryoratory data to categorise CD4 laboratoryoratory turn-around-time performance across a national programme. Afr J Laboratory Med 7, 665 (2018).

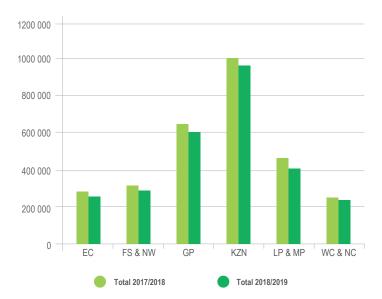


Figure NPP4: Annual CD4 volumes per regions comparing 2017/2018 to 2018/2019. EC (Eastern Cape), FS (Free State), NW (North West), GP (Gauteng), KwaZulu-Natal (KwaZulu-Natal), LP (Limpopo), MP (Mpumalanga), WC (Western Cape), and EC (Eastern Cape).

CD4 training and rollout of equipment

During 2018/2019 the second phase of the Aquios rollout was completed. Sixteen laboratories using MPL/CellMek instruments had single or multiple Aquios systems installed due to alterations in testing volumes (36 Aquios instruments). Training and instrument verifications were completed by December 2018.

Monitoring, support and training of laboratories from the first phase of the Aquios rollout, including laboratories utilising MPL/CellMek instrumentation, continued throughout 2018/2019. From the fourteen laboratories visited, four staff members from laboratories with a single Aquios system and 10 staff from three laboratories that use MPL/CellMek instruments were trained. In addition, the following laboratories were assisted with pre-SANAS internal audits: Prince Mshiyeni Memorial, Mahatma Gandhi Memorial, Ngwelezane, Edendale, Stanger, Hlabisa, Letaba, and Tambo Memorial.

Three laboratories ceased CD4 testing in 2018/2019, with two new CD4 testing facilities implemented in Krugersdorp (Leratong) and Kuruman (Tshwaragano).

Cryptococcal antigen testing

The national CrAg screening programme continued at all CD4 testing laboratories. In 2018/2019, 280 177 specimens were reflexed for CrAg, having CD4 counts <100 cells/microliter. The test volumes did not follow the 9% decrease in CD4 test volumes, with reductions from 297 552 in 2017/2018 (a difference of 17 375). Overall, 10% of all CD4 tests were reflexed for CrAg testing.

Gauteng Province contributed the most CrAg tests (23% of total), followed by KwaZulu-Natal at 21%. The region that contributed the lowest percentage CrAg tests, was Western- and Northern Cape at 6% (figure NPP 5).

The overall percentage positivity of all samples tested for CrAg in 2018/2019 was 6.2%, compared to 5.2% in 2017/2018. KwaZulu-Natal had the highest positivity rate of 8.5% and Free State and North West, 4.2% (figure NPP 6).

2017/2018

Figure NPP5: Annual CrAg test volumes per region comparing 2017/2018 to 2018/2019. EC (Eastern Cape), FS (Free State), NW (North West), GP (Gauteng), KwaZulu-Natal (KwaZulu-Natal), LP (Limpopo), MP (Mpumalanga), WC (Western Cape), and EC (Eastern Cape)

2018/2019

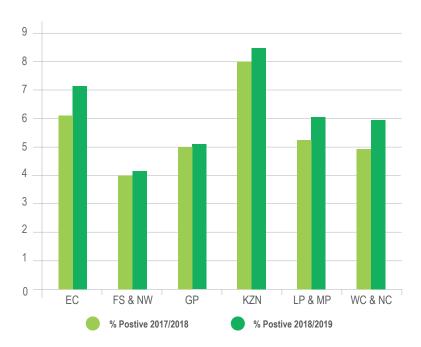


Figure NPP6: Annual percentage CrAg positivity comparing 2017/2018 to 2018/2019. EC (Eastern Cape), FS (Free State), NW (North West), GP (Gauteng), KwaZulu-Natal (KwaZulu-Natal), LP (Limpopo), MP (Mpumalanga), WC (Western Cape), and EC (Eastern Cape)

Output

The unit continued evaluating and validating new and existing CD4 and CrAg technologies across in-laboratory and in-field studies. In 2018/2019, all available new CrAg products were evaluated and compared to the gold standard CrAg platform.

The unit further focused on innovation for operational research and the development of systems to improve monitoring and management of laboratory performance. Improvement of TAT reporting is an ongoing project with CDW to simplify reporting and interpretation of laboratory performance for interventions. TAT comprises pre-analytical (pre-laboratory contributing factors like time during transfer of specimens to testing laboratories, time spent in specimen receiving sections), the in-laboratory processing or 'analytical' component, and post-analytical processing (largely comprising results verification and release).

Outcomes from the TAT dashboard revealed that amongst outlying TAT, pre-analytical issues contribute most to outlying TAT. To assist managers to identify where pre-analytical bottlenecks (and risk) are occurring within units, an additional dashboard was developed and piloted by the NPP CD4 team with CDW early in 2019, expanding detail on the pre-analytical stage of TAT. The aim is for this new dashboard to assist operations- and specimen transportation-focused managers to have a broader overview of where national logistics bottlenecks exist, assist in expediting corrective action, and improve overall service efficiency.

The routine clinical and laboratory data accumulated through the LIS, is collated through the CDW. CDW provides an invaluable and important national repository of health data, which, if mined appropriately, can provide important laboratory business intelligence for the NHLS and vital national epidemiological programmatic information. Working with AARQA and the Wits Ethics Committees, important operational and programmatic data was researched. Several projects were facilitated through CDW data and include:

- 1. Innovation addressing ART-related diagnostic coverage gaps across South Africa, using a programmatic approach¹²;
- 2. District and sub-district analyses of cryptococcal antigenaemia prevalence and specimen positivity in KwaZulu-Natal province, South Africa¹³;
- 3. Using laboratory data to categorise CD4laboratoryTAT performance across a national programme¹⁴; and
- 4. CrAg positivity combined with the percentage of HIV-seropositive samples with CD4 counts <100 cells/QI which identified districts in South Africa with an advanced burden of disease¹⁵,
- 5. Persistent high burden of advanced HIV disease among patients seeking care in South Africa's national HIV programme: data from a nationwide laboratory cohort.

Further, CDW data was furthermore utilised for operational and planning purposes, location and allocation of laboratory sites, predicting and planning of changes in test volumes, monitoring and evaluation of platform distribution and space requirements at CD4 laboratories, as well as addressing ART-related diagnostic coverage gaps across South Africa, to name but a few.

¹² Cassim N, Coetzee LM, Stevens WS, Glencross DK. Addressing antiretroviral therapy-related diagnostic coverage gaps across South Africa using a programmatic approach. Afr J Laboratory Med. 2018;7(1):681.

¹³ Cassim N, Coetzee LM, Govender NP, Glencross DK. District and sub-district analysis of cryptococcal antigenaemia prevalence and specimen positivity in KwaZulu-Natal, South Africa. Afr J Laboratory Med. 2018;7(1):757.

¹⁴ Coetzee L, Cassim N, Tepper M, Glencross DK. Standardizing individual laboratoryoratory turnaround time (TAT) performance amongst laboratoryoratories in a CD4 testing network. PathCape 2018: 56th International FSASP Congress; 16-18August 2018, 2018; Stellenbosch, South Africa.

¹⁵ Coetzee L, Cassim N, Govender N, Glencross DK. Distribution of Cryptococcal antigen positivity in severely immune-suppressed HIV patients in South Africa. PathCape 2018: 56th International FSASP Congress; 16-18August 2018, 2018; Stellenbosch, South Africa.

National HIV Viral Load Testing Programme

Overview

South Africa has the largest HIV treatment programme in the world, accounting for 20% of people on ART globally. The country also has one of the largest domestically funded programmes, with ~80% of the AIDS response funded by the government. The NHLS provides HIV VL testing services as part of this programme for the national DoH by means of 16 centralised HIV VL laboratories, Through the PEPFAR Surge Plan, with its aim to accelerate epidemic control in South Africa, initiation onto ARV's of a further two million people will allow for a total of 6.1 million individuals to receive ART in the public health system by December 2020, increasing viral load testing volumes to an estimated 7.1 million tests by 2020/2021.

Operations

Seven Cobas 6800, 10 Cobas 8800, 18 CAPCTM, and 14 m2000 platforms deployed across the 16 laboratories have a combined testing capacity of approximately eight million tests per annum.

Viral load tested volumes for 2018/2019 reached 5.22 million with KwaZulu-Natal processing 1.54 million specimens (29.4% of the annual volume), followed by Gauteng with 1.39 million (26.7%). Monthly HIV VL volumes vary between 318 510 and 492 670 tests. Overall, there were 200 482 more viral load tests performed in comparison to 2017/2018, which constitutes a 4% increase. Of tested volumes, 85.21% were representative of viral suppression (≤1 000 copies/ml).

As per the NHLS APP for 2018/2019, 75% of HIV VL should be tested within 96 hours. The target was exceeded with >80% of HIV VL processed within the required time period.

Tender and procurement processes

The newly awarded HIV VL tender (25 January 2019) will make use of Roche Cobas 8800 systems for high throughput testing laboratories (CMJAH, Nelspruit, Mankweng, Ngwelezane, Dr George Mukhari, and Universitas laboratories). Medium throughput testing laboratories (Tshepong, IALCH, Edendale, Addington, Madadeni, Nelson Mandela Academic, Port Elizabeth, Frere, Groote Schuur, and Tygerberg) will have the recently launched Abbott Alinity m instrumentation, which is currently being evaluated at the CMJAH laboratory.

Pre-analytical track systems

A total laboratory automation solution for HIV VL testing was made possible through the NHLS CDC Cooperative Agreement (CoAg) Grant that aims to improve pre-analytical processes at 27 PEPFAR-supported districts in South Africa and strengthen and improve access to HIV VL monitoring. The functional pre-analytical track systems were installed at CMJAH, Nelspruit, and Mankweng laboratories. Considerations for inclusion at additional sites, laboratory space permitting, are being explored.

Training

Onsite training for new staff members and refresher training for existing staff, on an ongoing basis. A successful Roche Cobas 6800/8800 training workshop was conducted at the Roche Training Centre, Midrand, from 8 - 12 October 2018. Abbott will also provide training on the Alinity m instrument platform as soon as the new HIV VL tender implementation commences.



Monitoring and evaluation

The monitoring and evaluation of the national HIV VL programme is achieved in collaboration with CDW. Results for Action (RfA) reports facilitate the fast-tracking of all HIV-positive non-suppressed (viral load results of >1000 copies/ml) patients into care. All HIV VL laboratories are enrolled on the Quality Control for Molecular Diagnostics (QCMD) and CDC viral load EQA programmes.

Connectivity

The Abbott M-View portal is functional and will be adapted to accommodate the newer platform, Alinity m instrument. The equivalent Roche dashboard is still in development.

National Early Infant Diagnosis HIV Polymerase Chain Reaction Testing Programme

Overview

In collaboration with the national, provincial, district and local Departments of Health and other partners, the early infant diagnosis (EID) Programme aims to assist in the delivery of quality HIV diagnostic services for neonates, infants and young children by providing training, mentoring, technical assistance, monitoring, and advocacy. The national training on EID for doctors, nurses, counsellors, and facility managers is performed by nursing sisters, Tsakani Mhlongo and Nthabiseng Kekana. The training scope spans from identification of which neonates should be tested, correct administration and completion of the NHLS request forms, quality specimen collection, and paediatric interpretation of HIV PCR and rapid test results, to management of the HIV-exposed including infant prophylaxis, ensuring that all identified HIV-infected infants have access to care.

Operations

HIV DNA PCR testing is performed across nine centralised laboratories nationally. Testing is performed on the Roche Cobas Ampliprep Cobas Taqman (CAPCTM) with a total of 16 systems providing capacity for approximately one million tests per annum. In 2018/2019, 602 795 HIV PCR tests (3% increase from 2017/2018) were performed. The EID assay on the high throughput Cobas 6800/8800 instruments will be made available in Quarter 2 of 2019, allowing two additional laboratories, Edendale and Ngwelezane, to perform EID testing. The Cobas 6800/8800 instruments allow for testing of both EID and HIV VL. The infection rate detection decreased from 2.10% (2017/2018) to 1.98% (2018/2019). The target is <2%. The target set by the NHLS 2019/2020 APP of having 80% of EID HIV PCR tests available within 96 hours was exceeded.

Monitoring and evaluation

In collaboration with the CDW, monitoring and evaluation of the national EID programme is achieved through the facility and RfA reports that are aimed at facilitating fast-tracking of all HIV-positive infants into care. The Missed Diagnostic Opportunities (MDOs) report facilitates careful monitoring of specimen rejections, assists in prioritising training interventions, and is presented at national, district, facility, and training meetings.

Training

National training of hospitals with Maternity Outpatients Units (MOUs) for birth PCR testing remains a priority. Changes to the national consolidated Prevention of Mother-to-Child Transmission (PMTCT) guidelines is expected in Quarter 2 of 2019. In 2018/2019, 2772 HCWs were trained, 879 EID facilities were visited, and 628 Short Message Service (SMS) printers checked for functionality, ensuring results are received to improve linkage to care.

Table NPP2: EID training conducted per month in 2018/2019.

Month	Province	Healthcare workers trained
April 2018	Gauteng, Mpumalanga, Free State	80
May 2018	Northern Cape, KwaZulu-Natal, Free State, Gauteng	209
June 2018	Gauteng, Free State	460
July 2018	Gauteng, KwaZulu-Natal, Mpumalanga, Free State	344
August 2018	Gauteng, Limpopo, Northern Cape, Mpumalanga, KwaZulu-Natal	293
September 2018	Gauteng, North West, Free State, KwaZulu-Natal	288
October 2018	Limpopo, Free State, Gauteng, KwaZulu-Natal, Mpumalanga	371
November 2018	Gauteng, Limpopo, North West	358
December 2018	KwaZulu-Natal, Limpopo	91
January 2019	KwaZulu-Natal, Free State, Limpopo, Gauteng	53
February 2019	Free State, North West, PMU	134
March 2019	Free State, Mpumalanga	91
Total		2772

National HIV Genotyping Programme

Overview

There are five NHLS HIV drug resistance testing laboratories located throughout South Africa: CMJAH, Tygerberg, IALCH, Universitas, and Dr George Mukhari Hospital laboratories. These are managed by the respective laboratory managers and supported by business- and area managers who are directly responsible to ensure continuous service delivery.

HIV drug resistance testing in the public sector is only recommended for patients failing ritonavir-boosted protease inhibitor-based ART. Confirmed resistance to protease inhibitor-based treatment, by means of a genotype, is required before patients can be switched to third-line integrase inhibitor-based ART. The possibility of changes to HIV drug resistance testing is expected, as the treatment guidelines are being updated by the national DoH.

Operations

Across all laboratories, 4409 specimens were processed for HIV drug resistance testing in 2018/2019, which constitutes a 14% increase from 2017/2018. CMJAH (40%), IALCH (22%), and Tygerberg (21%) laboratories processed the bulk of the testing volumes.

Three laboratories are SANAS-accredited for HIV drug resistance testing, and Universitas and Dr George Mukhari laboratories aim to be accredited in the next fiscal year. A new commercial HIV drug resistance kit is under evaluation for possible implementation, with the aim to standardise HIV drug resistance testing across the five laboratories.

The General Practitioner Care Cell Project

Overview

The Foundation for Professional Development (FPD) and the Professional Provider Organisation Services (PPO Serve) embarked on a pilot project to implement a private general practitioner network contracting model to deliver HIV testing and clinical management services.

This novel intervention allows for general practitioners to identify and initiate newly diagnosed HIV positive patients onto ART, using government-funded pharmaceuticals, commodities, and laboratory services, whilst ensuring complete alignment with government standards and protocols, guided by governance controls to prevent fraud and over utilisation. This is being funded by PEPFAR through USAID.

Operations

The pilot programme began in May 2018 with six practitioner practices in the Tshwane District. This was extended to four additional practices in 2019. The NPP's role is to monitor and ensure provision of quality testing services to the general practitioners. A TAT dashboard spreadsheet was established with the CDW to enable monitoring of laboratory test TATs, segregated per individual general practitioner.

Output

Findings of the pilot will inform wider programmatic implementation.

TESTING SERVICES FOR KEY POPULATIONS: TB AND HIV



Department of Correctional Services TB and HIV Programme

Overview

The NHLS is responsible for providing diagnostic laboratory services to the inmate population of the DCS. The Global Fund (grant period 1 April 2016 to 31 March 2019) stream at DCS focused on the following:

- 1. Ensuring that the seven NHLS DCS laboratories (Durban Westville, Barberton, Groenpunt, Tshwane, Pollsmoor, St. Alban's, and Mondeor) remained functional;
- 2. Screening DCS offenders for TB, HIV, and sexually transmitted infections; and
- 3. Continued funding of Xpert Ultra testing.

An annual target of 46 449 Xpert Ultra tests was set.

In 2018/2019 (year 3 of the grant period), funding was earmarked for the 16 prioritised management areas (PMAs) only: Allandale and Pollsmoor (Western Cape); Mthatha and St Alban's (Eastern Cape); Durban and Pietermaritzburg (KwaZulu-Natal); Johannesburg, Kgosi Mampuru II, and Modderbee (Gauteng); Groenpunt, Bizzah Makhate, and Grootvlei (Free State); Upington (Northern Cape), Rustenburg (North West); Barberton (Mpumalanga); and Polokwane (Limpopo). The 16 PMAs comprise 97 correctional centres. The Global Fund supported all Xpert Ultra tests across the 97 centres and assisted with procurement of 90 SMS printers to aid access to TB- and HIV-related results.

Through the second funding stream for DCS from CDC PEPFAR, administered through the Aurum Institute, activities in 2018/2019 focused on the provision of independent quality control (IQC) and PTS for HIV rapid testing across all DCS centres.

Operations

In 2018/2019, 51 005 Xpert Ultra tests were performed, which is 10.04% less than in 2017/2018, with Gauteng contributing the highest test volumes (11 088, 21.74%), followed by Eastern Cape (9 448, 18.52%), and Western Cape (9 212, 18.06%).

The seven Xpert Ultra NHLS DCS laboratories processed 10 516 (20.62%) of the total test requests from DCS, which is 12.69% less than in 2017/2018. 97.3% and 97.0% of Xpert Ultra tests (conducted onsite at the seven NHLS DCS laboratories, or referred to the nearest NHLS Xpert laboratory), were respectively available within the 40-hour target.

The PMAs contributed 34 420 (67.48%) Xpert Ultra tests, with the largest number (4 112, 8.0% of all DCS tests) submitted from St. Albans in Port Elizabeth, 3 550 from Durban (6.96%), and 3 455 from Pollsmoor in the Cape Town (6.77%).

Of the tested Xpert Ultra tests, 2 834 (5.56%) were positive for MTB, with 126 (4.45%) RIF resistant.

In 2018/2019, 27 312 CD4 tests were performed (17.03% less than in 2017/2018) with 4.48% registering values <100 cells/microliter. HIV VL volumes decreased by 1.55%, from 33 422 to 32 905 (2018/2019) with 5 127 HIV VL registering values >1 000 copies/ml (15.58%).

Two hundred and thirty-five active centres were enrolled on NHLS PTS with 47.5% submitting responses. Of the submitted results, 99.1% passed. The DCS centres are receiving their weekly IQC specimens for HIV rapid testing quality control.

Monitoring and evaluation

In 2018/2019, 1867 Xpert specimens were rejected (15.21% decrease from 2017/2018), largely due to insufficient specimen volume. In addition to Xpert Ultra, CD4, HIV VL, specimen rejections rates, and TAT data, screening periods (time period at which the specimen is collected: on admission, bi-annually, at primary health care assessment, X-Ray screening, or on retreatment) were added to the monthly data reported for programmatic monitoring and interventions. Of all Xpert Ultra specimens tested, 6 942 (13.61%) were linked by screening period with 447 (0.88%) positive for MTB. Linkage by screening period made it possible to intervene timeously, to maximise infection prevention and control (IPC) efforts and reduce TB transmission.

Mine and Peri-Mining Communities TB Programme

Overview

Through financial support from the Global Fund, the NHLS, together with the Aurum Institute, was appointed by the national DoH to provide services aimed at improving TB and HIV/AIDS management in vulnerable peri-mining communities, which involves an estimated 600 000 people in six mining districts. The selected six mining districts have a high proportion of mines within their boundaries and are: Lejweleputswa, Dr Kenneth Kaunda, and Bojanala districts in the North West, West Rand district in Gauteng, and Waterberg and Sekhukhune districts in Limpopo.

The NPP provided six Xpert MTB/RIF and Xpert Ultra mobile laboratory units for use in these communities since January 2015 to conduct testing for diagnosis of TB until the grant cessation, which is 31 March 2019. The mobile laboratory units consist of vans equipped as mini-laboratories, with refrigeration facilities, water supply, and generators for electricity supply for the Xpert analysers. There are four GX4 platform analysers per mobile laboratory, with a testing capacity of 16 Xpert Ultra tests every two hours. The mobile laboratories are connected to the LIS, providing patient results on site. Six drivers and six technologists/technicians were employed through the Global Fund mechanism to conduct the required testing.

Operations

The mobile units support the staff of the Aurum Institute during TB campaigns and contact tracing visits to the informal settlements. The Aurum visits include taxi ranks and mines. National, provincial, and district health campaigns are also supported by the mobile laboratory units and provide onsite testing services.

The Mines and Peri-Mining Communities (PMC) TB Programme tested 25 540 Xpert Ultra specimens in 2018/2019, of which 766 (3.0%) tested positive for MTB, and RIF resistance was identified in 32 (4.2%). The revised strategy from door-to-door screening to contact tracing, by the clinical partner, resulted in a significant increase in TB detection rate (87.5% increase)

Regular site visits and meetings are conducted with the mobile team members, parent laboratory managers, district DoH, and Aurum Institute teams for monitoring and evaluation purposes. Quarterly meetings were held between the district health partners and DoH to strengthen relations. At these meetings, TB transmission hotspots were identified, and action plans forged to benefit outcomes of the TB screening campaigns.

National and Provincial HIV Counselling and Testing and Tuberculosis Campaigns and Events

Overview

The NPP was invited to support various HIV counselling and testing and TB screening campaigns throughout the year, including activities around World TB Day, World AIDS Day, and others. The GeneXpert mobile laboratories are deployed at these events and provide onsite molecular diagnostic services for TB screening.

Supported campaigns

The mobiles supported national and provincial HIV and TB Day commemorations throughout South Africa in 2018/2019.

National World Aids Day was commemorated in Dobsonville, Soweto, on 1 December 2018. The national MHSC World AIDS Day commemoration was held at Bojanala, on the same day. Provincial events were held on alternate dates across Eastern Cape, Free State, Limpopo, and Gauteng provinces.

The National World TB Day event was commemorated in East London on 28 March 2019. In addition, mobile laboratories assisted the TB build-up campaigns in all the peri-mining districts (Lejweleputswa, Dr KK Kaunda, West Rand, Bojanala, Waterberg, and Sekhukhune).



Figure NPP7: Limpopo Province World AIDS Day 2018 event, 1 December 2018. Limpopo Minister of Executive Council for Health, Dr Popi Moremi attending a media briefina.



Figure NPP8: Limpopo province World AIDS Day 2018 event, 1 December 2018. The NHLS and Aurum Institute team with the Limpopo Province business manager are seated in front of the Xpert mobile testing laboratory.



Figure NPP9: The MHSC World AIDS Day 2018, in Rustenburg, 7 December 2018. Dr Balfour from the Chamber of Mines attending the media briefing.

DATA MANAGEMENT AND CONNECTIVITY



Overview

For programmatic monitoring and evaluation purposes, the NPP generates an array of monthly and quarterly reports for distribution to partners, funders, the provincial and national Departments of Health, and the TB and HIV coordinators. These reports are prepared in the form of password-protected Excel-based spreadsheets/dashboards to provide multiple, user-friendly views of aggregated, patient de-identified specimen and facility-level laboratory data. The data is extracted via the CDW. Data variables include test volumes, positivity rates, laboratory workflow analyses, TATs, instrument percentage utilisation rates, exception reporting such as tests with CD4 values <100cells/microliter, HIV VL >1'000 copies/ml, and test data disaggregated by sex and/or age.

In December 2016, the Wits Human Research Ethics Committee Ethics granted approval (Clearance M160978) for the NPP to analyse the LIS data, for programmatic monitoring and evaluation purposes under the established Integrated Laboratory Data Analysis for Care (ILDAC) Programme.

Programmatic data requests are directed to the operations manager, who ensures that the data requests comply with the conditions of the ethics approval, prior data release, under the ILDAC programme. Requests for patient identified data are referred to the CDW and Academic Affairs to follow their internal approval processes.

National Laboratory Result SMS Printer Project

Overview

The NHLS bi-directional SMS Printer rapidly delivers HIV- and TB-related results (upon authorisation of CD4 count, reflex CrAg, HIV VL, EID PCR, TB smear microscopy, Xpert Ultra, amended results, and notification of rejected specimens for priority tests). The printers are placed at healthcare facilities which initiate patients on ART treatment with prioritisation of primary and community healthcare centres (CHCs).

The SMS printer has the ability to retrieve patient results when the healthcare worker scans the NHLS barcode placed in the patient folder at the time of specimen collection. The bi-directionality aims to improve rapid delivery of priority diagnostic results throughout South Africa.

Operations

The NPP secured funding and successfully procured 2 096 printers covering primary health and CHCs that provide HIV and TB services. A number of challenges were experienced with the utilisation of the existing SMS printers. To counteract these challenges, the following improvements were implemented in the 2018/2019 financial year:

- 1. A switch was done from SMS to Global Data Services Platform (GDSP), to enable international roaming across all countries and improve network connectivity for the 1 342 existing printers;
- 2. Scanners and power supplies were modified and external antennae were internalised to reduce the likelihood of component loss/removal and installation of 801 version 5 printers were completed accordingly;
- 3. Due to SMS-character and cost limitations, addition of results to the existing test repertoire (creatinine and glomerular filtration rate estimates) were included in the conversion to GDSP technology;
- 4. Additional newer version printers were procured, which increased the healthcare facility coverage from 59.6% to 76.6%;
- 5. A real time monitoring dashboard was established, with capability to drill from province, district, and

- sub-district, to facility-level. The dashboard monitors parameters such as whether units are functional/ non-functional, whether paper is loaded for printing, the battery charge level, connectivity signal strength, scanner status, etc.; and
- 6. Weekly reports are compiled and distributed to business units and national DoH-approved healthcare professionals, listing facilities where printers are non-functional.

In 2018/2019, 2 880 190 results were successfully delivered to healthcare facilities through this mechanism. An SMS printer was furthermore installed at all healthcare facilities which was visited at least once in 2018/2019, to provide support, training, and troubleshooting.



Figure NPP10: Newer generation SMS printer with internalised accessories

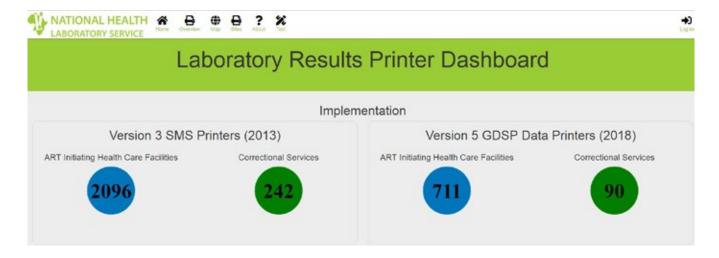


Figure NPP11: Newly developed SMS printer monitoring dashboard detailing implementation status and location of printers



Figure NPP12: The newly developed monitoring dashboard enables monitoring of individual healthcare facilities with SMS printers for functionality, battery charge level, connectivity signal strength and scanner status, on a day-to-day basis

RESEARCH AND DEVELOPMENT TO SUPPORT THE NATIONAL PROGRAMMES

Research and development activities

Overview

The NPP Research and Development Group comprises a multidisciplinary team specialising in applied research and implementation of new laboratory diagnostics for HIV and TB and includes QMS' of high to low throughput testing platforms. The group expanded during 2018 with the inclusion of specialists in biomedical engineering for data mining, and geographic information system (GIS) mapping brought about through the South African Medical Research Council (SAMRC) Newton Fund. Additional scientists and biomedical engineers were also included to focus on evaluating new diagnostic technologies to improve HIV and TB patient care and develop digital health interventions to improve the laboratory value chain.

This was brought about by the Innovation for laboratory Engineered Accelerated Diagnostics (iLEAD) initiative. Two new quality assurance products (Xpert HIV-1 VL thermo stable panel and Xpert MTB/RIF Ultra panel) were developed in collaboration with SmartSpot Quality (Pty) Ltd. The group's output, under the leadership of Prof Lesley Scott, contributed to improved services within the NHLS, knowledge transfers to the NPP, policy development for the national DoH, and global quality management for several diagnostic tests.

Development of verification and external quality assurance programmes

Xpert MTB/RIF EQA and Verification Programme: The NPP Research and Development Group continued to provide technical input to the Xpert MTB/RIF (Cepheid, Sunnyvale, CA, USA) EQA in collaboration with SmartSpot Quality (Pty) Ltd. The latter is a spin-off company that was initiated by the Department of Molecular Medicine and Haematology, where the dried culture spot technology was developed. A new quality panel was developed for verification and EQA of the Xpert Ultra assay, with a dried culture spot to target the new result category 'trace'. The NPP rolled this out nationally and implemented the Xpert Ultra in 2018.

MTB Combo EQA Programme: The MTB Combo EQA Programme, comprising the GenoType® MTBDRplus (HAIN diagnostics, Nehren, Germany) EQA and the Strip Interpretation Analysis (SIA) programmes, provided additional educational support to sites that perform the MTBDR*plus* assay. The programme was developed by the research and development team, and is now managed by SmartSpot Quality (Pty) Ltd. It was offered at 20 sites in 2018, the majority of which were through the AIDS Clinical Trials Group (ACTG) network.

HIV VL Programmes: The research and development team supplied the South African Viral Quality Assessment (SAVQA) panel for instrument verification and evaluation. No new panels were prepared in 2018, but its bio repository was drawn upon. The SAVQA panel was adapted (2017) for Xpert HIV-1 VL (Cepheid, Sunnyvale, CA, USA) instrument verification and successfully piloted at 13 NHLS POC Xpert HIV-1 VL trial sites. The panel was stabilised using a molecular transport medium (Longhorn Diagnostics, San Antonio, TX, USA) to enable sites in remote areas to obtain quality assessment panels, without the requirement of refrigeration or complicated shipping. In 2018, the verification panel was further modified into an EQA panel and supplied to the trial sites via the NPP in June and November 2018. All sites successfully completed an EQA, indicating ongoing acceptable performance at the 13 NHLS POC Xpert HIV-1 VL trial sites. This panel is in the process of being handed over to SmartSpot Quality (Pty) Ltd, to continue managing the panel supply and automated result and report uploading.

Contributing to national health TB policy: aiming for improvements in sensitivity of TB molecular diagnostics

Abbott RT MTB: The Abbott RT MTB assay (Abbott Molecular, Des Plains, IL, USA), designed for the Abbott m2000 platform, was evaluated by the research and development team in 2017. The platform, however, also lends itself to automating existing drug resistance molecular testing processes using the Abbott RT MTB RIF/ INH reflex assay. This was investigated by comparing this assay to the existing GenoType MTBDRplus line probe assay (LPA) platform (Hain Lifescience, Nehren, Germany). Ninety-three culture isolates were tested on both platforms and discordant results were sequenced. Results were presented at the Union Conference (The Hague, The Netherlands, 24-27 October 2018), which showed good performance of the automated system versus the LPA. The m2000 platform is also currently used for HIV VL monitoring, and hence shows the integration of HIV and TB diagnostics on a single multi-purpose platform.

Roche MTB: This approach was similarly applied by Roche, with the development of the new Cobas® MTB assay. on the Cobas® 6800/8800 multipurpose platform. The research and development scientists collaborated with Roche to evaluate their prototype assay, which obtained CE-IVD approval, and also won a scientific research prize at the International AIDS Society meeting (Amsterdam, 2018 Poster #6031. IAS 22-24th July).

Xpert MTB/RIF Ultra: The Xpert Ultra test was initially evaluated by the research and development group in collaboration with the Foundation for Innovative New Diagnostics (FIND) through a multi-site evaluation diagnostic trial. The outcome showed good performance of the Ultra test for the diagnosis of pulmonary TB. This study provided evidence for recommending the assay for the SA National TB Programme, and the NPP rolled out the Xpert Ultra test in September 2017. The performance of the Ultra test was then further evaluated for the use in the diagnosis of EPTB. Three laboratory sites were included in the laboratory verification for the use of Xpert Ultra on alternative specimen types (e.g. broncho-alveolar lavage, cerebrospinal fluid, pus, fluids, etc.). The evaluation yielded good outcomes and a recommendation was made for the implementation of Xpert Ultra testing on EPTB specimen types.

Molecular TB multi-platform evaluation: As a result of the teams' experience in evaluating several molecular diagnostic TB platforms, collaboration with FIND and WHO was strengthened, and a head-to-head evaluation of multiple molecular assays for TB diagnosis was established. The limit of detection and precision of multiple platforms as those mentioned above and others, is under investigation to provide recommendations to WHO. TB diagnostic results will be compared to the Xpert MTB/RIF assay, while resistance profiles will be compared to the GenoType MTBDRplus assay. The preliminary dilution study and the spiking of negative sputum with MTB is complete, with the clinical trial continuing into 2019. This body of knowledge aims to generate a framework for strategising the laboratory diagnostic algorithms for molecular TB tests and the national programmes.

Storage of positive-MTBC cultures: Preliminary evaluation of new TB diagnostics requires trials using stored MTB isolates prior to clinical evaluation. A protocol was developed and approved by the Wits Human Research Ethics Committee to ensure a constant and renewable supply of MTB isolates from residual clinical liquid culture. Briefly, the culture isolate is stored on 24 MicroBank Beads (Davies Diagnostics, Johannesburg, Gauteng, South Africa), each of which can be used to seed a new culture that can also be stored. Stored cultures have been re-inoculated and successfully grown from the microbeads for up to 14 months' post-storage, and a single stored isolate can yield 24 cultures compared to a single one using previous SOPs.

Contributing to national health TB policy: Information technology's superpower and its place in global disease control

A national Xpert MTB/RIF dashboard was developed by the data team in collaboration with BiTanium, with the aim to assist overall programmatic operations and be extended to the national DoH for overall programme performance monitoring. The initial layout was completed, but subsequently modified to incorporate the national roll out of the Xpert Ultra assay. The dashboards were reviewed by the NHLS TB Expert Review Committee and beta testing is ongoing, prior to presentation to the national DoH. The group continues to assist the NPP data analytics team as well as the operations group, using C360 (Cepheid supplier dashboard for Xpert). A full data dictionary and protocol for data extraction and cleaning was developed which feeds into several projects such as:

- 1. The NIOH (R21)-funded GIS TB project that investigated the value of the Xpert MTB/RIF cycle thresholds (Ct) to identify hot spots of TB transmission in the Eastern Cape Province in 2017;
- 2. This was expanded to the North West Province to include spatio-temporal GIS analysis of drug-resistant TB using the Xpert MTB/RIF hybridisation probes as an indicator for mutations conferring resistance. This approach is also strengthening the NPP through the application of GIS mapping to improve operations and ultimately improve patient care;
- 3. The Newton Medical Research Council/South Africa/United Kingdom funded project to investigate mapping of molecular characteristics from the Xpert MTB/RIF assay across districts in South Africa continues in collaboration with the Wits School of Public Health, the London School of Hygiene and Tropical Medicine and Boston University;
- 4. An investigation initiated in 2018 and nested under the Newton Medical Research Council/South Africa/ United Kingdom funded project, aims to determine the association between MTBDR*plus* version 2 assay missing wild types and corresponding Xpert MTB/RIF probes in the greater Gauteng Province, using GIS;
- 5. The group is investigating the melting temperatures output from Xpert Ultra for the identification of individual mutations per RIF resistant test. Preliminary work was presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in March 2019 (Eisenberg et al, Rifampicin Resistance Accurately Identified by Clustering Ultra Melting Temperatures), and may yield algorithms to improve individual patient level care for drug resistant TB; and
- 6. Development of a longitudinal TB/HIV cohort is underway in collaboration with Dr Jacob Bor and Dr William McLeod (Boston University), which will provide the opportunity to evaluate the impact of new TB diagnostics at a patient and population level, recommend interventions and identify areas in need of health-care support.

Innovating the laboratory value chain

iLEAD, which was established in late 2017 within the research and development group, through Bill and Melinda Gates Foundation seed funding, continued to expand and evaluate new technologies across the laboratory value chain (patient local testing, specimen collection, specimen transport, central laboratory testing, and system-wide connectivity).

The portfolio of iLEAD comprises several innovations at various phases of development, and range from technologies with incremental innovation, to those that are disruptive, game-changing technologies. There are currently four active work streams in the iLEAD portfolio: 1. HIV, 2. TB, 3. sexually transmitted infections, and 4. cross-cutting innovations, which are innovations within the digital health space and used across the laboratory value chain.

Several new innovations were sourced and vetted by the iLEAD teams, with a total of 22 projects selected in 2018. These originated from 68 initial, preliminary engagements identified through internal scouting processes, through website engagement (<u>www.ileadinnovation.africa</u>), existing partners or the Bill and Melinda Gates Foundation. Sixty-six of these projects were found to be in scope for further review, and 46 projects were suitable for further investigation, resulting in 22 entering product development. South Africa managed 18 of these, Mozambique two, and Senegal three. One project (Roche Plasma Separation Card) overlapped both South Africa and Mozambique. The portfolio saw five projects being completed, five exiting the portfolio, and 12 retained for ongoing development in 2019, either through iLEAD, the NPP, or the Wits Department of Molecular Medicine and Haematology in Johannesburg, Gauteng, South Africa.

iLEAD continues to expand its portfolio, and screen and develop innovations across the laboratory value chain that ultimately lead to impact on patient care. Selected projects from the portfolio are highlighted below:

- The Plasma Separation Card (PSC, Roche Molecular, Pleasanton, CA, USA) is an alternative plasma specimen collection device that eliminates the need for phlebotomy, provides stable specimen transport, and thereby increases access to accurate HIV VL testing. iLEAD demonstrated the technology to be as accurate as standard of care technologies. The package of delivery was improved for the intended settings, a cost model predicted cost-effective replacement and expansion of access to HIV VL testing (accepted manuscript), the pathway plan to scaled implementation was determined, and the product was presented to key opinion leaders with CE-IVD and WHO approval within 14 months. The PSC was also presented to the NHLS Virology Expert Review Committee;
- 2. eLABs (an electronic laboratory specimen tracking tool) is already being implemented in pilot clinics in Zambia through the Zambian Ministry of Health, and optimised for large-scale implementation in South Africa. eLABORATORYS-South Africa is currently being piloted in Gauteng province (2018/2019); and
- 3. The Deki Reader (Fio Corp) enables continuous quality monitoring and central surveillance of rapid HIV tests in South Africa. A manuscript of an early evaluation was submitted and field evaluations are ongoing.



Figure NPP13: Plasma separation care training conducted in Mozambique, assisted by the NPP trainers

GRANT FUNDED ACTIVITIES TO SUPPORT THE NATIONAL PROGRAMMES

Global Fund to Fight AIDS, Tuberculosis, and Malaria (Year 3)

Activities and progress for the final year of the grant period, Year 3, are detailed.

Provision of Xpert Ultra testing for improved case detection in peri-mining communities

The NHLS's interventions in this programme were to assist the national DoH to improve TB and HIV case findings by working closely with the Aurum Institute, another sub-recipient and the clinical partner, to screen and test for TB with Xpert Ultra in the peri-mining communities. community programme rollout. These six districts were provided with Xpert Ultra-equipped mobile laboratories. The mobile laboratories were run with two employees, a driver/clerk and a technician and were linked to the closest NHLS laboratory which supported the mobiles for reagents, consumables, and overflow of Xpert testing. The 2018/2019 activities are detailed in the 'Mines and Peri-Mining Communities TB Programme' section, above.

Provision of Xpert Ultra testing for improved case detection in the DCS

The NHLS as a pathology group that services the state sector in South Africa, was responsible for testing the inmate population in the DCS for TB diagnosis with the Xpert Ultra test. The success of this programme can be attributed to the face-to-face visits by the NHLS staff to the entire DCS management, to discuss all issues pertaining to a comprehensive care package, and to mentor DCS clinical staff to ensure that the national testing guidelines and algorithms are followed. The 2018/2019 activities are detailed in the 'Department of Correctional Services TB and HIV Programme' section, above.

Xpert Ultra diagnosis in informal settlements

The Global Fund requested that the PMC Programme also supports the Gauteng Informal Settlements Project. The funder allocated 28 742 Xpert Ultra cartridges for TB screening across Gauteng's informal settlements from December 2017 until 31 March 2019. Screening and specimen collection was specifically targeted at informal settlements in the Cities of Johannesburg and Tshwane, as well as Ekurhuleni metropolitan areas. The project processed 8 159 specimens in 2018/2019, and deteced 173 MTB cases of which seven showed RIF resistance.

Provision of Xpert Ultra training for both clinical and laboratory staff

The NHLS implemented the Xpert MTB/RIF test as the initial TB diagnostic test for individuals suspected of multi-drug resistant TB or HIV and TB co-infection from March 2011. Training of personnel is conducted on an ongoing basis, to support the national DoH on the clinical algorithm and to train laboratory staff on the most efficient operation of the analysers, whilst ensuring result quality. The 2018/2019 are detailed in the 'National Xpert MTB/RIF Ultra Testing Programme' section, above.

Infection Prevention and Control training for the DCS

Overview

On 11 December 2012, the Constitutional Court delivered a judgement upholding an appeal against a decision of the Supreme Court of Appeal, which overturned the decision of the Western Cape High Court in an action for delictual damages. The case concerned Mr. Lee who contracted TB while in prison. He sued the Minister for damages on the basis that poor prison health management caused his infection.

Following the Judgement in 2014, a National Task Team (NTT) was formed to address the issue of TB prevention in the DCS. The NTT included representatives of the DCS, the national DoH, and partners.

Joint national approach to standardise the implementation of IPC across all South African correctional facilities was developed. Infection control assessments at correctional facilities were identified as a core requisite to identify requirements and opportunities for improved prevention of TB and other diseases in the DCS.

The Laboratory and Infection Prevention and Control (Laboratory/IPC) sub-committee working group of the NTT commenced with the in-depth baseline IPC audits, which were conducted in 20 correctional centres spanning the six DCS regions in the country. The centres were selected by the regional DCS health services leadership. A second round of baseline assessments, support visits, and follow-up assessments was completed in year 3 of the grant period.

Operations

Prof Adriano Dusé, the IPC team at NHLS and Wits, together with the Laboratory/IPC working group, developed an IPC training course supported by trainer and trainee manuals.

The team conducted follow up assessments in all six regions. A Quality Improvement Tool (QIT) was developed and piloted which aims to track progress of the quality improvement interventions committed to by the centre staff members after completion of training. The QIT also provides guidance on addressing the findings raised by the in-depth baseline IPC assessments. The aim of the follow up visits was to assess whether sufficient measures were implemented in the DCS facilities to address the Constitutional Court expectation of "reasonable steps" being taken to prevent transmission of TB.

Output

- 1. In collaboration with DCS regional staff members, a DCS-specific IPC Policy was developed and SOPs were completed to support the implementation of the IPC Policy;
- 2. A DCS-approved IPC short audit tool was developed. This tool, which is currently in use, serves as a sixmonthly rapid IPC assessment tool which identifies key "red flag" issues;
- 3. The second round of training of 185 custodial and non-nursing officials was completed in February 2018;
- 4. A third round of training at management level was conducted from May 2018 to January 2019, focusing on management areas that were not previously addressed;
- Trainee and trainer DCS-specific IPC manuals were piloted, printed and used in the second round of training. The IPC manual was updated and expanded to include environmental and personal hygiene, and quality improvement methodology;

- 6. A QIT was developed to assist the DCS with tracking the progress of the implementation of IPC interventions, This tool was used at follow up assessments conducted in 2018/2019. There was an overall improvement of 20.3% in the centres assessed within a three- to six-month period;
- 7. Capacity was built to ensure sustainability of training at all levels, including local centre-, regional and national level. Eight hundred and fifty-eight DCS staff members were formally trained during the grant period;
- 8. Conducting the in-depth baseline IPC assessments paved the way for improving IPC systems and processes; for the developing of the IPC Policy and SOPs, the development of the QIT, and for driving change in the DCS:
- 9. The IPC Manual provided the DCS with a comprehensive and practical reference guide. This manual is unique as it was customised for the DCS environment and is the first of its kind in South Africa;
- 10. The use of the IPC QIT has driven change in the DCS as evidenced by the improvement in IPC compliance scores within a relatively short time; and
- 11. The Constitutional Court Judgement of 2012 required that "reasonable measures" for prevention of TB in correctional centres are implemented. The DCS is now equipped with tailor-made training materials, an IPC manual, QITs and practical guidance on how to implement reasonable measures to prevent TB and other communicable diseases and conditions.

Expansion of HIV VL testing services to address gaps in service delivery

Overview

The NHLS provides HIV VL testing services through 16 high throughput centralised laboratory sites throughout the country, but gaps remain in service coverage. The main goal of this pilot was to close identified service-related delivery gaps in provision of HIV VL testing services, utilising the existing Xpert technology (used for TB diagnosis) and its laboratory footprint. The objectives were aimed at:

- 1. Measuring improved access to HIV VL testing services;
- 2. Reducing HIV VL TAT; and
- 3. Decreasing the testing burden at HIV VL centralised sites.

Thirteen district level laboratories across six provinces were identified for placement of additional VL testing services, namely: St Elizabeth, All Saints, Ellisras, Tshilidzini, Bethlehem, Joe Morolong, Tshwaragano, Upington, Springbok, Vredendal, George, Beaufort West, and De Aar.

Operations

Testing of decentralised HIV VL commenced in November 2017 following setup, training, and analyser procurement at the thirteen sites. To distinguish the Xpert HIV-1 VL tests from routine centralised Abbott or Roche VL tests, a test method was established on the LIS (code HIVVLG). The Global Fund supported 35 360 Xpert HIV VL tests with set targets exceeded by 0.5% at the end of the pilot project. In 2018/2019, 25 082 Xpert HIV-1 VL tests were performed, with 74.85% demonstrating viral suppression (≤1 000 copies/ml). Since funding only allowed for eight tests to be conducted per day at each of the candidate laboratories, only 14.92% of the total 168 065 VL requests were processed at the 13 pilot laboratories, in 2018/2019. The main improvements seen were on TATs, as onsite Xpert VL testing was on average completed in 12.3 hours with 99.03% of Xpert HIV-1 VL tests available within the 96-hour target. In contrast, only 80.32% of the VL requests that were not tested onsite and referred for centralised testing, were available within the 96-hour target.

Output

In addition to the setup of thirteen functional Xpert HIV-VL laboratories, the first Xpert HIV-1 VL EQA programme was developed to support maintenance of ongoing QA at all testing sites. Two rounds of EQA were distributed independently, and all thirteen sites demonstrated satisfactory performance.

Improving quality of HIV rapid testing in the field

Overview

Widespread use of RDTs for HIV facilitated scale-up of testing in resource-limited settings and contributed to expediting and accelerating identification of HIV-infected individuals who are eligible for ART. While expanding access dramatically, HIV RDTs at clinic level or other sites outside of the conventional laboratory environment opens up a host of new challenges:

Thus, QA and improvement play a critical role in the strengthening of health systems and are included in the 2016 National HIV Testing Services Policy of the national DoH.

Innovative solutions using wireless telecommunications such as automated readers and smartphone concepts are being developed to address quality issues. These solutions have the capability to standardise the QA of RDTs and facilitate result reporting and data management at testing sites.

The main goal of this pilot was to investigate an option (use of an automated reader) to improve the quality of HIV lateral flow rapid testing.

The pilot laboratory validation to assess the performance (concordance and reproducibility) of the Deki Reader (V100) versus human visual result interpretation (gold standard) was completed on three commercially available HIV RDTs. Overall, the Deki Reader had a 99.5% concordance (n=774 individual RDTs measured) with visual result interpretation.

These results prompted the development of the clinical evaluation protocol in collaboration with Right to Care (ethics approval #M150160). The evaluation was conducted over two phases: Phase 2A and 2B. Phase 2A commenced in May 2017, and served to evaluate the Deki Reader's robustness, operability, data capture and connectivity capabilities.

Phase 2B followed shortly after the completion of Phase 2A (from October 2017 to June 2018). Phase 2B determined the performance (concordance) between visual interpretation by HCWs and the automated Deki Reader interpretation. Of HIV tests performed during Phase 2B, 98.5% followed procedures as per the national HIV testing algorithm. The overall procedural error rate was 9.4%. A discrepancy rate of 0.14% was observed (error rate between screening and confirmatory testing). Overall discordance rates (screening or confirmatory) where visual interpretation (as negative) was device (positive) - 2.45%; where visual interpretation (as positive) was device (negative) - 0.43%.

Based on the outcomes of the clinical evaluation and feedback received from the pilot users of the first generation Deki Reader (V100), a new generation (V200) was developed. The V200 Deki Reader version has improved features. Further laboratory and clinical investigations of the V200 are warranted and the outcomes will inform potential for larger scale-up.



The focus of the grant is on the "Comprehensive HIV and TB Prevention, Care and Treatment Services and Systems Strengthening of Facilities in South Africa's DCS." In the final year of the grant, the scope of work was amended, and this was reflected in the updated SLA between the NHLS and the Aurum Institute. The NHLS's interventions fall into the following categories:

- 1. Enrol DCS facilities on EQA for HIV rapid testing and ensure maximum participation by all the testing sites;
- 2. Ensure that 100% of DCS facilities are submitting their PTS responses timeously;
- 3. Ensure that at least 90% of DCS facilities obtain 100% PTS pass rate during each round of the PT run;
- 4. Ensure that 100% of DCS facilities performing HIV rapid testing are enrolled onto the IQC scheme; and
- 5. Ensure that of the facilities enrolled on IQC, 100% of their testers are trained on IQC handling, running, record keeping, as well as corrective action implementation.

For a single round of EQA: one hundred and twenty-four of 236 active DCS centres failed to return their EQA responses (52.5%). Of those who submitted their responses timeously, 111 of 112 centres performed satisfactorily.

Distribution of IQC materials (positive and negative controls) to all active DCS centres will continue to achieve 100% coverage. Controls assist with daily compliance with the QA aspects of the HIV rapid testing.

Centers for Disease Control Cooperative Agreement with NHLS Grant

The five-year CoAg between the CDC and the NHLS was established in 2015 with the aim to strengthen delivery, expand access to quality laboratory services and enhance healthcare worker and laboratory safety in South Africa. The key area of support under the CoAg involves the use of innovative technologies for the strengthening and improvement of pre-analytical and post-analytical processes for HIV VL monitoring in the 27 PEPFAR-supported districts in South Africa. The overarching goal of the support by the CDC is to strengthen and improve access to HIV VL monitoring.

HIV Viral Load Pre-analytics System Project

An automated in-laboratory pre-analytical system was piloted at three high-throughput HIV VL laboratories: CMJAH, Nelspruit, and Mankweng. The objective of the project was to strengthen and enhance the in-laboratory pre-analytical component of the NHLS value chain through workflow engineering and automation of HIV VL. The placement of the pre-analytical instruments are designed to optimise the analytical utility of the Roche instruments that are currently being used by the NHLS for HIV VL testing (namely the Cobas 6800 and Cobas 8800 analysers). An assessment tool to measure laboratory efficiency pre-automation was developed and used to assess the three laboratories at the end of March 2019.

Post-assessment surveys demonstrated that the pre-analytical instruments contributed to an overall reduction in hands on time (31-45%) by technologists, prior to, and post loading onto the VL analysers. Despite the reduction in hands on time, limited throughput volume increases were noted. The supplier is introducing improvements to maximise throughput and efficiency.

eLABS Digital Health Intervention

The eLABS Digital Health Intervention was piloted in 24 healthcare facilities within the Ekurhuleni and Sedibeng Districts in Gauteng. The key indicators for the project are:

- 1. Improvement in TAT;
- 2. Reduction in specimen rejection rates; and
- 3. An increase in the rate of VL result acknowledgement by the healthcare facilities.

Evaluation of the V200 Deki Readers to improve QA of the HIV RDTs

This project is an extension of the "Improving Quality of HIV Rapid Testing in the Field" pilot discussed above and involves five PEPFAR-supported facilities that perform HIV testing services who will assess the feasibility and usability of the FIO V200 Deki Reader over a three-month period.

Specimen Route Optimisation

The NHLS currently utilises a courier network for the transportation of specimens from healthcare facilities to the laboratories. Couriers collect specimens from the facilities at least once a day and more frequently at the high volume facilities. Motor vehicles are utilised for the transportation of specimens. Transportation however remains largely restricted by provincial boundaries and as such, a model is required to optimise service coverage, TAT, and cost at national level. The Health Economics and Epidemiology Research Office (HE2RO)/Boston University and Right to Care will develop a geospatial cost optimisation model to optimise the transport of the top ten tests (by volume), taking their stipulated TAT targets into account. The primary objective is to determine whether any cost savings are possible by:

- 1. Improving specimen routing;
- 2. Ignoring district and provincial political boundaries; and
- 3. Improving specimen TAT and maintaining specimen integrity.

HIV viral load support

Acceleration of optimised HIV testing is critical in attaining the 95% treatment coverage by December 2020. At present, only one staff member is available within the NPP to coordinate the HIV VL programme and there is a gap in terms of clinical training. The initiation of an additional two million people into the ARV programme requires additional human resources to ensure an effective and successful programme outcome. Recruitment of clinical trainers will ensure that the clinical-laboratory environment is able to provide safe and quality patient care, including reliable testing, clinical proficiency, and professionalism. Technical trainers will ensure that HIV VL testing needs are aligned to national guidelines and help ensure a well-coordinated and functional programme.

2.4.2.4. Academic Affairs, Research and Quality Assurance

Executive Manager Prof. Koleka Mlisana

Academic Affairs and ResearchIntroduction

The main objectives of the AARQA division of NHLS is to strengthen the Academic Affairs, Teaching and Training as well as the Research with Innovation mandate of the organisation whilst maintaining and providing quality improvement processes throughout the platform. The QA unit provides the quality assurance support to the entire NHLS platform aiming to achieve and maintain accreditation of all NHLS laboratories. This division is also responsible for preparation and distribution of various Proficiency Testing Schemes (PTS) to all NHLS laboratories, private laboratories and other African laboratories.

The Academic Affairs and Research (AAR) unit, on the other hand is accountable for the teaching, training and research mandate of the NHLS. This unit, in collaboration with the medical universities and universities of technology supports an academic platform staffed with skilled personnel that provide technical pathology training. The training outputs include skilled pathologists, medical scientists, medical technologists and technicians who are responsible for laboratory service provision. The office provides support for research undertaken mainly in the academic institutions; ensuring cutting edge yet locally responsive research with a focus on translational research to enhance the service platform and influence health policy.

Core professionals in training

The NHLS provides vocational training to registrars, intern medical scientists and student medical technologists towards qualifications as pathologists, medical scientists and medical technologists in compliance with the Health Professions Council of South Africa (HPCSA) requirements. During the 2018/2019 financial year, 59 new registrars and 35 new intern medical scientists were enlisted for training. This increased the total number of interns trained on the NHLS platform by 38% from 47 to 65 by the end of March 2019.

Fifteen intern medical scientists qualified and registered with the HPCSA. The steady increase in the number of intern medical scientists trained on the NHLS platform is a result of the organisation's commitment to address the shortage of medical scientists in the country.

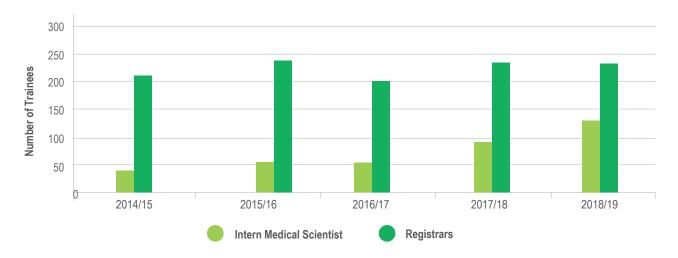


Figure 1: Registrar and intern medical scientists in training on the NHLS platform (including NICD and NIOH).

Two semester exit examinations managed by the Colleges of Medicine of South Africa (CMSA) are written by all registrars at the end of their training period. To qualify to register as pathologist specialists, the registrars must pass this examination and complete a Master of Medicine (MMed) research project. Table 1 and figure 2 below show the results of the examinations completed in March 2018 and September 2018. In total, 81 registrars (41 and 40 in May 2018 and October 2018, respectively) wrote the examinations. The overall pass rate was 38%, with 31 of the 81 registrars passing their examinations (table 1).

Table 1: Registrar pass rates for the 2018/2019 financial period

Discipline	No. Registrars	Passed Exit Exam	Pass Rate
Anatomical Pathology	34	8	24%
Chemical Pathology	11	11 4	
Clinical Pathology	6	4	67%
Haematology	15	6	40%
Medical Microbiology	9	6	67%
Medical Virology	6	3	50%
Grand Total	81	31	38%

The NHLS continues to work with the Expert Committees' Chairs (ECCs) representing the different disciplines in pathology, academic leadership of the SA medical universities and the South African Committee of Deans of Medical Schools (SACOMD) to review and implement initiatives to improve these low pass rates.

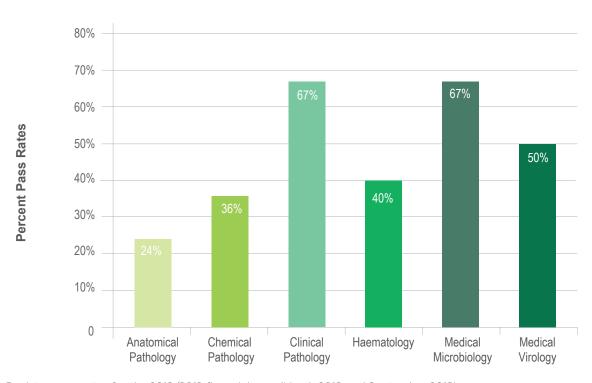


Figure 2: Registrar pass rates for the 2018/2019 financial year (March 2018 and September 2018)

In September 2018, the NHLS commenced with piloting of the Project Extension for Community Healthcare Outcomes (Project ECHO), which is a lifelong learning and guided practice model that revolutionises medical education and exponentially increases workforce capacity to provide best-practice specialty care and reduce health disparities. This was introduced in the form of a network of videoconferencing facilities that links professionals across all ten medical universities in South Africa to provide tailored and focused skills development training to the registrars. The programme is currently funded through the Centers for Disease Control and Prevention (CDC), Atlanta, USA.

Academic support and development

The NHLS in partnership with the 10 South African Universities that offers a degree in medicine and dentistry (hereafter referred to as medical universities) is strengthened through the quarterly meetings of the National Academic Pathology Committee (NAPC) and the Institutional Academic Pathology Committees (IAPC) as well as a number of other NHLS driven collaborative initiatives. The discussions to finalise the Bilateral Agreements (BA) with the medical universities continue and to date five of the 10 have signed the agreement. Discussions are underway to finalise the signing of this BA by the outstanding medical universities institutions. Meanwhile the overarching Umbrella Agreement (UA) that has already been signed by all medical universities is currently under review.

The NAPC also includes the eight South African Universities of Technology (UoTs) and Comprehensive universities (CUs) that offer training for the Diploma in Biomedical Technology (qualifying as medical technologists) and the Bachelor of Health Sciences (qualifying as Medical Laboratory Scientists). The UA with the UoTs and CUs has been finalised and signed by the vice chancellors of seven of the eight institutions. It is envisaged that Tshwane UoT will sign by end of May 2019. Engagements on the bilateral agreements with these institutions started in March 2019 during the IAPC meetings and will continue in the next financial period. Table 2 below lists the 17 universities that are collaborating with the NHLS, including the medical universities, UoTs and CUs.

Table 2 below lists the 17 universities that are collaborating with the NHLS, including the medical universities, UoTs and CUs.

Table 2: Universities collaborating with the NHLS

Medical University			University of Technology/ Comprehensive University		
SMU#	Sefako Makgatho Health Sciences University		CPUT	Cape Peninsula University of Technology	
SU#	Stellenbosch University		CUT	Central University of Technology	
UCT	University of Cape Town		DUT	Durban University of Technology	
UFS	University of the Free State		MUT	Mangosuthu University of Technology	
UKwaZulu- Natal#	University of KwaZulu-Natal		NMU	Nelson Mandela University ^	
UL	University of Limpopo		TUT *	Tshwane University of Technology	
UP#	University of Pretoria		UJ	University of Johannesburg	
UWC#	University of the Western Cape		VUT	Vaal University of Technology	
WITS	University of the Witwatersrand				
WSU	Walter Sisulu University	Ī			

[#]BA not signed

Research support, development and training

Research compliance

NHLS Research Compliance Services support and protect the proprietary interests of the NHLS through policy developments, guidance, monitoring and compliance. This is achieved by ensuring that the NHLS complies with the legislative and regulatory requirements, as well as the practices of the industry within which the

^{*} Umbrella agreement to be signed by the end of May 2019

[^] Current scope includes that of the medical university and the CUs

organisation is operating.

The NHLS filed two invention reports with the Companies and Intellectual Property Commission (CIPC). The NHLS is also filing the second patent application with the Patent Cooperation Treaty (PCT), to have protection for its intellectual property (IP) in various countries. The grant fund to establish the Technology Transfer Office (TTO), was granted last year. The organisation is finalising the establishment of the TTO to manage its IP.

The following policies are in draft stage and will be implemented in the next financial year period:

- Ethics and Governance Policy;
- Research Contracts Management Policy;
- Request for Approval Policy; and
- Data Transfer Agreement and Material Transfer Agreement.

Project extension for community healthcare outcomes

The NHLS introduced Project ECHO as an innovative distance-based training solution which links subject matter speciality experts with the academic centres, to multiple secondary urban and rural learning sites, especially at the sites that are medically underserved. The programme was first piloted in September 2018 for the chemical pathology registrar training programme. The pilot phase focused on the teaching and training through provision of interactive lectures for registrars, in an attempt to improve the Registrar, pass rates which have been low for several years.

This programme is offered to registrars across the ten medical universities at scheduled timeframes, and provides for each of the following disciplines: Anatomical Pathology, Chemical Pathology, Haematology and Immunology, Medical Microbiology, Medical Virology and Research and Development. The other disciplines commenced with their formal training programmes in 2019. The table below indicates the number of sessions that were conducted on each of the disciplines, as well as the average attendance per session.

Table 3: Project ECHO overview for the 2018/19 period

	Number of	Number of learning sites	Average numbers			
Discipline	sessions		Attendance	% Feedback	Weekday	
Anatomical Pathology	10	5	46	0	Tue, Wed or Thu, Fri	
Chemical Pathology	18	14	28	15	Tuesday	
Haematology and Immunology	12	12	56	13	Wednesday	
Medical Microbiology	5	8	51	16	Wednesday	
Medical Virology	4	7	25	9	Thursday	
Research and Development	1	6	28	0	Friday	
Grand Total	50		39			

The programme has been very well received by both the pathologists (trainers) and the registrars (trainees) and is now being expanded to include medical scientists. In the next financial year, the programme will be expanded to other professionals on the NHLS platform.

Research development and training

The research development training and mentorship programme was initiated to promote support for researchers across the NHLS. The initial focus of the programme was to raise funds to support the medical intern scientists programme. To date, this initiative has raised around R10 million for the intake of ten (10) intern medical scientists that will be trained on the NHLS platform, including their two-year work back programme.

The fundraising programme will be expanded in the next financial year.

The NHLS also provides funding for its employees to attend relevant scientific conferences and training seminars, through the Scientific Travel and Events Attendance (STEA) programme for attendance of scientific conferences and training. In the 2018/2019 financial year, the programme supported a total of 528 applicants, 431 (81.6%) of which attended national events whilst the remaining 97 (18.4%) were supported to travel internationally. Four hundred and eighty-nine (489/528) of these applications were funded through NHLS funds and 39 were externally funded (Table 4).

Table 4: STEA applications supported through the NHLS during the 2018/2019 financial year period

		International	National	All	External sponsor	NHLS-funded
Q1	Apr '18	17	17	34	4	30
	May '18	4	9	13	1	12
	Jun '18	6	6	12	1	11
Q2	Jul '18	4	2	6	2	4
	Aug '18	1	282	283	1	282
	Sep '18	20	75	95	11	84
Q3	Oct '18	10	16	26	7	19
	Nov '18	9	11	20	5	15
	Dec '18	13	4	17	3	14
Q4	Jan '19	0	0	0	0	0
	Feb '19	6	7	13	4	9
	Mar '19	7	3	10	1	9
		97	431	528	39	489

Pathology Research and Development Congress

The PathReD Congress is an initiative of the NHLS and offers an opportunity for our researchers, staff, collaborators and stakeholders to unite and gain insights into the research activities of the organisation. In the past, the congress has proven to be a tremendous opportunity for NHLS researchers, especially young emerging researchers, medical scientists and technologists, registrars, and pathologists to connect and experience the diverse culture of research excellence that exists within the NHLS.

PathReD Innovation Summit 2018

The NHLS PathReD Innovation Summit 2018 was held from 1 – 3 August 2018. The summit forms part of the NHLS's strategy to position itself as a key and effective strategic partner for cooperative innovation. The summit was attended by one hundred and fifty-eight (158) delegates, including industry partners, representatives of research institutions, university research and innovation offices, NHLS senior researchers, members of the Executive Management Committee (EXCO) and the NHLS Board.

The summit enabled the NHLS to leverage its strong national footprint and investigate innovative strategies to enhance service delivery and explore options for improved quality and more affordable and sustainable health laboratory services and solutions. The summit outcomes will be incorporated in a comprehensive strategic innovation plan for the NHLS. The following key matters were highlighted during the summit:

- The NHLS must develop an innovative strategic plan to define the direction of the organisation;
- The structure of the IP within the organisation should be based on revenue, service and business development models;

- Researchers must receive induction on the significance of their research as potential IP and for commercialisation. While publications are indeed important, it is critical to understand that potential IP can be lost through the dissemination of such knowledge. It is therefore advised that there is a paradigm shift in the thinking of researchers about publications and patents. The new approach should ideally be based on best practices taken from both developed and developing countries who regard the development of patents as more valuable output from their researchers, than work that is published in academic journals;
- It is essential to leverage existing skills and available national assets and resources optimally, including data from the CDW, national sample pool, renowned researchers, etc.;
- The NHLS must strive for excellence in all its endeavours. To this end, the organisation must form strategic partnerships and networks and must cultivate collaborative relationships with other agencies to promote innovation and grow its innovation platform. This should be aligned to building its own capacity; and
- Resources will be key to successfully execute such an innovation strategy. For this reason, the NHLS should leverage existing opportunities to the maximum, while making a commitment to allocate dedicated funds to this initiative in future.

The Research Innovation Committee of the Board requested the development of the innovation plan to address the findings of the summit and drive NHLS innovation initiatives. The Innovation Strategic Plan is currently in development and an implementation plan will immediately be compiled upon completion of this plan.

Research Strategic Plan

The NHLS Research Strategic Plan (2019-2023) was approved by the NHLS Board. The plan outlines the role of research in maintaining world-class diagnostic services in South Africa and beyond its borders. The organisation's support of research is predicated on the following two main pillars:

- Maintaining and growing pathology-related expertise in South Africa, as a means of ensuring the pathology services provided by the NHLS to the public are relevant and of world-class quality. Underpinning this expertise is the ongoing support of globally competitive research and development, knowledge generation and human capital development within the various pathology disciplines; and
- Providing appropriate, accurate, reliable and competitive diagnostic tests. This requires the selective support of technology research, development, clinical trialling, demonstration and technology commercialisation, which can lead to new or improved diagnostics and diagnostic capability, improved efficiency of diagnostic services and innovative approaches to diagnostic pathology and alleviation of health disparities.

The strategic plan outlines the strategies and interventions that will be adopted to accomplish the NHLS vision. It is centred on the following five key strategic objectives:

- Develop and sustain research programmes that contribute to the knowledge base of South Africa;
- Develop, evaluate and roll out state-of-the-art diagnostic tests to support pathology services;
- Educate the next generation of leaders in pathology and laboratory medicine;
- Create an enabling and healthy environment to work in; and
- Establish scientific knowledge centres that promote innovative research.

This is a five-year strategic plan for the period from 2019 to 2023. The implementation of the strategy will be in the next financial year period and the current focus is to establish expert working groups to drive the establishment of the Scientific Knowledge Centres in the two selected priority research areas, namely, noncommunicable diseases (NCD) and Maternal Child Health (MCH).

Academic Affairs Research Management System

The Academic Affairs and Research Management System (AARMS) was deployed in January 2019. This is an online management system that is utilised to ensure the efficient submission, review, management, monitoring and evaluation of research, scientific and training related applications and output by NHLS staff, the academic community, and stakeholders. Functions of the AARMS include the following:

- User Registration Process;
- Application Process:
 - » Application for Data Request CDW System
 - » Application for Research Sample Request
 - » Application for Permission to Use NHLS facility
 - » Application to Administer Survey and Questionnaire
 - » Application for STEA
 - » Application for Research Funding Through NHLS
- Research Project Registration Only;
- Research Output Profiling Journal publications, Books, Chapters, Research Translations, Abstracts and IP; and
- Standard Reporting.

Grant Programme Management

The main function of the NHLS Grants Office is to provide support to the NHLS researchers whose projects are managed by the office. In the 2018/2019 financial year, the NHLS managed a total sum of over R702 million in funds. The table below shows the top ten grantors that contribute to 83% of the total funds available. The largest grantor is the Centers for Disease Control and Prevention (CDC) US initiative, which contributes about 29% of the total funds.

Table 7: Top ten grantors whose funds are managed by the Grants Finance Office (To be updated)

Grantors	Awarded budget	Total expenditure	Balance available	Number of projects
CDC	224,832,358	152,886,202	71,946,156	41
DoH	98,800,263	91,126,227	7,674,036	2
Department of Science and Technology (DST)	31,766,483	5,533,070	26,233,413	2
Medical Research Council (MRC)	25,280,971	13,277,492	12,003,479	11
Mine Health and Safety Council (MHSC)	12,146,561	2,954,822	9,191,738	1
NCIRD-Epirescoagip001048-02	128,668,704	116,170,978	12,497,726	1
NHLS Research Trust	40,217,818	17,000,400	23,217,418	200
Other	91,502,936	43,767,927	47,735,009	96
The Biovac Institute	31,511,799	8,318,197	23,193,602	1
WHO	17,309,518	4,431,613	12,877,905	6
Total	702,037,409	455,466,927	246,570,481	361

Expert Chairs Committee

The expert committees comprise heads of pathology disciplines (departments) including microbiology, haematology, virology, anatomical pathology, immunology, genetics, clinical pathology and chemical pathology. These committees enable effective communication between academics and executive management. The Expert Chairs Committee (ECC), comprises the chairpersons of these committees of the various disciplines.

During 2018, the expert committees contributed to the performance assessment process for scientists and pathologists by providing input in the assessment matrices and coordinating members for assessment, moderation and review panels. The ECC drafted a list of appropriate laboratory tests necessitating call-outs of staff after hours, to minimise unnecessary call-outs. The committees also supported the 2018 Congress of the Federation of South African Societies of Pathology (FSAS), namely PathCape, in Cape Town.

The committees provide ongoing support to Project ECHO, via remote consultations and online training. The committees also support the health technology assessment (HTA) unit of the Quality Assurance (QA) division of AARQA, with evaluations of new equipment. The committees increased communication around the submission of information on capital expenditure, to ensure that all departments respond to requests for submissions timeously.

The ECC continues to play a significant role in highlighting discipline specific challenges on the academic platform and seek to identify solutions. Anatomical pathology required a review and revision of its operational plans to mitigate the critical staff shortages experienced by the discipline. Clinical pathology as a discipline, needs to be strengthened and requires sustained intake of registrars annually in regions able to train. The ECC also submitted a proposal to enhance retention of pathologists and scientists.

The Quality Assurance Division

The Quality Assurance Division (QAD), is the division of AARQA responsible for the following portfolios at the NHLS:

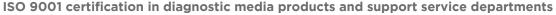
- Accreditation of laboratories.
- Certification of support service departments and diagnostic media products;
- National document control of policies and procedures;
- Evaluation of new in vitro diagnostic devices at HTA agencies;
- Monitoring and compliance of laboratories;
- PPTS and external QA; and
- QA-related projects.

Accreditation and certification

Accreditation of medical laboratories

The NHLS is reporting a record of 21 new pathology laboratories accredited by the SANAS, in line with the International Organisation for Standards (ISO) 15189:2012, compared to 12 in the previous financial year. This resulted in a total of 50/53 (94%) departments in the National Central laboratories, 12/17 (70%)Provincial Tertiary laboratories, 17/44 (39%) Regional laboratories and 11/147 (7%) district laboratories accredited by SANAS.

Three of the four tiers of laboratories show an improvement compared to the previous reporting period. Provincial tertiary is the only tier that did not have any laboratory accredited during the 2018/2019 financial year. The accreditation strategic and APP target for the period under review was met and exceeded by the district and regional laboratories as shown in figure 1 below.



Two of the three diagnostic products from Diagnotic Media Products (DMP) maintained their ISO 9001 certification. The implementation and maintenance of ISO 9001:2015 QMS continued during the reporting period. This financial year concentrated in continued training, closing gaps identified during assessments and conducting internal audits.

The year 2018/2019 had 28 staff members attending ISO 9001 Overview training, 211 underwent the Implementation training whilst 36 attended the course on Internal audits.

Gap assessments were completed in all support service departments at corporate. By the end of March 2019, 18/32 (56%) units addressed 80% - 100% of the gaps identified.

Proficiency Testing Schemes

The NHLS QAD continues to provide PTS to laboratories both inside and outside of the NHLS, to facilitate the implementation of the QMS and measure the quality of the results achieved by these laboratories. In addition to the NHLS laboratories, the PTS enrolments continued to be open to private laboratories in South Africa, as well as countries outside of South Africa. The subscription increased from 4709 in the previous reporting period to 7499 in 25 countries. A total of 53% (3972/7499) of these enrolments were for HIV POCT.

The performance of the NHLS laboratories continued to exceed the annual strategic targets of 90% for PTS performance with 96% of reporting laboratories achieving results above 80%.

During the period under review, QAD continued to contain costs by introducing new internal schemes by participating in the external PTS for certain tests and pay the external suppliers. Therefore, three new schemes were introduced namely; D- dinner; quantitative beta - hCG and a separate malaria Rapid Diagnostic Test (RDT).

Technology transfer for Viral Load PTS started when two staff members attended a one-week training in CDC, Atlanta, USA. A follow up visit by two staff members from CDC Atlanta occurred to complete the second phase in South Africa. This scheme will now be offered by the NHLS from the coming financial year.

Proficiency Testing Schemes accreditation

The number of SANAS-accredited PTS schemes increased from 12 to 13 with Human Immunodeficiency Virus (HIV) and Early Infant diagnosis (IED) having a successful ISO 17043:2010 initial assessment, and the remainder of the schemes maintained their accreditation.

PTS Regional Centre of Excellence for quality

The NHLS QAD continued its responsibilities as the Regional Centre of Excellence (RCE) for the Southern African Developing Community (SADC), by hosting two countries for benchmarking, namely Tanzania in October 2018, and Botswana in November 2018. Representatives from the Cote D'Ivoire region also visited the NHLS PTS outside the SADC RCE agreement with the ministers.

Quality compliance audits

The department underwent many changes during the review period. In addition to the checklist being thoroughly improved, the auditors attended three in-depth training sessions and some of the audits were combined with the SLIPTA audits to avoid multiple audits and increase the number of auditors per discipline in laboratories.

The percentage of laboratories achieving a score of 80% in PTS in 2018/2019 decreased to 79% when compared to 90% in 2017/2018. The reduction in the score can be attributed to the following:

- The top performing laboratories were accredited and not included in this year's analysis; and
- Due to the additional auditors, more gaps could be identified in the laboratories, over the same period.

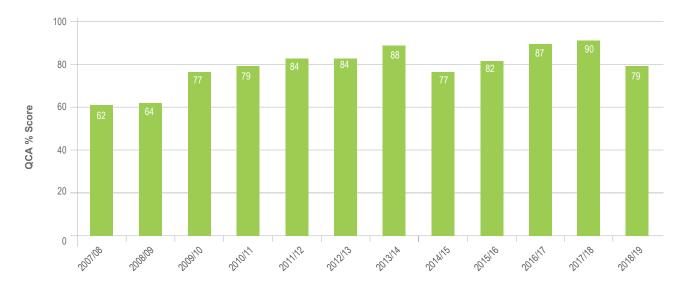


Figure 2: Quality compliance results from 2007/08 to 2018/19 financial years

Health Technology Assessment

The HTA unit of the NHLS continues to ensure that the NHLS complies with various ISO standards for selection of suppliers of devices that yield critical results. The unit continued to work closely with the DoH, the South African Health Products Regulatory Authorities (SAPHRA), and suppliers of in vitro devices in the NHLS to evaluate the performance of devices before they were made eligible for procurement.

The unit embarked on a transformation exercise, which led to modified processes that will in turn improve the response to the requirements of both the NHLS and its suppliers.

During the 2018/2019 financial year, the HTA unit had a total of 63 recorded HTA applications which includes: instrument/upgrade, new instrument, new reagent, POCT instrument, POCT reagent and reagent upgrades. Seven evaluation reports were published on the Q-Pulse Reporting and Incident Management System, of which three were for new instruments and four were for new reagents.

Q-Pulse

The Q-Pulse unit continues to support the control of documents for the organisation. Activities on the Q-Pulse Reporting and Incident Management System during the 2018/2019 financial year, includes the total number of documents that was available on Q-Pulse (8433), activated (2627), deactivated (504) and made obsolete (156). During the reporting period, the Q-pulse team completed in-depth training to equip new and existing staff on different modules and trained a total of 226 staff members.

QAD grant projects

The Continuous Quality Improvement (CQI) project funded by the CDC, continues to complement activities in the QAD for both accreditation and certification purposes, and supports the implementation of QMS at the South African HIV POCT site.

CQI in laboratories and support service department

A multitude of training sessions were conducted, including the following:

- SLIPTA auditor training which yielded an increased number of SLIPTA auditors within the organisation;
- · Training of trainers (TOT) which employs a rigorous teach-back methodology to train trainers; and
- SLMTA 2, which targets the measurement, analysis, and improvement of the requirements of the QMS that performed poorly as identified through the SLIPTA audits.

Both the NHLS local SLIPTA audits and the external ASLM audits were conducted during 2018. Score ratings of 5 stars were obtained in 2/14 laboratories from the local audit and 4/10 laboratories from the ASLM audit.

Implementation of rapid HIV testing PTS

The PTS for rapid HIV testing facilities was conducted at all nine provinces in South Africa during the reporting period, as indicated in figure 4. The HIV POCT Programme that has been funded by the United States President's Emergency Plan for AIDS Relief (PEPFAR) CDC South Africa since October 2016, aims to assess the integrity of the rapid HIV testing processes, and to educate and help improve facilities' performance in QA. The objective of the HIV PTS is to monitor performance and continuously build capacity in the field of HIV diagnostics, by allowing participants to obtain an objective measure of their diagnostic ability and to make improvements, where necessary.

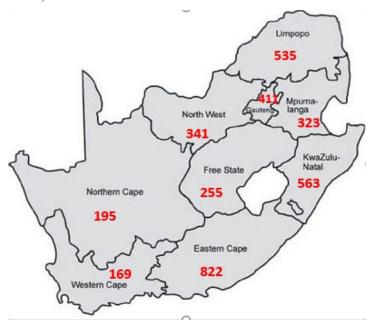


Figure 3: Map showing number of PTS participants per province

A total of 3614 panels were sent out to participating facilities with results submission by email or fax. The average performance of the facilities was above 80% in both surveys, as indicated in figure 4 below.

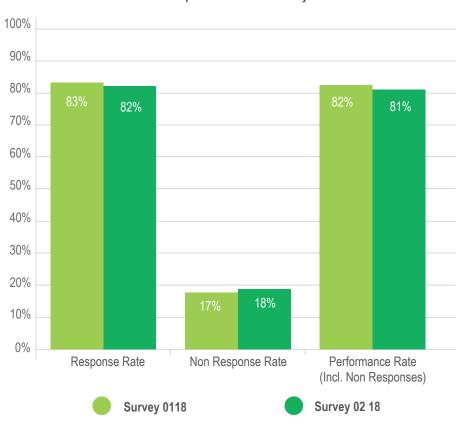


Figure 4: Comparison of survey 0118 and 0218 results

2.4.3. Performance information by institutes



Prof. Lynn Morris

National Institute for Communicable Diseases

Interim Executive Director: Prof Lynn Morris

The National Institute for Communicable Diseases (NICD) plays a vital role in the early detection, containment and response to infectious disease threats across South Africa, the Southern African Development Community (SADC) and Africa. It provides technical support to the National Department of Health (NDoH), as well as the World Health Organization (WHO), Africa Centers for Diseases Control and Prevention (CDC) and other relevant bodies, through surveillance of communicable diseases, outbreak response, specialised diagnostic services, research and training, capacity building and provincial epidemiology services.

The past financial year saw the declaration of the end of the Listeria outbreak by the former Minister of Health, Dr Aaron Motsoaledi, at a press conference held at the NICD on 3 September 2018. The Listeria outbreak highlighted the vital role of the Emergency Operations Centre (EOC) in tackling a public health crisis and the power of molecular epidemiology through next-generation sequencing to pinpoint the source.

Resolution of the outbreak was achieved through the joint WHO/RSA Incident Management Team (IMT) and the combined efforts of WHO, NDoH, NICD and other stakeholders. For this, the NICD received the Alfred Nzo Environmental Health Excellence Award from the NDoH.



Award being presented to Dr Kerrigan McCarthy by the DG of Health, Ms Precious Matsoso

The NICD supported the NDoH in the advancement of the National Public Health Institutes of South Africa (NAPHISA) Bill. Both the Select Committee of the National Council of Provinces and the Portfolio Committee on Health approved the Bill. However, the Bill did not make it through the National Assembly before Parliament closed on 21 March 2019, and will need to be tabled when the new Parliament is reconstituted. This afforded the NICD and the National Institute for Occupational Health (NIOH) further opportunity to streamline some of the shared transversal functions needed for NAPHISA.

The NICD supported the NDoH with the Joint External Evaluation (JEE) exercise of the International Health Regulations (IHR) and led the development of aspects of the JEE action plan. A medical epidemiologist was deployed to the Butembo health zone of the Democratic Republic of Congo (DRC), under the Global Outbreak Alert and Response Network (GOARN), to assist in the Ebola outbreak relief efforts.

The NICD retained its membership with the International Association of National Public Health Institutes (IANPHI) that links and strengthens public health institutes and chairs the Africa IANPHI network. In this role, the NICD supports the implementation of the Africa CDC strategy and the Regional Collaborating Centre in Zambia. The network collaborations have grown with other global public health institutions, formally through a memorandum of understanding (MOU) with China CDC and through maintaining research and training collaborations.

Biosafety and biosecurity is an important and unique aspect of the NICD. A number of biosafety level (BSL) 3 laboratories and a BSL 4 laboratory housed on-site are used to diagnose and research formidable pathogens. The Biosafety and Biosecurity Division played a significant role in informing national legislation for the Hazardous Biological Agent Regulations of the Occupational Health and Safety Act 85 of 1993 and the regulations related to the registration of Microbiology Laboratories of the National Health Act 61 of 2003. The division supported the upgrade of the BSL 3 and BSL 4 facilities and assisted the NDoH with inspections of outside BSL 3 facilities. The division represented South Africa at the NTI Bio Global Biosecurity Dialogue in London and the 5th Global Health Security Agenda Ministerial Meeting in Bali, Indonesia.

The Division of Public Health Surveillance and Response (DPHSR) through the Group for Enteric, Respiratory and Meningeal Disease Surveillance (GERMS) in South Africa surveillance platform, underpins much of the surveillance activities within the seven centres at the NICD. GERMS continues to expand to cover a larger number of pathogens across the country. The Notifiable Medical Conditions Surveillance System (NMCSS) designed for real-time data reporting was successfully rolled-out and received over 6 500 monthly notifications from the National Health Laboratory Service (NHLS) laboratories, and private and public sector clinicians in the past year. The NICD 24-hour hotline handled over 250 calls per month from healthcare providers requesting assistance with laboratory diagnostics and advice on rabies post-exposure prophylaxis.

The Centre for Emerging Zoonotic and Parasitic Diseases (CEZPD) continued to play an important role in supporting the malaria control and elimination agenda of the provincial, national and regional programmes. Routine surveillance by the newly established reference laboratory for Antimalarial Resistance Monitoring and Malaria Operational Research (ARMMOR) addresses the need for regular drug efficacy monitoring to ensure effective malaria treatments are in place. CEZPD is a long-standing partner of GOARN and plays an important role in alerting and responding to public health events by coordinating national, regional and global capabilities for risk assessment, management, communication, operational research, training and preparedness. In recognition of this role, the NICD was re-elected for another four-year term as a member of the GOARN Steering Committee.

The Centre for Enteric Diseases (CED) continued surveillance of acute diarrhoeal disease and national listeriosis surveillance. Nationally, the centre actively participated in outbreak investigation and response activities for more than 20 outbreaks, providing technical and epidemiological support, as well as performing diagnostic and reference laboratory testing.

The year under review presented a number of high-profile outbreaks of neonatal sepsis in public sector hospitals.

The Centre for Healthcare-Associated Infections, Antimicrobial Resistance and Mycoses (CHARM) assisted in identifying the source of these outbreaks and piloted several interventions including a new surveillance programme (called Baby GERMS), a mobile application (APP) to detect neonatal unit outbreaks (NEO-HAI) and a plan to train healthcare workers in neonatal units.

Scientists within the Centre for HIV and Sexually Transmitted Infections (CHIVSTI) were part of the team that successfully performed a liver transplant from an HIV positive mother to her HIV negative child. This groundbreaking study creates a potential new pool of living donors that could save more lives in the future. The antenatal HIV seroprevalence survey conducted at the NICD now includes new measures of HIV incidence estimates as well as the accuracy of HIV rapid testing. An interactive web-based dashboard was developed to triangulate data from multiple sources for paediatric HIV surveillance. The STI section has focused on the monitoring of antimicrobial susceptibility profiles for the emergence of extensively drug-resistant (XDR) Neisseria gonorrhoeae resistance to extended-spectrum cephalosporins (ESCs).

The Centre for Respiratory Diseases and Meningitis (CRDM) through the NMCSS and syndromic surveillance platforms documented a nationwide increase in the number of pertussis cases. This data was presented to the National Advisory Group on Immunisation (NAGI) and guided policy recommendations on vaccination. CRDM also completed enrolment and follow-up for the Prospective Household Observational Cohort Study of Influenza, Respiratory Syncytial Virus and other Respiratory Pathogens Community Burden and Transmission Dynamics in South Africa (PHIRST-SA). This is a large and intensive study of the community burden and transmission of important respiratory pathogens (influenza, respiratory syncytial virus, pertussis and pneumococcus) aimed at providing data to guide the most appropriate strategies to control and prevent these diseases.

Tuberculosis (TB) continues to be a national priority in terms of disease burden in South Africa. The Centre for Tuberculosis (CTB) completed the first ever national TB prevalence survey and data are being used to find the missing TB patients. Geospatial mapping in 21 priority districts was used to identify hotspots of TB and to guide implementation plans for targeted interventions by the NDoH and partners. The CTB also defined interpretive criteria for identifying bedaquiline resistance that is being used to set global policy.

There were 50 measles cases confirmed over the past year by the Centre for Vaccines and Immunology (CVI). Since measles is targeted for elimination in the African region, each case is investigated to ensure that there is no further spread of the disease. CVI identified vaccine-derived poliovirus type 2 (VDPV2) from 57 samples in the DRC, Niger and Mozambique. A case of immune-deficiency associated vaccine derived poliovirus (iVDPV) was identified in a child born with an inherited genetic immune disorder. The event prompted an outbreak response with multiple stakeholders including the national and provincial departments of health, WHO and the United Nations Children's Fund (UNICEF).

The National Cancer Registry (NCR) continued to serve as South Africa's main source of national cancer incidence data, through pathology-based cancer surveillance. The NCR released the first Ekurhuleni Populationbased Cancer Registry (EPBCR). incidence report and published key research in cancer epidemiology and genetics.

The South Africa Field Epidemiology Training Program (SAFETP) was one of six in Africa to be accredited by the global Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET). This is a 2-year, competency-based training programme, that was initiated in 2006, as a collaboration between the NDoH, the NICD and the U.S. Centers for Disease Control and Prevention (CDC), to build field epidemiology capacity for the country. SAFETP uses an established applied epidemiology curriculum, providing an accredited Masters in Public Health (MPH) degree from the University of Pretoria (UP) and a Masters in Science (MSc) degree from the University of the Witwatersrand (Wits), with mentored competency-based practical field experience. To date, the programme has trained 94 health professionals of which 83 have graduated. In 2018, SAFETP had a cohort of 11 first-year and seven second-year residents that were involved in 25 outbreak investigations, conducted 15 large database analyses and completed six surveillance evaluation projects.

SAFETP also builds epidemiology capacity for the Provincial Department of Health through the Frontline short course in-service training. In the year under review, 54 participants from Gauteng and Free State Departments of Health and for 12 participants in Lesotho for the Lesotho Ministry of Health were trained.

The NICD houses seven WHO reference laboratories and maintained a South African National Accreditation System (SANAS) accreditation of all its laboratories. The Proficiency Testing Scheme (PTS) performance reported a success rate of 96% for the past four years with 98% successful returns in the period under review. There were also a number of laboratory refurbishments and other infrastructure projects and the acquisition of a new sequencing instrument, PacBio Sequel, the first on the African continent.

The Communications Unit expanded during the reporting period, in which media coverage grew significantly across the world in terms of people accessed; broadcast reached over 804 million, online 188 million and print media 37 million respectively. It also monitored over 2 021 news items and articles. The NICD Pulse, an internal newsletter, launched in May 2018, published four issues with a reach of 657 email users per issue. The integrated electronic newsletter, Round-Up, summarised weekly communicable diseases news and 18 pieces were circulated to staff on a weekly basis via email. Four issues of the Science Focus were published, profiling the research publication output with a reach of 1 657 per issue. A total of 180 peer-reviewed articles were published in the last financial year in journals with high-impact factors, such as the New England Journal of Medicine, Lancet Infectious Diseases, BMJ Global Health, Lancet Global Health, Cell Host and Microbe, Nature Communications and Lancet HIV. An integrated approach to the use of social media platforms has also enabled the institution to monitor and dispel rumours concerning communicable diseases outbreaks. Facebook reached over 54 800 users and continues to grow while Twitter reached over 335 700 users. A total of eight videos were produced, and nine audio podcasts were recorded. In addition, 72 infographics were produced; these were aimed at strengthening information reach on communicable diseases and engagement. The NICD's website (www.nicd.ac.za), a primary entry point for visitors, was revamped and attracted more than 109 600 visitors accessing the site as it holds a significant repository of communicable diseases content spanning over many years.

The stability of the NICD IT infrastructure and systems availability exceeded 99%, and the user satisfaction scores improved by 34% from the previous year to a final satisfaction rating of 77%. With a full complement of staff, a new local area network was established with an increase in local data throughput to 10Gbps. Skype for Business was implemented to enable efficient unified communications and the specialist call phone for the NICD hotline was fully, digitised, and a new mobile application was developed. A number of new innovations were developed to streamline data collection for the Cancer Registry, private laboratories data and medical aid data acquisition and the replacement for the GERMS access databases.

The NICD has achieved its diverse range of activities through the dedication and commitment of its 507 employees, 78% of this critical skill pool held permanent positions while 22% were grant-funded employees. A total of 76 new staff members were recruited in the last financial year with an average staff turnover of 1.5%. Capacity building was supported through the 318 workplace skills plan interventions and the six internal workshops on recruitment, performance management and disciplinary processes.

Staff at the NICD continue to strive for excellence and for improvements in public health and I would like to thank them all for their hard work over the last year. The donors, partners and collaborators are acknowledged for contributing to the success of the NICD.

Performance information by institutes



National Institute for Occupational Health

Acting Executive Director: Dr Spo Kgalamono

Under the leadership of the NHLS, the NIOH had numerous highlights in the area of OEHS. The multidisciplinary teams of the institute participated in a substantial number of challenging OEHS engagements in both the public and private sectors, ranging from partaking in cutting-edge research at a national and global level, to supporting innovative programmes to reduce workplace violence. In the process, the NIOH collaborated with a significant number of key players in the world of work; locally, nationally and internationally. This in turn contributed to the institute gaining a new body of knowledge that will enhance and supplement our future efforts to help ensure OEHS in all workplaces.

Prevention of occupational and environmental diseases and injuries

The NIOH continued to collaborate with government departments, the private sector, trade unions and employer organisations to instil a culture of prevention in workplaces. This is not only aligned to the NIOH's mission to help reduce the national and global burden of disease through workplace interventions, but it also serves as a notable contribution to achieving the SDGs of the UN, especially those that address health, decent work and gender equity. The successes of these efforts confirm the importance of the independence and unique expertise of each department in the NIOH, as well as its collective role as part of the NHLS, as a critical national resource.

The changing world of work

The NIOH conducted a number of teaching and training initiatives to integrate the local, regional and global changes that have a notable impact on OHS, such as changes in the arrangement of work and technology, including digitisation and ICT, platform work, artificial intelligence, automation and robotics. There is also a multitude of traditional OEHS risks such as TB, exposure to silica and asbestos, occupational allergens, cancer and occupational stress that continue to re-emerge across continents and between developing and developed countries that require new approaches to worker and community health and safety. The emergence of new technologies and innovations provide ideal opportunities to establish sustainable preventive practices in OEHS.

Gender and the world of work

During previous financial years, with assistance from national and international gender experts as well as the NIOH Gender Committee, the institute conducted an extensive review of OEHS systems, which included a participatory gender audit that indicated that gender issues are not sufficiently addressed in the world of work. Based on the findings of the audit, the NIOH launched the Gender@WorkProgramme which enjoys the full support of government departments, trade unions, employer organisations and international agencies. The programme celebrated its third anniversary on 8 March 2018 and has contributed significantly to greater gender equity in the world of work over the years. Through the programme, the NIOH has also provided input in a critical issue that affects workplaces locally and globally, namely violence at work.

Specialised and other services

The NIOH and its partners in government and in the private sector implemented a comprehensive range of activities to address OEHS needs in different sectors of the economy. These activities include but are not limited to:

- OEHS policy advice;
- Teaching and training;
- · Technical support to several government departments, trade unions and employers;
- Research:
- A number of OEHS surveillance and information services; and
- Provision of specialised laboratory services.

The NIOH furthermore enhanced the understanding and practice of workplace ethics among OEHS professionals, an activity that will continue to remain a priority.

The NIOH also continues to provide discipline-specific information to many industrial sectors and government departments. Its laboratory services include:

- Asbestos identification and counting;
- Diagnostic lung pathology;
- Analytical chemistry (e.g. for biological monitoring of specimens);
- Identification of components of dusts and respirable crystalline silica in particular;
- Microbial air sampling;
- Allergy diagnostics;
- Nanoparticles; and
- In vitro risk assessments.

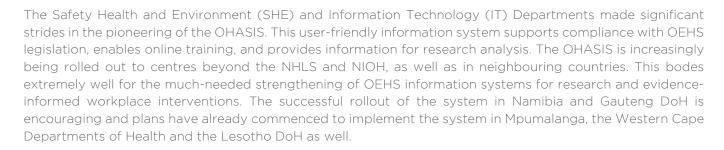
Discipline-specific services include:

- Occupational medicine:
- Ergonomics;
- Occupational hygiene;
- · Occupational toxicology, immunology and microbiology; and
- Occupational epidemiology.

As is the case with many national institutes of health around the world, and partly due to the general scarcity of sources of information, information services is a core service in South Africa as well. The unique national occupational health library continues to provide support and information well beyond the borders of South Africa.

The Biobank that is located in the NIOH, grew significantly in the year under review, and is successfully housing thousands of specimens from different government departments. The Workplace HIV and TB Unit continues to make important contributions to both scientific research and service delivery, especially in the mining and health sectors, in close collaboration with the WHO and the ILO. This includes support for health workers through the rollout of training in different countries in Southern Africa through the WHO/ILO HealthWISE Programme.

The Marketing and Communication Section continued to raise the profile of the institute through strengthening engagement with OEHS programmes nationally and internationally, and coordinating the development of a new website, as well as through thought leader pieces and editorial placements in a multitude of publications. During the period under review, the Finance and General Services Section also made sure that NIOH building is strategically and meticulously upgraded in line with the relevant health and safety standards.



Research

The NIOH aims to continue generating new knowledge through the rigour of good scientific research on key OEHS issues, especially those that affect South Africa and the rest of the African continent. Collectively, the research projects completed are testimony to the many OEHS issues that require new knowledge. It is also important to grow the scope of the institute's research efforts and to strategically increase engagement of younger researchers. This was especially evident in the presentations by young researchers at the NIOH Biennial Research Day.

It is notable that the research focus of the NIOH has increasingly broadened to include aspects of environmental health, gender concerns and reproductive health, informal economy, problems related to coal workers and climate change, as well as important policy concerns. The scientific publications demonstrate a focus on many of the priority OEHS issues with which our country is faced. The topics covered included:

- Asbestos exposure in schools and homes;
- Preventing TB in individuals with silicosis;
- TB prevention in healthcare workers;
- Noise-induced hearing loss and hearing conservation;
- Occupations and lung cancer;
- Water quality in hospitals;
- Health effects in populations living around gold mine tailings;
- Pesticides: and
- Nanoparticles and health.

International collaboration

The annual report details the institute's extensive collaboration with neighbouring countries in Africa, including joint work with the Africa Union (AU) and the New Partnership for Africa's Development (NEPAD). The NIOH participated with the AU and NEPAD in a TB side event when the UN General Assembly adopted the declaration of the first-ever UN high-level meeting on ending TB. It is envisaged that, through the NHLS and the International Commission on Occupational Health (ICOH), the NIOH will continue to support the active role of workplaces towards the implementation of this declaration.

Through active participation in the committees and subcommittees of the century-old ICOH, the institute has excellent collaboration with colleagues and OSH institutes across the globe. Members of the NIOH are often also the lead in these committees. The institute works extensively also with different departments in the ILO to provide research and service delivery, as well as teaching and training in Southern Africa.

As a WHO Collaborating Centre, the NIOH collaborates with many of the 44 WHO Collaborating Centres, including those from the Brazil, Russia, India, and China (BRICS) countries. The NIOH is also a leading coordinating centre for the global project on the informal economy and vulnerable workers.

Key public health reports

The NIOH is proud to be associated with the collaborative development of reports, which we trust can be catalysts for ongoing collaboration and implementation of more systematic OHS services for health workers. This includes a road map for OHS for health workers in South Africa, a situational analysis of OHS in one of the provinces and a position paper for the ICOH on TB in health workers.

The future

Looking to 2019 and beyond, the NIOH will continue to help reduce the decent work deficit in our country, support ongoing efforts to reduce workplace inequality and strengthen the protection of human rights. Given the heavy burden of disease, it is incumbent upon the institute to help nurture a culture of greater prevention of OEHS diseases and injuries and to urgently find ways to continue to support greater OEHS awareness.

Health challenges, such as hypertension, diabetes, TB and stress, which are very often exacerbated by poor conditions of work, will also be addressed. Important areas that will require more attention relate to OEHS gender concerns, and OEHS for migrant workers, subcontracted workers, young workers and workers with disabilities.

It is the aim of the institute to systematically contribute to specific areas of work such as the end of TB by 2030 and support for the SDGs. The NIOH staff members and the City of Johannesburg made concerted efforts on a voluntary basis throughout the year to provide workers in the fields of security, cleaning and gardening services with training. This involved skills ranging from fire fighting and first aid competency, to basic computer training. More strategic efforts are however required to reach more workers in precarious work.

Conclusion

The NIOH invites key role players from the world of work and the broader South African public to participate in the journey to build on our collective strength to utilise the potential of all workplaces for better OEHS, decent jobs, safer workplaces, the protection of human rights, greater productivity, greater equity and ultimately, sustainable economies.

2.4.4. **Support Services performance**

Information Technology



Digital business strategy

The healthcare industry, like most industries, is also on a digital business transformation journey. This means we face the same challenges and are presented with the same opportunities to leverage new technologies that arise from the Fourth Industrial Revolution (4IR). The aim of IT is to be a strategic enabler to the business operations of the NHLS and to ensure that the organisation transforms into a digital business. This will be achieved through the implementation of robust infrastructure and innovative digital and analytics solutions.

An IT strategy and roadmap was developed and approved by the NHLS Board. The main objective of this strategy is to articulate the vision and provide a roadmap on how IT will enable the NHLS to achieve its business objectives, transform into a state-of-the-art laboratory service and become a sustainable digital healthcare business. The strategy also outlines strategic IT actions, which will be executed to enable the NHLS to strengthen its service delivery, and improve operational- and cost efficiency.

Data and analytics

The CDW of the NHLS is a strategic source of laboratory test data that presents the organisation with an opportunity to effectively use data and analytics to drive innovation, improve efficiency and enable evidencebased decision-making. A number of dashboards and reports with actionable business insights were produced by using data from the CDW. These analytical dashboards enabled the NHLS to monitor a wealth of business elements such as revenue, laboratory test volumes, the prevalence of TB and controllable expenses. It also enabled the organisation to improve reporting on the strategic initiatives that form part of its annual performance plans (APPs). The plan is to enhance the capability of the CDW even further, to enable the provision of more business insights that will lead to the improvement of cost optimisation, laboratory test TATs, workforce modelling and customer billing, to name but a few.

Business operations digitisation

A number of projects were implemented in the 2018/2019 financial year, with the aim to ensure that the NHLS commences its journey to transform into a digital healthcare business. Amongst other, this includes:

- Rollout of the web-based Academic Affairs and Research Management System (AARMS), to enable online research applications management;
- Upgrade of the LIS to the latest version, to improve user functionality;
- Integration of the LIS with the Health Patient Registration System (HPRS), which is a flagship project by the national DoH aimed at improving patient data management and establish a foundation for the successful rollout of the NHI:
- Development of interfaces with a number of healthcare facilities and other healthcare industry partners to deliver the replicable and context-appropriate implementation of a health information exchange model for clinical data;
- The Continuous rollout of the Enterprise Content Management (ECM) solution, to digitise critical business documents and improve efficiency in the work flow of the business; and
- Implementation of a contract management system to monitor procurement expenditure and commitments.

Infrastructure and connectivity optimisation

Network infrastructure and connectivity remain a business challenge for the NHLS and projects aiming at upgrading the infrastructure kicked off in the 2018/2019 financial year. These included a local area network (LAN) upgrade project to refresh the following sites: Sandringham, Braamfontein, Chris Hani Baragwanath Hospital and Charlotte Maxeke Academic Hospital (CMAH). In an effort to address network bandwidth challenges, the NHLS partnered with the Council for Scientific and Industrial Research (CSIR), and it is now part of the South African National Research Network (SANReN), which is a high speed connectivity network operated by the Tertiary Education and Research Network of South Africa (TENET). To further improve business operations and increase productivity, network bandwidth was upgraded at a number of prioritised NHLS sites.

Conclusion

With this knowledge that Information Technology is a critical and a strategic enabler of the NHLS' current and future success, we will continue to fulfil our role to ensure that the environment is fit for purpose and designed for agility and efficiency. Furthermore, we will continue to enable business to achieve its mandate among others, laboratory test TATs, workforce modelling and customer billing as part of our plan to enhance the capabilities of our Technologies. We will improve the business operations by continuing to upgrade our network infrastructure and bandwidth to the rest of the NHLS sites.

Support Services performance

Communication, Marketing and Public Relations



Introduction

Communication is not only one of the most powerful tools that any organisation has to drive and support its business objectives, but it is also the bridge between confusion and clarity among stakeholders. Taking this into consideration, the Communication, Marketing and Public Relations department ensured that the flow of information between the organisation's internal and external stakeholders is as seamless as possible, in the 2018/2019 financial year.

This is in direct alignment with the main purpose of the department, which is to ensure that communication across the NHLS is well coordinated, effectively managed and responsive. We accomplish this through a blend of communication services such as public relations, editorial placements, photography, graphic design and website management. The department also works closely with the communication departments of the NHLS institutes, namely NICD and NIOH. In the reporting period, the senior communication manager resigned from the department, but this did not have any significant impact on its performance, as the department continued to deliver productive results.

Annual report

The department successfully produced the 2017/2018 NHLS annual report in line with National Treasury guidelines, through engaging the various departments and coordinating and consolidating input from them.

Media relations

The department continued to maintain good working relationships with the media, by building the organisation's reputation, communicating key organisational events and responding to media queries, as necessary.

Corporate social responsibility

The department supported and coordinated the Cell C Take a Girl Child to Work Day, which took place at the Sandringham offices on 24 May 2018. At the event, we hosted 20 Grade 10 to 12 learners from KwaBhekilanga Secondary School in Alexandra township. The theme of the initiative was: "Facing Fear and Embracing Ambition," with the aim to wake these learners up to possibilities by exposing them to the real world of work and the different cultures in various organisations.

Editorial services

The Editorial Services unit facilitates information sharing between external and internal stakeholders through utilising various communication channels such as newsletters, advertorials, intranet and the Internet.

One of the highlights in the reporting period includes the placement of an advertorial in the Africa Outlook magazine, to create awareness of the NHLS and its contributions to the health sector. This magazine is published in both digital and print format and its readership comprise C-suite executives and key decision-makers across a wide range of industries on the continent. To view this article, simply follow this link: https://www.africaoutlookmag.com/outlook-features/national-health-laboratoryoratory-service-nhls

Graphic design services

The department's graphic design services brought a specialised skill to the table and undertook numerous creative projects such as the design and layout of conceptual artwork for several purposes such as ensuring that the organisational corporate identity and branding is maintained across all creative elements.

This included the creation of a logo, design of marketing brochures and newsletters, and artwork for mailers and exhibition stands. The team also designed academic posters for conferences in which the organisation's employees participated in, including those who work for the NICD and the NIOH.

Among the creatives designed, were the NHLS human resources newspaper advertisement that was shortlisted for the best advert design by the Times Media Annual Recruitment Awards (AMARA). The team also completed a logo for the AARMS and coordinated the branding of all the NHLS and NICD visitors centres, as well as the artwork for the Pathology Research and Development (PathRed) Congress in 2018.

Conferences

The 5th South African TB Conference

In line with its responsibility to enhance the reputation of the organisation, the Communication, Marketing and Public Relations department exhibited at several conferences to strategically position the organisation and continue to grow the brand presence among targeted audiences. One such conference, was the 5th South African TB Conference, which provided an ideal platform to position the NHLS brand and engage with current and potential stakeholders. The conference was hosted at the Inkosi Albert Luthuli International Convention Centre Complex, more commonly known as the Durban ICC, from 12 - 15 June 2018. The department partnered with the NICD TB Unit and the National Priority Programmes (NPP), to showcase the NHLS flagship TB programmes. All queries, comments, suggestions and concerns raised at the conference were noted and reported to the organisation's leadership after the event.

2018 Southern African HIV Clinicians Society Conference

The Southern African HIV Clinicians Society (SAHCS) Conference was held at the Gallagher Convention Centre in Johannesburg, from 24 - 27 October 2018. The focus of the conference was on HIV/AIDS clinical content, which differentiates it from similar conferences held to date in South Africa. The Communication, Marketing and Public Relations department partnered with Diagnostic Media Products (DMP) to showcase the NHLS products. The SAHCS is a membership organisation of over 3000 health care workers with an interest in HIV. The SAHCS's mission is to promote evidence-based, quality HIV healthcare in Southern Africa. The congress served as a platform for the clinicians to share best practices, acquire knowledge and debate innovative approaches for combating global threats.

Photographic services

The department's photographic services are instrumental as it helps to ensure the maintenance of the organisational memory, through capturing and storing all organisational images. In the period under review, the unit captured a total of 2546 photographs, a number of which was also captured at the various NHLS regions. All these photos are available on the ECM drive.

Promotional items

It is important to showcase the organisational brand at all NHLS events. The department is responsible for executing this task through procuring and distributing promotional items to support all organisational events.

Web management services

The web management services unit is responsible for content management, and offers a specialist service, which keeps internal and external stakeholders informed of activities in the organisation through updating, uploading and communicating organisational information on the intranet, Internet and all communication channels. The department embarked on a project to refresh the NHLS website by evolving the look and feel and making it more user-friendly.

Conclusion

The department is striving hard the fulfil its mandate and be more visible in the organisation.

2.4.5. Performance Information by subsidiary



South African Vaccine Producers

Former UN Secretary-General Kofi Annan said: "Snake bite is the most important tropical disease you've ever heard of." Mr Annan firmly believed that victims of snakebite envenoming should be recognised and afforded greater efforts at improved prevention, treatment and rehabilitation. During the last years of his life, he advocated strongly for the WHO and the global community to give greater priority to this disease of poverty and its victims.

Snakebite envenoming (SBE) affects as many as 2.7 million people every year, most of whom live in some of the world's most remote, poorly developed communities. Annual mortality statistics are between 81 000 and 138 000 with 400 000 surviving victims suffering permanent physical and psychological disabilities (source: PLOS One: Neglected Tropical Disease).

The following are interesting facts about snakebites:

- Snakebites are common in impoverished rural areas;
- Snakebite envenoming is an occupational and environmental disease;
- Snakebite envenoming can lead to chronic disability, including amputations, post-traumatic stress disorder and blindness; and
- Intravenous administration of antivenom remains the only specific treatment for systemic envenoming.

South African Vaccine Producers (SAVP) sold 12 302 units of antivenom in the last financial year. This is an increase of 13% from the previous year. Polyvalent antivenom is the biggest seller, followed by Scorpion, Spider Boomslang and Echis antivenoms.

Small animals

The small animal unit is still being run as a conventional unit, as a direct result of the prolonged strike action in August 2017. All bedding and water that are utilised in the unit are sterilised and we have not yet had any disease outbreaks.

It is hoped that the unit will once again be able to use and offer specific-pathogen-free (SPF) animals by 2020. We have budgeted for revamping the SPF1 unit and decided to split the upgrades into phases. The first phase will entail physical building renovations, i.e. re-screeding of floors with epoxy, painting of all walls and ceilings, and sealing of all expansion joints. Contractors were engaged to evaluate the current state of the unit and renovations will commence in the second quarter of the new financial year.

A request to for an upgrade of the air handling equipment services was submitted. A meeting with the biosecurity department and specialists was scheduled for April, to finalise the specifications. It is envisaged that the new services will commence in the second or third quarter of the 2019/2020 financial year. This will enable the unit to become compliant with international regulations and compete effectively.

Despite a downgrade, SAVP continues to supply various universities with animals, including Wits, Sefako Makgatho University, the universities of KwaZulu-Natal, Johannesburg, Cape Town, Pretoria, North West, Nelson Mandela Metropolitan, and on occasion, the Eastern Cape (previously Transkei).

The National Control Laboratories in Bloemfontein suspended the importing and purchasing of animals for safety testing of drugs. This is as a result of changes to their testing methods and is not related to the SAVP's downgrade. We also continue to supply Retrasol (University of Pretoria), who is conducting TB research in Witbank.

Stables

The stables were revamped through rubberisation. Stables 3, 5 and 9, the quarantine and the bleeding hall ramp was laid with rubber. This rubberisation has the following advantages:

- Improved traction;
- Isolation of concrete floors for protection against cold;
- Reduction in the use and costs of shavings;
- Reduction in labour; and
- Reduction of injuries during colic cases.

Sales

A total of 1022 x 500 ml units of horse blood were sold, of which 272 units were for the NHLS and 750 units for private laboratories. A total of 60 x 500 ml units of sheep blood was sold, of which one was for the NHLS and 59 units was for private laboratories.



Vile of Bloomslang Anti -venom.



3.PART C: GOVERNANCE



3.1 Introduction



The NHLS ensures that its processes and practices are reviewed on an on-going basis to ensure, compliance with legal obligations, use of funds in an economic, efficient and effective manner and adherence to good corporate governance practices. Processes and practices purposefully serve to report on the economic, environmental and social responsibilities of the entity. Our reporting processes are underpinned by principles of openness, integrity and accountability, and follows an inclusive approach that recognises the importance of all stakeholders who have an impact on the viability and sustainability of the NHLS.

Our corporate governance practices are concerned with structures and processes for decision making, accountability and control, and clearly sets the tone for behaviour from the top down to the lowest level of the organisation.

3.2 Portfolio committees

The Parliamentary Portfolio Committee on Health exercises oversight over service delivery performance of the public entities that report to the national DoH.

The NHLS appeared before the Parliamentary Portfolio Committee on Health on the dates as indicated below:

Date	Parliamentary Structure	Activity/ Focus						
18 April 2018	Portfolio Committee on Health	Presentation of the strategic plan for (2018/2021) and the Annual Performance Plan (APP) for (2018/2019)						
11 October 2018	Portfolio Committee on Health	Presentation of the Annual Financial Statements (AFS) and annual report for (2017/2018)						

3.3 Executive Authority

The Minister of Health is the Executive Authority of the NHLS in terms of the Public Finance Management Act (PFMA). The Minister appoints members of the Board in terms of section 8 of the NHLS Act.

The Board is the Accounting Authority of the NHLS in terms of the NHLS Act and the PFMA.

3.4 The Accounting Authority

The Accounting Authority submits their report for the financial year that ended 31 March 2019.

Statement of commitment

The Accounting Authority is committed to business integrity, transparency and professionalism in all its activities. As part of this commitment, the Accounting Authority supports the highest standards of corporate governance and the ongoing development of best practice.

The mandate of the Board

The mandate of the NHLS Board is set out in the NHLS Act and is stipulated in the NHLS Board Charter. The mandate of the Board as set out in the Board Charter is aligned to the requirements stipulated by the Protocol on Governance in Public Entities.

Independence of the Board

Board members are appointed by the Minister of Health. The Board considers submissions and recommendations made by management and makes independent decisions based on their fiduciary responsibilities and the strategic direction of the service.

The various Board committees meet independently and then report back to the Board. Each committee has a formal charter that clearly defines its roles and responsibilities.

The Audit and Risk Committee regularly meets individually with the external and internal auditors. Furthermore, the Board, its committees and individual Board members may engage independent counsel and advisors upon request and at the discretion of the Board.

Role and function of the Accounting Authority

The Board is scheduled to meet on a quarterly basis and is responsible for providing strategic direction and leadership, ensuring good corporate governance and ethics, determining policy, agreeing on performance criteria and delegating the detailed planning and implementation of policy to the Executive Committee (EXCO).

The Board must comprise of twenty-two (22) members including the Chief Executive Officer (CEO), Chairperson and Vice Chairperson of the Board (Twenty-one members are non-executive members and one is an executive member).

The Board evaluates and monitors management's compliance with policy and achievements against objectives. A structured approached is followed for delegation, reporting and accountability, which includes reliance on $various\,Board\,committees.\,The\,chair person\,guides\,and\,monitors\,the\,input\,and\,contribution\,of the\,Board\,members.$

The Board has unlimited access to professional advice on matters concerning the affairs of the economic entity, at the Entity's expense. The Board has approved a code of corporate practice and conduct which includes terms of reference to provide guidance to the Board members in discharging their duties and responsibilities.

The Board evaluates its effectiveness on an annual basis and formulates plans to mitigate any shortcomings identified by the evaluation process

Board composition

The Accounting Authority is a Unitary Board comprising a majority of non-executive members. The members of the Board are appointed by the Minister in accordance with Section 7 of the NHLS Act.

In terms of the NHLS Act No. 37 of 2000, the Board should comprise twenty-two (22) members, including the CEO, Chairperson and Vice-Chairperson of the Board. In terms of Section 9 of the NHLS Act, the Minister of Health has appointed a Chairperson and a Vice-Chairperson.

The members of the entity during the year and to the date of this report are tabled below.

#	Title	Surname First name		Constituency	Date of Appointment	End of term	Chairpersonship /Position in the NHLS
1	Prof	Buch (Chairperson)	Eric	Minister of Health	01 January 2017 Re-appointed 01 May 2018	30 April 2018 30 April 2021	Board and GSEC
2	Dr	Zungu (Vice-Chairperson)	Sibongile	Minister of Health	20 April 2017	31 August 2018	

#	Title	itle Surname First name Constituency		Constituency	Date of Appointment	End of term	Chairpersonship /Position in the NHLS	
3	Mr	Durham	Ben	Department of Science and Technology	01 November 2014 Re-appointed 01 February 2018	01 November 2017 31 January 2021		
4	Dr	Goosen	Gerhard	Mpumalanga Province	Reappointed 01 November 2018	01 November 2021		
5	Dr	Mavuso	Zwelibanzi	SALGA	21 December 2016	21 December 2019		
6	Mr	Manning	Michael	Western Cape Province	30 April 2015	30 April 2018	ITGC	
7	Mr	Van der Merwe	lan	NDoH	01 February 2018	31 January 2021	FinCom	
8	Dr	Chetty	Karmini	Acting CEO	04 October 2017	Aligned to acting term	EXCO/OPCO	
9	Dr	Mzangwa	Balekile	Free State Province	18 November 2016	18 November 2019		
10	Ms	Mkhize	Nelisiwe	KwaZulu-Natal Province	01 September 2015 Re-appointed 01 September 2018	01 September 2021	RHRC	
11	Ms	Mayinga	S'phiwe	Public Nominee: Legal	20 April 2017	20 April 2020		
12	Prof	Ross	Mary	Gauteng Province	01 September 2015 Reappointed 14 September 2018	14 September 2021	RIC	
13	Dr	Saloojee	Haroon	Minister of Health	01 September 2015	01 September 2018		
14	Mr	Shingange	Michael	Organised Labour National Education, Health and Allied Workers' Union (NEHAWU)	01 February 2015 Re-appointed 01 February 2018	01 February 2018 31 January 2021		
15	Prof	Obi	Larry	Council on Higher Education (CHE)	20 April 2017	20 April 2020		
16	Prof	Schoub	Barry	Council on Higher Education (CHE)	20 April 2017	29 April 2018		
17	Dr	Tucker	Tim	Public Nominee: Research	01 January 2016	31 December 2019	NAPC	
18	Dr	Tom	Monde	Public Nominee: Finance	14 November 2017	31 December 2019	ARC	

Board member qualifications and external directorships

The NHLS Board members have the relevant skills, knowledge and experience to bring judgement to bear on the business of the NHLS. In situations where Board members may lack experience, detailed induction and formal mentoring and support programmes are implemented.

The Chairperson, together with the Board, carefully considered outside chairpersonships that members hold. The relative size and complexity of companies in question were taken into cognisance. The Board members are satisfied that they have the ability and capacity to discharge their duties.

The qualifications and external directorships of NHLS Board members are disclosed in the table below.

Names	Qualifications and External Directorships
Prof Eric Buch	Qualifications MBBCh, MSc (Med), FFCH(CM)(SA), DTM&H, DOH <u>Directorships</u> None
Dr Sibongile Zungu	Qualifications MBChB, BAdmin, Strategic Transformation Programme, Postgraduate Certificate in Occupational Health, Improving Quality in the Health Sector, Entrepreneurial Management of Health Services, Public Sector Reform, Postgraduate Studies in Applied Population Studies, Training and Research, Making Decentralization Work, Human Resources for Health. <u>Directorships</u> Inkosi of the Madlebe Traditional Authority

Names	Qualifications and External Directorships
Dr Tim Tucker	Qualifications MBChB, PhD, FC Path (SA) Viro, Diploma in Business Strategy <u>Directorships</u> SEAD Consulting, NHLS Research Trust, SA HIV Clinicians' Society, Tucker Family Trust
Mr Michael Manning	Qualifications BCom, BCom (Hons), PG Dip (Accounting) SAICA, CA (SA) Directorships Trustee Isele Trust, Independent Audit Committee Member of Mine Health and Safety Council
Prof Mary Ross	Qualifications BSc (Hons), MBChB, Diploma in Data metrics, Diploma in Health Administration, DTM&H, DPH, DOH, FCPHM (SA), FOM (UK), FPH(UK), FFTM (RCP &S GLASGOW), FACTM (Australia) <u>Directorships</u> None
Mr Ben Durham	Qualifications MSc, BSc (Hons), BSc, currently pursing PhD in Technology and Innovation Management Directorships None
Mr Michael Shingange	Qualifications Certificate in Negotiating Skills, Diploma in Trade Union Movement, Certificate in Governance Directorships 1st Deputy President of NEHAWU
Ms Nelisiwe Mkhize	Qualifications MBA, PG Dip Business Management, BSc, National Diploma in Medical Technology, Directorships None
Dr Gerhard Goosen	Qualifications MBChB, Diploma in Obstetrics (SA) Directorships ALENTI 25 (Not for Profit)
Dr Zwelibanzi Mavuso	Qualifications Dental Therapy, MBBCh, MBA Directorships None
Dr Balekile Mzangwa	Qualifications MBChB Directorships None
Dr Monde Tom	Qualifications PhD, MSc in Financial Economics, Postgraduate Diploma in Economic Principles, BSc in Applied Mathematics, National Diploma in Cost Management. <u>Directorships</u> IkweziLomso Investments, Vice-President: Alexander Country Club
Mr. Ian van der Merwe	Qualifications BCom, BCom (Hons), MBA Directorships None
Ms Sphiwe Mayinga	Qualifications BProc, LLB, LLM, MAP, SLDP, Advanced Banking Law, Corporate Governance, Compliance Management Directorships Tiyisela Construction, UNISA SBL (Member of Risk and Audit Committee and Chairperson of Remuneration and Human Resources Committee)
Prof Obi Lawrence	Qualifications BSc (Hons), MSc, PhD Directorships None
Dr Karmani Chetty	Qualifications MBChB, MSc URP, FFCH, BSc Epidemiology (Hons), Dip Occupational Health Directorships None

Changes in Board membership

In terms of Section 8(4) of the NHLS Act, 2000, the members of the Board may hold office for a period of at least three (3) years, as the Minister may determine at the time of appointment, but must be eligible for reappointment. The table below indicates the changes to Board membership that took place during the year under review.

Name	Constituency/ representing	Date of appointment/ * reappointment	Date of resignation/ * retirement
Prof Barry Schoub	Minister of Health	1 May 2015 re-appointed 20 April 2017	29 April 2018
Mr. Michael Manning	Western Cape Province	30 April 2015	30 April 2018
Ms. Ntombikayise Mapukata	Eastern Cape Province	1 February 2015	1 February 2018
Mr. Stanley Harvey	Northern Cape Province	1 February 2015	1 February 2018
Mr. André Venter	National DoH	02 January 2015	02 January 2018

Board meeting attendance

The Board meets on pre-arranged dates at least once a quarter and other times as deemed necessary. The Board holds annual workshops to review the strategy and to conduct an annual risk assessment. During the past 12 months, the Board convened thirteen (13) times (including special meetings).

A quorum was met at each of the meetings. In each meeting, members were also provided an opportunity to declare any personal conflicts of interest, to be recused from deliberation of any matter in which a member has decline such interest

Attendance of Board meeting from 01 April 2018 - 31 March 2019

		Meeting dates												
Names	29 May 2018	30 May 2018	25 Jul 2018	26 Jul 2018	23 Aug 2018	24 Aug 2018	18 Sep 2018	9 Nov 2018	28 Nov 2018	29 Nov 2018	17 Jan 2019	27 Feb 2019	28 Feb 2019	Total
Prof Eric Buch (Chairperson of the Board)	✓	✓	✓	✓	√	✓	✓	✓	✓	✓	√	√	✓	13
Dr Sibongile Zungu (Vice- Chairperson)	√	√	√	√	√	√	n/m	n/m	n/m	n/m	n/m	n/m	n/m	6
Dr Karmani Chetty(Acting CEO)	√	✓	√	√	√	√	√	√	√	√	√	√	√	13
Mr Ben Durham	✓	✓	✓	✓	✓	А	✓	А	✓	✓	А	✓	✓	10
Dr Balekile Mzangwa	А	✓	✓	✓	✓	✓	✓	√	✓	✓	✓	✓	✓	12
Dr Gerhard Goosen	✓	А	✓	✓	√	√	√	✓	✓	✓	✓	√	А	11
Prof Haroon Saloojee	√	√	√	✓	√	√	n/m	n/m	n/m	n/m	n/m	n/m	n/m	6
Mr Ian Van der Merwe	А	А	А	А	√	✓	✓	√	✓	✓	✓	А	А	7
Prof Larry Obi	✓	✓	✓	✓	✓	✓	✓	✓	А	А	✓	✓	А	10
Prof Mary Ross	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	А	12

							Meetin	g dates						
Names	29 May 2018	30 May 2018	25 Jul 2018	26 Jul 2018	23 Aug 2018	24 Aug 2018	18 Sep 2018	9 Nov 2018	28 Nov 2018	29 Nov 2018	17 Jan 2019	27 Feb 2019	28 Feb 2019	Total
Mr Michael Shingange	✓	✓	А	А	А	А	А	√	✓	✓	✓	✓	А	7
Dr Monde Tom	✓	А	А	А	А	А	А	А	А	А	✓	✓	А	3
Ms Nelisiwe Mkhize	А	А	√	✓	✓	✓	√	✓	√	√	√	✓	✓	11
Mrs Nicolene Van der Westhuizen	√	✓	✓	✓	✓	√	√	√	√	✓	✓	√	✓	13
Ms Sphiwe Mayinga	√	✓	✓	✓	А	А	√	А	√	✓	√	А	А	8
Dr Tim Tucker	✓	✓	А	А	✓	✓	✓	✓	✓	✓	✓	✓	✓	11
Dr Zwelibanzi Mavuso	√	✓	✓	✓	✓	✓	√	√	√	✓	√	✓	✓	13
Total number o	f meetin	gs = 13												

Legend:

Committees of the Board

- Remuneration and Human Resources Committee;
- Executive Committee:
- Finance Committee;
- Audit and Risk Committee;
- National Academic and Pathology Committee;
- · Governance, Social and Ethics Committee; and
- Research and Innovation Committee.

The various committees of the Board each have formal terms of reference (ToR) that are captured in a charter, which further defines the mandates, roles and responsibilities of each committee. The charters are reviewed and updated on an annual basis, as required.

The NHLS Board is governed by the NHLS Act 2000 (Act No 37 of 2000) and the NHLS Rules made in terms of the Act supra. The Board complies with the PFMA. In addition, the NHLS Board subscribes to the principles of King Code of Governance Principles (King IV).

In the period under review, the Board complied with its ToR as detailed in the NHLS Rules. In addition, the Board provided strategic direction to the organisation, in alignment with the principles of King IV.

Minutes of meetings were noted and recorded in the minute book as a true and accurate representation of the proceedings at meetings.

The majority of the Board members attended the meetings during the year under review. Board resolutions were captured in the board resolution file.

Remuneration and Human Resources Committee

In terms of the NHLS Act, the Remuneration and Human Resources Committee (RHRC) is a committee of the Board, which serves to assist the Board with the performance of its functions and exercising of its powers. The committee reports on employment equity, employee turnover, skills development and labour relations.

As part of the CPD programme, the Board invites corporate governance experts as recommended by the Institute of Directors from time to time, to present on topical matters and latest developments in corporate governance practices.

In terms of good corporate governance practices, the RHRC met on five (5) separate occasions during the financial year. A joint RHRC and Finance Committee (FinCom) meeting was convened on 22 August 2018, to consider cost of the proficiency projects and the final results of the proficiency assessment.

- *Dr Sibongile Zungu term of office expired on 31 August 2018;
- * Mr Ian Van der Merwe retired from the RHRC
- *Dr Balekile Mzangwa was elected as Vice-Chairperson

Meeting attendance of the Remuneration and Human Resources Committee for the financial year from 1 April 2018 to 31 March 2019.

	Meeting dates										
Names	12 April 2018	11 July 2018	22 Aug 2018	1 Nov 2018	6 Feb 2019	Total					
Ms Nelisiwe Mkhize (Chairperson)	✓	✓	✓	✓	✓	5					
Dr Balekile Mzangwa (Vice- Chairperson)	n/m	n/m	А	✓	А	1					
Dr Gerhard Goose	✓	✓	✓	✓	А	4					
Dr Zwelibanzi Mavuso	А	✓	✓	А	✓	3					
Mr Michael Shingange	А	А	✓	✓	✓	3					
Dr Sibongile Zungu	✓	n/m	n/m	n/m	n/m	1					
Prof Larry Obi	✓	✓	✓	✓	✓	5					
Ms Sphiwe Mayinga	✓	✓	А	✓	✓	4					
Mr Ian Van der Merwe	✓	n/m	n/m	А	n/m	1					
Dr Karmani Chetty(Acting CEO)	✓	✓	✓	✓	✓	5					
Total number of meetings=5			1		1						

Legend:

✓	= Present	A = Apology	n/m = Not a member

The Executive Management Committee

In terms of the NHLS Act, The Accounting Authority appointed an EXCO, which consists of:

- a. The CEO, who acts as chairperson; and
- b. Regional Executive Managers and Executive Managers from Support Services.

The EXCO is responsible for the management of the NHLS in accordance with the policy of the NHLS and assists with performance of the Accounting Authority's functions and the exercise of its powers. In terms of good corporate governance practices, the EXCO met ten (10) times during the financial year.

Management Com- mittee for the year that ended 31 March 2019Names		Meeting dates										
	9 Apr 2018	4 Jun 2018	5 Jun 2018	23 Jul 2018	13 Aug 2018	15 Oct 2018	19 Nov 2018	20 Nov 2018	4 Feb 2019	4 Mar 2019	Total	
Dr Kamy Chetty (Chairperson)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
Mr Tashen Dokie (Acting CFO)	√	✓	✓	n/m	n/mw	n/m	n/m	n/m	n/m	n/m	3	
Mr Michael Sass (Acting CFO)	n/m	n/m	n/m	✓	✓	✓	✓	✓	✓	✓	7	
Mr Shaun Grimett (Acting CIO)	√	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	1	
Mr Letlhogonolo Tlhako (Acting CIO)	n/m	✓	✓	✓	✓	✓	✓	✓	✓	✓	9	
Dr Sophia Kisting	✓	✓	А	✓	А	А	✓	✓	✓	✓	7	
Prof Lynn Morris	✓	А	А	А	✓	✓	✓	✓	✓	✓	7	
Dr Mojaki Mosia	✓	✓	А	✓	✓	✓	✓	✓	✓	✓	9	
Dr Elizabeth Mayne (Acting AARQA Executive)	√	√	А	n/m	n/m	n/m	n/m	n/m	n/m	n/m	2	
Prof Koleka Mlisana	n/m	n/m	n/m	А	А	✓	✓	✓	✓	А	4	
Ms Violet Gabashane	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
Advocate Mpho Mphelo	✓	✓	А	✓	✓	✓	✓	✓	√	А	8	
Prof Wendy Stevens	✓	✓	✓	А	✓	✓	✓	✓	✓	✓	9	
Ms Tabita Makula	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10	
Mr Bahule Motlonye	✓	√	✓	✓	✓	✓	✓	✓	✓	✓	10	
Mr Jone Mofokeng	✓	√	✓	✓	А	✓	✓	✓	✓	✓	9	
Mr Sibulele Bandezi	✓	✓	✓	✓	✓	✓	✓	✓	✓	А	9	
Mr Jacob Lebudi	✓	✓	✓	✓	А	✓	✓	✓	✓	✓	9	
Ms Nasima Mohamed	✓	√	✓	√	✓	✓	√	✓	✓	✓	✓	
Total number of meet	ings = 10											

Legend:

✓ = Present	A = Apology	n/m = Not a member
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The Finance Committee

The Finance Committe FinCom assists the Accounting Authority in fulfilling its oversight responsibilities on an ongoing basis for matters relating to the financial practices and condition of the economic entity. This is done by reviewing the entity's financial policies and procedures; remaining informed of the entity's financial conditions, requirements for funds, and access to liquidity; whilst considering and advising the Accounting Authority regarding the entity's sources and uses of funds.

In line with good corporate governance practices, the Finance Committee met on six (6) separate occasions during the financial year under review. Two (2) special meetings were convened to consider procurement and finance submissions which required urgent attention and Board approval.

- *Mr Michael Manning's term of office ended on 30 April 2018
- *Mr Ian van der Merwe was elected as the Chairperson on 30 April 2018.

Meeting attendance of the Finance Committee for the financial year that ended 31 March 2019

	Meeting dates								
Name	13 Apr 2018	4 Jul 2018	24 Oct 2018	23 Nov 2018	7 Feb 2019	27 Mar 2019	Total		
Mr Ian Van der Merwe (Chairperson)	✓	✓	✓	✓	✓	✓	6		
Dr Gerhard Goosen (Deputy Chairperson)	✓	✓	✓	А	✓	✓	5		
Mr Michael Manning	✓	n/m	n/m	n/m	n/m	n/m	1		
Mr Michael Shingange	А	А	А	✓	✓	✓	3		
Ms Nelisiwe Mkhize	✓	✓	✓	✓	✓	✓	6		
Dr Balekile Mzangwa	А	А	✓	✓	А	А	2		
Dr Karmani Chetty(Acting CEO)	✓	✓	✓	✓	✓	✓	6		
Total number of meetings: 6				'					

Legend:

✓ = Present A = Apology n/m = Not a member
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The Audit and Risk Committee

ARC to assist in the discharge of its duties by reviewing and reporting on the governance responsibilities of the Board and the NHLS. The ToR of the ARC, its duties and functions, its composition and its modus operandi were approved by the Board. Details of the ARC's activities and meeting attendance are outlined in the 'Risk Management' section of this report, which follows below.

The National Academic and Pathology Committee

The National Academic and Pathology Committee (NAPC) met on four (4) separate occasions during the financial year.

The attendance schedule is as follows:

		Meeting dates								
Name	3 May 2018	12 July 2018	7 Nov 2018	13 Feb 2019	Total					
Dr Tim Tucker (Chairperson)	✓	✓	✓	✓	4					
Prof Mary Ross	А	✓	✓	✓	3					
Ms. Nelisiwe Mkhize	✓	✓	✓	✓	4					
Mr Ben Durham	✓	А	✓	✓	3					
Prof Larry Obi	✓	А	А	✓	2					
Mrs. Nicolene Van der Westhuizen	n/m	n/m	✓	✓	2					
Dr Karmani Chetty(Acting CEO)	✓	✓	✓	А	3					
Total number of meetings = 4										

Legend:

The functions of the committee are to facilitate formulation of policy through:

- a. Conducting of basic research in association or partnership with any tertiary educational institution;
- b. Cooperating with persons and institutions undertaking basic research in the Republic of South Africa, and in other countries, by the exchange of scientific knowledge and the provision of access to the resources and specimens available to the NHLS;
- c. Participating in joint research operations with departments of state, universities, UoTs, colleges, museums, scientific institutions and other persons;
- d. Cooperating with educational authorities and scientific or technical societies or industrial institutions that represent employers and employees, respectively, for the promotion of the instruction and training of:
 - a. pathologists;
 - b. technologists;
 - c. technicians;
 - d. scientists;
 - e. researchers;
 - f. technical experts and other supporting personnel in universities, UoTs, and colleges; and
- e. Any other matter as may be referred to the committee from time to time by the Board.

As part of its duties, the committee must monitor and manage the agreements entered into between the NHLS and each tertiary education institution through:

- a. Developing policies and guidelines to determine the number of registrars for each discipline and the distribution of the registrar posts between the laboratories associated with each university health science faculty;
- b. Developing policies and guidelines to determine the number of technologist training posts for each discipline and the distribution of the posts between the laboratories identified for this purpose;
- c. Proposing guidelines relating to part-time, honorary and guest appointments of employees of the NHLS by tertiary education institutions;
- d. Monitoring the guidelines for consultant appointments of personnel of tertiary education institutions in the NHLS, as determined by the agreement between the organisation and the universities;
- e. Ensuring that employees of the NHLS participate in the CPD programmes provided by tertiary education institutions, to comply with career programme development requirements;
- f. Reviewing and managing arrangements for research undertaken by tertiary education institutions in the laboratories of the NHLS;
- g. Advising Executive Management on matters relating to indemnity for employees of the NHLS or a tertiary education institution working between the facilities of both partners;

- h. Advising the EXCO on matters relating to the discipline of personnel of the NHLS or a tertiary education institution working between the facilities of both partners;
- i. Advising the EXCO on financial matters, such as subsidies, bursaries and payment for academic related services;
- j. Monitoring, evaluating and managing SLAs and performance measures;
- k. Advising, monitoring and evaluating the resolution of disputes as and when they arise;
- I. Ensuring the integrity of the process of managing partnerships;
- m. Ensuring that professional ethics are adhered to; and
- n. Ensuring that the NHLS complies with the requirements of the Health Professionals Council in respect of registration requirements, ethics and conduct.

IT Governance Committee

The IT Governance Committee (ITGC) is established in terms of section 12 of the NHLS rules. The committee ensures that IT is a regular item on the Accounting Authority's agenda and that it is addressed in a structured manner. In addition, the committee ensures that the Accounting Authority has the relevant information to its avail, to make informed decisions that are essential to achieve the ultimate objectives of IT governance.

The IT governance objectives are:

- 1. Alignment of IT and the business;
- 2. The Delivery of value by IT to the business;
- 3. The sourcing and best use of IT resources;
- 4. The management of IT-related risks; and
- 5. The tracking, monitoring and measurement of IT performance.

The committee furthermore offers expert insight into and timely advice and direction on topics such as:

- a. The relevance of the latest developments in IT from a business perspective;
- b. The alignment of IT with the strategic business direction;
- c. The formulation and achievement of strategic IT objectives;
- d. The availability of suitable IT resources, skills and infrastructure to meet the strategic objectives;
- e. Optimisation of IT costs;
- f. The role and value delivery of external IT sourcing;
- g. Risk, return and competitive aspects of IT investments;
- h. Progress on major IT projects;
- i. The contribution of IT to the business (i.e. delivering the promised business value);
- j. Exposure to IT risks, including compliance risks; and
- k. Containment of risks of critical systems.

The ITGC met once in this reporting year. The Board took a resolution to temporary incorporate the committee with the ARC, due to the depletion on the number of members and inadequate skills and expertise in the IT environment.

Meeting attendance of the IT Governance Committee for the financial year that ended on 31 March 2019

- * Mr Michael Manning's term of office lapsed on 30 April 2018
- * Prof Barry Schoub's term of office lapsed on 30 April 2018

Name	24 April 2018	Total
Mr Michael Manning % (Chairperson)	✓	1
Dr Zwelibanzi Mavuso	✓	1
Prof Barry Schoub %	✓	1
Mr Joseph Appiah-Yeboah	А	0
Total number of meetings = 1		

Legend:

= Present	A = Apology	% = Retired / resigned

Governance, Social and Ethics Committee

The Governance, Social and Ethics Committee (GSEC) is established to assist the Board with the oversight of corporate governance, social and ethical matters and in ensuring that the organisation is and remains a committed socially responsible corporate citizen. The commitment to sustainable development involves ensuring that the organisation conducts business in a manner that meets existing needs without knowingly compromising the ability of future generations to meet their needs.

The committee's primary role is to supplement, support, advise and provide guidance on the effectiveness or otherwise of management's efforts in respect of governance, social and ethics and sustainable development related matters which, inter alia, include the following:

- a. Safety;
- b. Health and wellness, including occupational hygiene;
- c. Environmental management;
- d. Climate change;
- e. Ethics management;
- f. Corporate social investment;
- g. Mining community development
- h. Stakeholder engagement; and
- The protection of company assets.

The committee is also responsible for:

- a. Reviewing and approving the policy, strategy, structure to manage governance, social and ethics issues in the organisation;
- b. Overseeing the monitoring, assessment and measurement of the organisation's activities relating to social and economic development, including the organisation's standing in terms of the goals and purposes of:
 - The 10 principles set out in the UN Global Compact Principles;
 - The OECD recommendations regarding corruption;
 - The Employment Equity Act; and
 - The Broad-Based Black Economic Empowerment Act.
- c. Overseeing the monitoring, assessment and measurement of the organisation's activities relating to

- good corporate citizenship, including the organisation's promotion of equality, prevention of unfair discrimination, addressing of corruption, contribution to development of the communities in which its activities are predominantly conducted, or within which its services are predominantly marketed, and recording of sponsorship, donations and charitable giving;
- d. Overseeing the monitoring, assessment and measurement of the organisation's activities relating to the environment, health and public safety, including the impact of the organisation's activities and services; verseeing the monitoring, assessment and measurement of the organisation's stakeholder relationships, including its advertising, public relations and compliance with consumer protection laws to ensure that the organisation adheres to its values;
- e. Overseeing the monitoring of the organisation's labour and employment, including its standing in terms of the ILO Protocol on decent work and working conditions, the organisation's employment relationships, and its contribution to the educational development of its employees; Reviewing the adequacy and effectiveness of the organisation's engagement and interaction with its stakeholders;
- Considering substantive national and international regulatory developments as well as practices in the fields of social and ethics management;
- g. Reviewing and approving the policy and strategy pertaining to the organisation's programme of corporate social investment:
- h. Establishing clearly articulated ethical standards (Code of Ethics) and ensuring that the organisation implements measures to achieve adherence to these in all aspects of the business, thus achieving a sustainable ethical corporate culture within the organisation;
- Monitoring that management develops and implements programmes, guidelines and practices congruent with its social and ethics policies;
- Reviewing the material risks and liabilities relating to the provisions of the Code of Ethics, and ensuring that such risks are managed as part of the risk management programme; btaining external assurance of the organisation's ethics performance on an annual basis, and facilitation of the inclusion of an assurance statement related to the ethics performance of the organisation in the Integrated Report; and
- k. Ensuring that management allocates adequate resources to comply with social and ethics policies, codes of best practice and regulatory requirements.

During the period under review, the committee met ten (10) times. The committee was obliged to conduct four additional meetings, to deal with matters relating to the disciplinary proceedings of the erstwhile CEO, CFO, Head of Internal Audit and Risk and Legal Manager. A joint meeting of the Remuneration and Human Resource Committee and the Governance and Social Ethics Committee was convened to consider different proposals for the annual salary negotiations and the union's demands, to avert potential industrial actions.

Meeting attendance of the Governance and Social Ethics Committee for the financial year that ended 31 March 2019

*Dr Sibongile Zungu's term of office ended on 31 August 201	*Dr Si	bongile	Zungu's	term of	office	ended	on 3	31 August 2018
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		Meeting dates									
Names	30 Apr 2018	11 May 2018 Joint meet- ing	19 Jul 2018	2 Aug 2018	21 Aug 2018	15 Oct 2018	6 Nov 2018	27 Nov 2018	30 Jan 2019	5 Feb 2019	Total
Prof Eric Buch (Chairperson)	✓	✓	✓	✓	√	✓	✓	✓	✓	✓	10
Dr Sibongile Zungu (Vice-Chairperson)	✓	А	✓	А	А	n/m	n/m	n/m	n/m	n/m	2
Dr Gerhard Goosen	n/m	✓	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	1
Mr Ian Van der Merwe	А	✓	✓	А	✓	А	А	А	√	А	4
Dr Karmani Chetty(Acting CEO)	А	√	√	✓	✓	✓	✓	√	√	√	9

	Meeting dates										
Names	30 Apr 2018	11 May 2018 Joint meet- ing	19 Jul 2018	2 Aug 2018	21 Aug 2018	15 Oct 2018	6 Nov 2018	27 Nov 2018	30 Jan 2019	5 Feb 2019	Total
Prof Larry Obi	n/m	✓	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	1
Mr Michael Shingange	n/m	✓	n/m	n/m	n/m	n/m	n/m	n/m	n/m	n/m	1
Prof Mary Ross	А	✓	✓	✓	✓	✓	✓	✓	✓	А	8
Dr Monde Tom	✓	А	А	А	✓	А	А	А	✓	А	3
Ms Nelisiwe Mkhize	✓	✓	✓	✓	✓	✓	✓	А	✓	✓	9
Ms Sphiwe Mayinga	n/m	✓	А	✓	✓	✓	А	А	✓	✓	6
Dr Tim Tucker	✓	✓	✓	А	✓	✓	✓	А	✓	✓	8

Legend:

= Present	A = Apology	n/m = Not a member
	1	1 1 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Research and Innovation Committee

Total number of meetings: 10

The Research and Innovation Committee (RIC) was established as a vehicle to ensure that the NHLS research mandate receives attention at Board level. Members of the RIC may be called on from time to time to interact with external stakeholders and funding agencies.

The role of the RIC is to advise the NHLS Board and the NAPC on research policies, strategies, initiatives and innovation that promote the research interests of the organisation and that nurture and enable high quality research.

The objectives of the RIC are aligned with those stipulated in the South African Health Research Policy of 2001, the national DoH 10-Point Plan and the National Health Research Committee (NHRC).

The Board at its meeting held on 27 February 2018; the Board approved the revised charter of the committee. The revised charter includes additional focus areas on innovation and broadens the scope of the committee.

Meeting attendance of the Research and Innovation Committee for the financial year that ended on 31 March 2019

Names	2 May 2018	1 Aug 2018	6 Nov 2018	12 Feb 2019	Total			
Prof Mary Ross (Chairperson)	✓	✓	✓	✓	4			
Mr Ben Durham (Vice-Chairperson)	✓	✓	✓	✓	4			
Dr Tim Tucker	А	А	✓	✓	2			
Prof Haroon Saloojee	А	✓	n/m	n/m	1			
Prof Larry Obi	✓	✓	✓	✓	4			
Dr Karmani Chetty (Acting CEO)	✓	✓	✓	А	3			
Total number of meetings = 4								

Legend:

= Present	A = Apology	n/m = Not a member

3.5. Risk management

The governing body (NHLS Board) governs risk in a way that supports the organisation in setting and achieving its strategic objectives.

The ARC is responsible for the oversight of enterprise-wide risk management practices and processes and to ensure that the entity's risk management policy and strategy is implemented.

The Board treats risk as an integral component of its decision making and the execution of its duties. A welldesigned and structured system of enterprise-wide risk management was implemented during the year under review, to provide assurance that the goals and objectives of the NHLS are achieved.

The daily operational activities and focuses on identifying, assessing, managing and monitoring all risks. The system is designed on the premise that identified risks are often integrated and cannot be managed in isolation.

The Board also emphasised the need to receive periodic independent assurance on the effectiveness of this system.

The NHLS risk management framework was implemented to review aspects of economy, efficiency and effectiveness of the entity's risk management processes. The accountability for managing risk is assigned at appropriate levels, to ensure proper responses. The NHLS defined three broad risk categories, namely: strategic risks, operational and/or divisional risks and emerging risks.

Strategic risks

The NHLS implemented effective mechanisms for identifying and monitoring strategic risks that impact the NHLS's ability to deliver on its mandate and achieve its strategic goals and objectives.

During the period under review, a strategic risk assessment workshop was conducted, and a strategic risk register was developed that is being monitored and assessed on an ongoing basis. The register is presented to the ARC and the Board on a quarterly basis, to ensure independent monitoring of the effectiveness of the NHLS's enterprise-wide risk management processes.

Operational and/or divisional risks

The NHLS minimises operational risks by ensuring that there is appropriate infrastructure, controls, systems and personnel. Key processes employed in managing operational risks include a Code of Ethics, internal controls, segregation of compatible functions, delegation of authority, financial and management reporting; and monitoring of key performance indicators to highlight positive and negative performance across a broad range of key results areas. The EXCO, and area and business managers oversee operational matters.

During the period under review, operational and/or divisional risk assessment workshops were conducted, and a risk register was developed that is being monitored and assessed on an ongoing basis, and regularly presented to the EXCO.

Emerging risks

Emerging risks originate from macro-economic and national challenges pertaining to the environment that the NHLS's operates within. During the year under review, the emerging risks identified were incorporated into both the strategic and operational risks registers of the entity.

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3.6 Internal control unit

The NHLS Board has ultimate responsibility for the system of internal control designed solely to mitigate risks, identify, evaluate, manage and provide reasonable assurance against near misses and losses. The system employed consists of self-assessment controls to allow for corrective action to be taken as and when deficiencies are identified. A combined assurance approach is in place to assist in addressing key enterprise risks.

Management and the Risk Management Unit jointly identifes controls that are necessary to mitigate risks. Internal Audit is the third line of defence and provides assurance on the effectiveness of the system of internal control.

During the year under review, the entity's enterprise-wide internal controls were assessed as satisfactory.

3.7. Internal audit and the Audit and Risk Committee



The NHLS has a co-sourced internal audit function that reviews NHLS operations. The ARC approves the internal audit charter, the three-year rolling strategic audit plan and the one-year operational audit plan, as well as the budget of the NHLS internal audit function. To ensure that it maintains its independence, the function reports administratively to the NHLS CEO and functionally to the Chairperson of the ARC.

The three-year strategic audit plan and one-year operational audit plan are based on the key risks of the entity, as well as the outcomes of an enterprise-wide risk assessment, including specific areas highlighted by internal audit and the ARC. The areas highlighted by internal control reviews that are conducted by the external auditors, are also incorporated in the internal audit plan.

The one-year operational audit plan is purposefully agile, to ensure responsiveness to any changes in the business environment of the entity, as well as emerging risks.

A comprehensive report on all internal audit findings is regularly presented to Management, as well as on a quarterly basis to the ARC.

During the period under review, the committee met four (4) times. A joint ARC and FinCom meeting was also convened on 18 September 2018, to consider the audited annual financial statements for recommendation to the Board for approval.

- *Prof Haroon Saloojee term of office ended on 31 August 2018;
- *Dr Sibongile Zungu term of office ended 31 August 2018;
- *Dr Balekile Mzangwa retired from the Audit and Risk Committee.

Names	25 May 2018	31 Oct 2018	18 Sept 2018	15 Feb 2019	TOTAL
Dr Monde Tom (Chairperson)	✓	✓	А	✓	3
Dr Sibongile Zungu	А	n/m	n/m	n/m	0
Dr Balekile Mzangwa	А	n/m	n/m	n/m	0
Prof Haroon Saloojee	✓	n/m	n/m	n/m	1
Mr Goolam Manack	✓	✓	✓	✓	4
Ms Sphiwe Mayinga	✓	✓	✓	✓	4
Mr Ian Van der Merwe	✓	А	✓	А	2
Dr Karmani Chetty (Acting CEO)	✓	√	✓	✓	4
Dr Gerhard Goosen	n/m	n/m	f/m	✓	1
Ms Nelisiwe Mkhize	n/m	n/m	f/m	✓	1
Mr Michael Shingange	n/m	n/m	f/m	А	0
Total number of meetings = 4					

Legend:

✓ = Present A = Apology	f/m = FinCom member n/m	= Not a member
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3.8. Compliance with laws and regulations

The NHLS is required to comply with, inter alia, the following:

- Constitution of the Republic of South Africa, Act 108 of 1996 (as amended)
- Public Finance management Act, No 1 of 1999 (as amended)
- National Health Laboratory Service Act, No 37 of 2000
- National Health Act, no 61 of 2003
- Preferential Procurement Framework Act, No5 of 2000
- Companies Act, No 71 of 2008
- General rules established in terms of Section 27 of the NHS Act
- Protocol on Good Governance in the Public sector
- King IV Code of Corporate Governance
- Treasury Regulations issued in terms of PFMA
- All laws that are applicable to the health sector

The nature of NHLS's business requires assessment of integration of legal, regulatory and public policy requirements into the strategy and operational processes of the organisation to meet its contractual, moral and corporate citizenship obligations. The observation of laws that govern the company and its activities forms the foundation for good corporate governance and demonstrates stewardship and responsibility to all stakeholders. There were no material non-compliances with laws and regulations applicable to our business environment identified during the year under review.

3.9. Fraud and corruption

NHLS implemented a Fraud Prevention and Response Plan to enhance integrity and to reduce the risk of fraud and provide staff with guidance in the reporting of fraud, corruption, criminal offences and other unethical behaviours that may affect the organisation. The plan is designed to protect public funds and assets, as well as to protect the integrity, security and reputation of the organisation; while maintaining a high level of services to the community that is consistent with the NHLS code of conduct objectives.

The NHLS maintains a consolidated record of allegations of fraud and corruption received and report these together with their resolutions to the Board, through the ARC. As a result, fraud and corruption risks are managed effectively and threats to the NHLS receive the necessary priority and attention.

The NHLS protects the rights of whistle blowers to prevent victimisation by fellow employees or managers which is in contravention of the Protected Disclosures Act 26 of 2000. Such victimisation could have severe negative implications for the NHLS, such as negative media publicity, for example.

The NHLS uses the Vuvuzela Hotline as its fraud hotline and it is externally managed by an independent service provider. The entity dismissed an employee that fraudulently transferred R22 million to a fraudulent bank account. Through the swift actions of management, R20 million was recovered from the bank and the balance was claimed from insurers. A criminal case was opened with the South African Police Service (SAPS). The NHLS furthermore terminated the employment contracts of both the CEO and Chief Financial Officer (CFO) who were charged with failure to fulfil their duties in three (3) procurement irregularities equating to approximately R200 million. The charges related to exceeding delegations of authority, irregular payments made to service providers and irregular appointment of service providers. These irregularities were reported to Chief Procurement Officer of the National Treasury and charges were laid with the SAPS. The Board also requested the Special Investigation Unit to investigate these matters. The Board trusts that the implemented actions will lead to successful convictions of all those implicated in fraud and corruption.

3.10. Minimising conflict of interest

The NHLS Board adopted a business Code of Conduct and Ethics for its members. The code aims to:

- Assist the Board and its members to focus on ethical risks;
- Provide the directors with guidance on how to recognise and deal with ethical issues;
- Provide mechanisms to report unethical conduct; and
- Help foster a culture of honesty and accountability.

The code requires all Board members to avoid conflict of interest, and encourages members to promptly disclose any situation that involves, or may reasonably be expected to involve, a conflict of interest.

Some of the more common conflicts from which Board members must refrain include:

- Organisational relationships with third parties: "Directors may not engage in any conduct or activities that are inconsistent with the organisation's best interest or that disrupt or impair the organisation's relationship with any person or entity with which the organisation has or proposes to enter into a business or contractual relationship;"
- Compensation from other sources: "Directors may not accept compensation (in any form) for services performed for the organisation from any source other than the organisation;" and
- Gifts: "Directors and members of their families may not accept gifts from persons or entities who deal with the organisation in those cases where any such gift is being made in order to influence the director's action as a member of the Board, or where acceptance of the gifts could create the appearance of a conflict of interest. All members are requested to declare their interest in any matter included in the agenda before every meeting commences. Should any member declare any interest, he / she will be recused from the meeting when the matter is discussed

3.11. Code of conduct

The NHLS has a Code of Conduct, which refers to the philosophical study of values and rules that all employees, executives and non-executives members of the Board must abide to. The NHLS is committed to a policy of fair dealing and integrity in the conduct of its business.

This commitment is actively endorsed by the NHLS Board and executives, and is based on a fundamental belief that business should be conducted honestly, fairly and legally. All employees are expected to share this commitment to high moral, ethical and legal standards.

3.12. Health, Safety and Environmental Issues

While the Governance, Ethics and Social Committee provides guidance on health, safety and environment, the NHLS has systems and processes in place that deal specifically with these issues. Health and safety issues are reported extensively in the National Institute for Occupational Health (NIOH) Annual Review 2018 / 19 published concurrently within this Annual Report.

3.13. Company secretary

The Company Secretary fulfils a critical role in the provision of secretarial and advisory services to the Board and its committees. The Company Secretary is also a liaison officer between Management and the Board, and between the Board and Shareholder on issues relating to governance, thus giving effect to governance protocols. The Company Secretary is the custodian of the register of the Board and committees' decisions. The Company Secretary provides guidance to both the executives and non-executive members of the Board in the discharge of their fiduciary duties and ensures that Board proceedings are executed in accordance with the relevant legislative requirements.

The Company Secretary is well experienced and qualified to fulfil the following roles:

- Induction of new Board members;
- Providing Board members collectively and individually with guidance on their duties, responsibilities and
- Familiarising Board members with any laws relevant to, or affecting the entity;
- Providing guidance to and advising the Board on ethical matters and good governance principles; and
- Recording of the proceedings of the Board and its committees.

Board members have unlimited access to the advice and services of the Company Secretary.

3.14. Social responsibility

The NHLS continued to partner with the South African National Blood Services (SANBS) to encourage NHLS employees at Corporate to donate blood on a regular basis. This is done to assist SANBS in collecting units of bloods to ensure a safe and sufficient blood supply in the health care system.in order to save lives. Blood donor drives were hosted six times during the year under review, and a total of 288 units of blood were collected from participating employees. There was an increase compared to the previous year where 264 units of blood were collected. The NHLS also participated in the Cell C Take a girl-child to work initiative on 24 May 2018, which was hosted under the theme ""Facing Fear and Embracing Ambition". The initiative was aimed at the Grade 10 to 12 learners, to shadow them and to make it a day they will treasure for the rest of their lives. The NHLS selected 20 girls from Kwa-Bhekilanga Secondary School in Alexandra to participate in this educational campaign, in order to expose them to the various career possibilities that exist within the organisation.





3.15. Audit and Risk Committee Report

The Audit and Risk Committee hereby presents its report for the financial year that ended 31 March 2019.

Audit and Risk Committee Responsibility

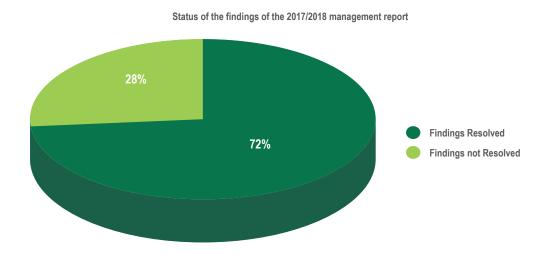
The committee reports that appropriate formal terms of reference were adopted in its charter, in line with the requirements of section 51(1)(a) (ii) of the Public Finance Management Act (PFMA) and Treasury Regulation 27. The committee further reports that its affairs were conducted in compliance with this charter.

The Effectiveness of Internal Control

The committee reviewed various reports prepared by the internal and external auditors, to evaluate the adequacy and effectiveness of internal control systems as well as the accuracy of the group's annual financial statements. To this end, the committee utilised a dashboard with eight (8) business processes as well as a heat map to demonstrate the impact of the auditors' findings on the control environment. The results are depicted below:

No	Business process	Co	ntrol assessm	nent
1	Compliance		<u>:</u>	
2	Financial health	\odot		
3	Financial management		<u>:</u>	
4	Human resources		<u> </u>	
5	Information technology			8
6	Procurement and contract management			8
7	Performance management			8
8	Oversight and monitoring		<u>:</u>	
Heat ma	p legend: Satisfactory ©	Weak 😐	Unsati	sfactory 😊

The committee has concerns about the business processes that have 'weak' and 'unsatisfactory' controls, but received assurance from management that these issues will be resolved. Progress will be monitored at every Audit and Risk Committee meeting. The committee noted management's efforts to resolve the issues that were reported by external auditors in the management report for the 2017/2018 financial year. The graph below depicts the status of the findings:





The committee acknowledges the content and quality of the quarterly reports prepared and issued by the management of the NHLS during the year under review, but requested that it is improved. The committee is satisfied with the commitment from management to resolve this matter.

Risk Management

The responsibility of risk management resides with management at all levels. Risk management is embedded throughout the organisation, right through from members of the Board, to every single employee. The approach followed by the NHLS, is to ensure that significant risks are adequately identified and managed.

The NHLS has a dedicated Risk Management and Internal Audit Department to coordinate the implementation of its risk management approach and strategy as approved by the Board. The Board continues to discharge this responsibility through its Audit and Risk Committee. The strategic and operational risk registers were prepared and reviewed by the Audit and Risk Committee.

Fraud and Corruption

The committee is satisfied with management processes that were implemented subsequent to a fraudulent transaction of R22 million and three (3) procurement irregularities totalling approximately R200 million. The Special Investigating Unit (SIU) is investigating some of these procurement irregularities with a view to enforce accountability for governance of public funds and to assist with civil proceedings. The committee trusts that the implemented actions will lead to successful convictions of all those implicated in fraud and corruption.

The committee is concerned about the R5,132 billion irregular expenditure reported in the 2018/2019 financial year, and requested management to categorise the total irregular expenditure amount based on the root causes and where applicable, indicate which disciplinary actions will be taken against the perpetrators. This will be monitored at every Audit and Risk Committee meeting.

Evaluation of group annual financial statements

The committee reviewed:

- The audited group annual financial statements with SNG Grant Thornton and the Board;
- SNG Grant Thornton's management report and management's response thereto;
- Changes in accounting policies and practices;
- The entity's compliance with legal and regulatory provisions; and
- Significant adjustments resulting from the audit.

The committee concurs with and accepts the external auditors' report on the group annual financial statements, and is of the opinion that the statements should be accepted.

Competency of the finance department

In compliance with principle 8.59(f) of the King IV code of governance principles, the committee acknowledges that there are inadequate resources and competency gaps in the Finance Department. Management however committed to resolve the issues, correct the identified gaps and strengthen the skills and competency of this department.

Internal Audit

The committee is satisfied that there is an internal audit function in the organisation, however accepts that it requires additional capacity and resources to adequately address the risks pertinent to the NHLS and its audits. The committee reviewed the internal audit reports and will ensure that the reported items are effectively addressed by management. This included the following reports:

- Property, plant and equipment;
- Revenue and accounts receivable;
- Payroll and human resources;
- Audit of performance information;
- Laboratory reviews;
- Compliance reviews; and
- Follow up on reported audit findings.

Conclusion

The committee agrees that the adoption of the going concern premise is appropriate in preparing the group annual financial statements for the 2018/2019 period. The committee therefore recommended the adoption of the group annual financial statements by the NHLS Board at the meeting held on 21 August 2019.

Chairperson: Audit and Risk Committee

MONDE M Tom



Human Resource



Human Resource

Executive Manager: Dr Mojaki Mosia

Our people strategy is underpinned by a detailed implementation plan, that sets out clear actions and measures of success that must be deployed in a performance cycle. This is achieved through creating an environment in which all colleagues are equally valued, honestly supported and truly recognised for their contributions. 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.

Introduction

All our people, irrespective of their roles and levels within the organisation, are key in achieving our mandate and strategic objectives, especially to ensure that we have a skilled, competent and motivated workforce. Our people are supported by a culture in which we unite inspirational people and provide an enabling environment for them to share knowledge and expertise, for progressive collaboration. Several external and internal factors influence the realisation of the mandate and vision of the organisation, such as an ever-increasing global competition for talent, changing workforce demographics, potential changes to pay bargaining, linking rewards to performance, the need to maximise income and the efficient application of resources.

There is a need to promote and secure excellent leadership and management across all levels with the necessary competency to enable, model and impart the necessary capability required to deliver greater results. Notwithstanding these factors, the NHLS managed to make good progress in the implementation of a revised performance management framework, performance pay progression, proficiency project for four core health professional roles, and a sustainable diversity and inclusion programme.

In the year under review, we achieved a staff retention rate of 94.6%, which implies that we had a total staff turnover rate of only 5.4%. We remain committed to the development and support of our staff. In this regard a total of 5 905 staff members received various forms of training, which constitutes 81% compliance against our APP.

Talent Management Policy Framework is critical to ensure that we focus on enabling our staff to fulfil their potential and meet their career aspirations. This framework is on track for deployment in the next performance cycle.

Being a public entity within the context of South Africa, including our historical background, we are pleased to report that our representation of race and gender across all occupational levels continues to improve. The only area which remains a challenge is the skilled, professional and middle management level, which is the level that consists of our registrars and pathologists. With guidance from the EXCO and the relevant executives, an employment equity (EE) plan will be developed and implemented. At the skilled and supervisory level, our profile revealed overrepresentation of women across all races, while males are underrepresented. This could be attributed to the cohort of student medical technologists we received from academic institutions.

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

- i. Develop our employer reputation to further enhance our overall brand identity and standing, to attract top talent;
- ii. Embed our remuneration and reward principles to equal remuneration for work of equal value, by further identifying key jobs in which grade discrepancies exist;
- iii. Establish clear performance objectives and expectations to ensure differentiation of performance across different levels, and to provide clarity on roles;
- iv. 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
- v. Continually identify, grow and manage our internal talent and staffing profile, to uphold our international profile.

Human Resources Oversight Statistics

Table 1: Personnel Cost by programme/activity/objective

Programme/ activity/ objective	Total expenditure of the entity (R'000)	Personnel expenditure (R'000)	Personnel exp. as a % of total exp. (R ² 000)	No. of employees	Average personnel cost per employee (R'000)
Total remuneration cost	7,672,834,646.54	3,603,009,350.58	46.96%	7532	478,360.24

The total annual salary bill/personnel expenditure for the financial year from April 2018 - March 2019, amounts to R3.6 billion, with a total number of 7532 employees across all levels as detailed in the table below.

Table 2. This personnel expenditure constitutes 46.96% of NHLS total expenditure.

Table 2: Personnel cost by salary band

Level	Personnel expenditure (R'000)	% of Personnel exp. to total personnel cost (R'000)	No. of employees	Average personnel cost per employee (R'000)
Top management	17,949,035.81	0.5%	8	2,243,629.48
Senior management	107,876,508.79	3%	49	2,201,561.40
Professional qualified	829,588,944.54	23%	716	1,158,643.78
Skilled	1,678,686,072.55	46.6%	3016	556,593.53
Semi-skilled	831,449,010.03	23.1%	2617	317,710.74
Unskilled	100,910,825.38	2.8%	794	127,091.72
Training	36,548,953.48	1%	332	110,087.21
TOTAL	3,603,009,350.58	100%	7532	478,360.24

The majority of the NHLS staff is classified in the 'skilled' occupational level, representing 46.6% of our total staff compliment, with personnel expenditure equating to R1.6 billion. Training of students/interns such as medical technicians, technologists, scientists and laboratory assistants constitutes 1% of the total personnel cost, with top management constituting only 0.5%. It is worth noting that the personnel expenditure increased considerably in this financial year, which can be attributed to the annual salary increase (at a cost of R 155 million, which represents 7% of our personnel expenditure) and performance pay progression (1.5% across the board) that was paid out in the 2018/2019 financial year.

Table 3: Performance rewards

Programme/activity/objective	Performance rewards	Personnel expenditure (R'000)	% of Performance rewards to total personnel cost (R'000)
Top management	176,588.26	17,949,035.81	0.98
Senior management	1,351,280.90	107,876,508.79	1.25
Professional qualified	7,466,203.04	829,588,944.54	0.90
Skilled	14,915,378.99	1,678,686,072.55	0.89
Semi-skilled	7,093,098.94	831,449,010.03	0.85
Unskilled	509,680.25	100,910,825.38	0.51
TOTAL	31,512,230.38	3,566,460,397.10	0.88

The NHLS implemented performance pay progression during the 2018/2019 financial year, which is linked to the overall organisational performance. A total of 6607 employees were eligible for the performance reward payout, which equates to 1.5% of their packages. The performance pay progression constitutes 0.88% of our personnel expenditure.

Table 4: Training costs

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 (R)
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 were 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 5631 employees who attended technical and non-technical short learning programmes, workshops, seminars, on-the-job training and conferences in the 2018/2019 period.

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.

Table 5: Employment and Vacancies

Programme/activity/	2017/2018 No. of	2018/2019	2018/2019	2018/2019 Vacan-		
objective			No. of employees	cies	% of Vacancies	
Top management	6	11	8	3	27.2%	
Senior management	57	26	25	1	3.8%	
Professional qualified	844	1053	920	133	12.6%	
Skilled	2897	3116	2810	306	9.8%	
Semi-skilled	2623	2859	2584	275	9.6%	
Unskilled	700	832	790	42	5%	
Interns - learnerships	488	300	288	12	4%	
TOTAL	7615	8197	7425	772	9.4%	

Table 5 above, reflects a vacancy rate of 9.4%. A total of 83.5% of these posts advertised in the 2018/2019 financial year, were filled within 90 days. only critical roles that were deemed to be core roles to the business, were prioritised.

Table 6: Employment changes*

Salary band	Employment at be- ginning of period	Appointments	Terminations	Employment at end of period
Top management	6	3	1	8
Senior management	57	1	4	25
Professional qualified	844	157	126	920
Skilled	2 897	231	222	2 810
Semi-skilled	2 623	76	178	2 584
Unskilled	700	121	53	790
Interns - learnerships	488	253	246	288
TOTAL	7 615	842	830	7 425

^{*}The columns will not necessarily add up, due to proficiency project which was undertaken in the year under review. Employees progressed to different occupational categories without those being deemed as appointments nor promotions.

The highest number of appointments in the 2018/2019 period were medical technologist at 18%, followed by medical technology students at 16%. A high number of security personnel (11%) was also appointed, due to the insourcing of security personnel which occurred at the beginning of the financial year.

The reason stated most for service terminations, was 'personal reasons', which constituted 55.6% of the total resignations. Nineteen (19) employees passed away during the 2018/2019 period, which is an increase of 15.7% when compared to the 2017/2018 period.

Table: 7 Reasons for leaving

Reason	Number	% of Total no. of staff leaving
Death	19	0.2%
Resignation	257	3.4%
Dismissal	26	0.4%
Retirement	90	1.2%
III health	10	O.1%
Expiry of contract	424	5.7%
Other	4	O.1%
TOTAL	830	11.1%

Voluntary resignations in the 2018/2019 reporting period equals to 3.4%, which equates to 31% of the total terminations. During the reporting period, thirty-nine (39) employees left the organisation without serving notice, which constitutes 4.6% of the total terminations. The overall staff turnover for 2018/2019 equals to 5.4%, excluding end-of-contracts.

It is worth noting that the percentage of employees who left the organisation due to ill health in 2018/2019 dropped by 23% compared to the 2017/2018 period.

Table 8: Labour relations: Misconduct and disciplinary actions

Nature of disciplinary action	Number
Verbal warning	10
Written warning	18
Final written warning	46
Dismissal	26
TOTAL	100

^{**}Out of all the disciplinary cases that were attended to, 26 resulted in dismissals.

Table 9 a): Equity target and employment equity status: Males per ethnic group

			MALE					
Levels	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	3	5	0	0	0	0	1	1
Senior management	8	14	1	1	4	4	9	7
Professional qualified	110	148	24	26	50	46	98	88
Skilled	625	705	66	80	51	59	57	75
Semi-skilled	728	767	67	82	42	44	11	22
Unskilled	293	311	9	11	0	1	1	2
TOTAL	1 767	1 949	167	200	147	154	177	195

This report is based on Oracle data as at 31 March 2019 and reflects the progress achieved on equity targets for the 2018/2019 period. Our numerical targets are informed by existing approved vacancies and future vacancies based on employees due for retirement.

The targeted race and gender groups are African and coloured males as they are the most under-represented

groups according to the EAP demographics of the EEC report of the DoL. Under-representation can be observed in the top, senior, professionally qualified, as well as skilled levels. There is under-representation of White males in the skilled level.

When comparing to the 2017/2018 financial year, positive movements were recorded in the senior management level on African males (+1), and White males (-1); in the professionally qualified level on African males (+4) and Coloured males (+2); and on the skilled level on Indian males (-11).

Negative movements were recorded in the professionally qualified level on Indian males (+7) and White males (+6); in the skilled level on African males (-5), coloured males (-2) and White males (-4).

Table 9 b): Equity target and employment equity status: Females per ethnic group

Levels			FEMALE						
	Afri	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target	
Top management	2	3	0	0	1	1	1	1	
Senior management	8	8	2	1	8	7	20	14	
Professional qualified	258	257	29	28	109	101	205	189	
Skilled	1 407	1 401	158	163	162	174	255	255	
Semi-skilled	1 413	1 415	184	187	61	64	67	73	
Unskilled	463	463	24	27	1	1	0	1	
TOTAL	3 551	3 547	397	406	342	348	548	538	

The target groups in the senior and professionally qualified levels are African and Coloured females as they are also underrepresented in the organisation as per the EEC report of the DoL. All the female groups in the skilled level are overrepresented.

When comparing to the 2017/2018 reporting period, positive movements were recorded in the top management level on the African females (+1); the senior management level on Coloured females (+1); the professionally qualified level on African females (+25) and Coloured females (+3); and the skilled level on Coloured females (-5), Indian females (-15) and White females (-31).

Negative movements were observed in the senior management level on White females (+4) and African females (-1); the professionally qualified level on Indian females (+12) and White females (+15); as well as the skilled level on African females (+20).

Table 9 c): Equity target and employment equity status: People with Disabilities

	Disabled staff							
Levels	M	ale	Female					
	Current	Target	Current	Target				
Top management	0	0	0	0				
Senior management	0	0	1	0				
Professional qualified	1	3	0	3				
Skilled	3	8	19	23				
Semi-skilled	4	9	5	9				
Unskilled	2	2	3	3				
TOTAL	10	22	28	38				

The people with disabilities recorded an increase of (+4) when comparing to the previous financial year. This increase can be attributed to an ongoing re-disclosure of the disability campaign.



5.PART E: FINANCIAL INFORMATION



Chief Financial Officer's report



Overview: Statement of Financial Performance

The financial performance of the NHLS for the 2018/19 fiscal year can be summarised as follows:

- The NHLS generated a surplus for the year, amounting to R996 million compared to a R1.4 billion surplus in the previous financial year.
- Revenue grew from R7.9 billion to R8.5 billion. Revenue from provincial budgets amounted to 87% of the total revenue generated. The increase in revenue was largely due to the increases in Viral Load, Cytology(Gynae) by LBC, GeneXpert PCT TB, Creatinine Automated, Stains Group 1 Crésyl Violet, C-Reactive Protein Nephelometer, Profile Discrete Analyser U & E, HIV PCR tests.
- Production costs including direct labour and material grew from R6.2 billion to R6.7 billion. This equated to a 7% increase which was mainly due to increases in labour, volume, price increases and fluctuations in the exchange rate. Labour costs constituted 42% of the total revenue compared to 40% in the previous financial year.
- Operational costs increased by 67%, due mainly to R458 million increase in debt impairment and a R54 million increase in employee costs.

Overview: Statement of Financial Position

The financial position for the 2018/2019 fiscal year can be summarised as follows:

- Assets increased from R5.0 billion to R5.9 billion which translates to a 17% increase, mainly due to a 97% (R1.1 billion) increase in cash. The closing bank balance ended at R2.2 billion compared to R1.1 billion in the previous financial year, which indicates a net cash inflow of R1.1 billion for the NHLS.
- The NHLS made extra payments to its suppliers and settled its accounts, which resulted in a decrease in its current liability from R1.6 billion to R1.5 billion (5% decrease),

The NHLS continues to grow its business which is demonstrated by the 2% increase in volumes and its revenue also increased by 7%. The NHLS collected R7.5 billion from provincial departments compared to R6.4 billion in the prior year. Despite the improvements shown in the provision of cost- effective and efficient services, further savings can only be realised through better revenue management. This will be achieved by further reducing the debtor collection period. The NHLS will continue to engage the provinces with regards to timely payments of debt in arrears.

The NHLS financial viability has improved when compared to the prior year, with all liquidity ratios indication positive movement. The solvency position of the NHLS also improved significantly thereby indicating sustainability of the entity in providing services to hospital and clinics. The NHLS is in a better condition to deliver on its mandate.

Cash flow

During the current financial year, the NHLS received R9.1 billion (2017/2018: R8.0 billion) from customers. Of the R9.1 billion, R3.6 billion (2017/18: R3.3 billion) was utilised for personnel costs and R4.2 billion (2017/18: R3.7billion) was utilised for goods and services.

The long outstanding accounts payable balances from the procurement of goods and services significantly reduced, resulting in a reduction of creditor days from 59 days (equivalent to R655m) to 29 days (equivalent to R162m) year-on-year.

Budget variance analysis

The total revenue is 6% over budget (R486 million) due to an increase in the demand for diagnostic laboratory services and increases in transfer revenue during the current financial year. The positive variance is mainly attributable to the increase in priority tests as per alignment with the NDoH's protocols.

Personnel costs are underspent compared to the budget by 9%, due to the budget vacancies which were not all filled. Material expenditure is at 41% in the current year (2018: 43%) as a percentage of test revenue.

The NHLS continues to underspend on its budget in certain areas, specifically around filling of vacant/new posts and capital expenditure due to cost control.

Going concern

Given its significance in the public and private health sectors and its ability to deliver affordable pathology health services to the South African public, the NDoH has neither the intention nor the need to liquidate or curtail the scale of the NHLS materially.

Management considered a wide range of factors in determining whether the organisation is a going concern. These factors include its current and expected performance as a Schedule 3A public entity, its restructuring plans and the likelihood of future government funding.

Despite the continued difficulty in receiving regular payments from all the provinces for the debt owed for services rendered by the NHLS, it is anticipated that the settlement of disputes will be resolved. The Group's Annual Financial Statements were therefore prepared based on the accounting policies applicable to a going concern. In line with the applicable accounting standard, the basis presumes that funds will be available to finance future operations, and that the realisation of assets and liabilities, contingent obligations and commitments will occur in the ordinary course of business. This specifically assumes that the debt owed by all the provinces will be settled.

Outstanding debt owed by provinces

The collection of money from the provincial DoHs has been an ongoing issue for many years. As at 31 March 2019, the DoH debt payable amounted to R5.3 billion. The majority of the debt is owed by KwaZulu-Nata and Gauteng constitutes R4.3 billion or 82% of trade receivables. A settlement agreement was reached with the Gauteng DoH on debt in arrears and there are ongoing negotiations with KwaZulu-Natal DoH regarding the settlement of overdue amounts owed to the NHLS.

Maintenance of financial control systems

The Board is ultimately responsible for systems of internal financial control within the NHLS and places considerable importance on maintaining a strong control environment. Based on assessments of internal and external audits, assurance is provided that the NHLS's internal controls are effective.

Subsequent events

The Board and management are not aware of any other matters or circumstances arising since the end of the financial year, not otherwise dealt with in this report, that would affect its operations or the results thereof significantly.

Borrowing limitations

In terms of the NHLS rules, the Board may exercise all the powers of the economic entity to borrow money, by following the PFMA, as they consider appropriate. During the current financial year, the entity did not borrow funds to finance its operations.

Michael Sass

Acting Chief Financial Officer

Date:

General Information

Country of incorporation and South Africa

domicile

Nature of business and prin-

cipal activities

Healthcare, research and training

Board members

B. Durham

B.E. Mzangwa

E. Buch G. Goosen F. Salooiee

I. van der Merwe

K. Chetty M. Ross

M. Shingange

M. Tom N. Mkhize C.L. Obi S. Mayinga S. Zungu T. Tucker

N. Van der Westhuizen

Z.A. Mavuso

Registered office 1 Modderfontein Road

Rietfontein Sandringham Johannesburg 2000

Postal address Private Bag X 8

Johannesburg 2131

Shareholder National Department of Health

Bankers First National Bank Ltd

> Nedbank Ltd Investec Ltd Rand Merchant Bank Ltd

Hogan Lovells Inc. **Attorneys**

Gildenhuys Malatji Inc.

Sizwe Ntsaluba Gobodo Grant Thornton Inc **Auditors**

Website www.nhls.ac.za **Practice number** PR5200296

Legislation governing NHLS

operations

The National Health Laboratory Service (NHLS) Act, no. 37 of

2000

The general rules ito Section 27 of the NHLS Act

The Public Finance Management (PFMA) Act, no. 1 of 1999 National Treasury regulations issued in terms of PFMA, 1999 The Companies Act, No. 71 of 2008

The National Health Act, No 61 of 2003

Published 06 August 2019

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The reports and statements set out below comprise the audited group annual financial statements presented to the Parliament:

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Statement of Financial position as at 31 March 2019	193
Statement of Financial Performance	194
Statement of Changes in Net Assets	195
Cash Flow Statement	196
Statement of Comparison of Budget and Actual Amounts	197
Accounting Policies	198
Notes to the Audited Group Annual Financial Statements	229
The following supplementary information does not form part of the audited group annual financial statements and is unaudited:	
Detailed Statement of Financial Performance	277

Accounting Authority's Responsibilities and Approval

The Accounting Authority is required by the Public Finance Management Act (Act 1 of 1999), to maintain adequate accounting records and is responsible for the content and integrity of the audited group annual financial statements and related financial information included in this report. It is the responsibility of the Accounting Authority to ensure that the audited Annual Financial Statements fairly present the state of affairs of the economic entity as at the end of the financial year and the results of its operations and cash flows for the year then ended. The external auditors are engaged to express an independent opinion on the audited Annual Financial Statements and was given unrestricted access to all financial records and related data.

The audited Annual Financial Statements have been prepared in accordance with Standards of Generally Recognised Accounting Practice (GRAP) including any interpretations, guidelines and directives issued by the Accounting Standards Board.

The audited Annual Financial Statements are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The Accounting Authority acknowledges that it is ultimately responsible for the system of internal financial control established by the economic entity and place considerable importance on maintaining a strong control environment. To enable the Accounting Authority to meet these responsibilities, the Accounting Authority sets standards for internal control aimed at reducing the risk of error or deficit in a cost effective manner. The standards include the proper delegation of responsibilities within a clearly defined framework, effective accounting procedures and adequate segregation of duties to ensure an acceptable level of risk. These controls are monitored throughout the economic entity and all employees are required to maintain the highest ethical standards in ensuring the economic entity's business is conducted in a manner that in all reasonable circumstances is above reproach. The focus of risk management in the economic entity is on identifying, assessing, managing and monitoring all known forms of risk across the economic entity. While operating risk cannot be fully eliminated, the economic entity endeavours to minimise it by ensuring that appropriate infrastructure, controls, systems and ethical behaviour are applied and managed within predetermined procedures and constraints.

The Accounting Authority is of the opinion, based on the information and explanations given by management, that the system of internal control provides reasonable assurance that the financial records may be relied on for the preparation of the audited Annual Financial Statements. However, any system of internal financial control can provide only reasonable, and not absolute, assurance against material misstatement or error.

The Accounting Authority has reviewed the economic entity's cash flow forecast for the year to 31 March 2020 and, in the light of this review and the current financial position, it is satisfied that the economic entity has access to adequate resources to continue in operational existence for the foreseeable future.

The economic entity is wholly dependent on public healthcare providers for continued funding of operations. The audited Annual Financial Statements are prepared on the basis that the entity is a going concern and that the National Department of Health has neither the intention nor the need to liquidate or curtail materially the scale of the economic entity. Although the Accounting Authority is primarily responsible for the financial affairs of the economic entity, it is supported by the economic entity's internal auditors.

The audited group Annual Financial Statements set out on pages 229 to 276, which have been prepared on the going concern basis, were approved by the Accounting Authority on 06 August 2019 and were signed on its behalf by:

Prof E

Chairperson: Accounting Authority

Dr Karmani ChettyActing Chief Executive Officer

(CEO)

Independent auditor's report to Parliament on National Health Laboratory Service

Opinion

- 1. We have audited the consolidated financial statements of the National Health Laboratory Service and its subsidiary (the group) set out on pages 193 to 276, which comprise the consolidated and separate statements of financial position as at 31 March 2019, the consolidated and separate statements of financial performance, statement of changes in net assets, cash flow statements and statement of comparison of budget and actual amounts for the year then ended, as well as the notes to the consolidated and separate financial statements, including a summary of significant accounting policies.
- 2. In our opinion, the consolidated and separate financial statements present fairly, in all material respects, the consolidated and separate financial position of the National Health Laboratory Service as at 31 March 2019, and the group's financial performance and its consolidated and separate cash flows for the year then ended in accordance with the Statement of Generally Recognised Accounting Practice (GRAP) and the requirements of the Public Finance Management Act of South Africa, 1999 (Act No. 1 of 1999) (PFMA).

Basis for opinion

- 3. We conducted our audit in accordance with the International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the auditor's responsibilities for the audit of the consolidated and separate financial statements section of this auditor's report.
- 4. We are independent of the public entity in accordance with section 290 and 291 of the Independent Regulatory Board for Auditors' Code of professional conduct for Registered Auditors (Revised January 2018), parts 1 and 3 of the Independent Regulatory Board for Auditors' Code of Professional Conduct for Registered Auditors (Revised November 2018) (together the IRBA Codes) and other independence requirements applicable to performing audits of financial statements in South Africa. We have fulfilled our other ethical responsibilities, as applicable in accordance with the IRBA Codes and in accordance with other ethical requirements applicable to performing audits in South Africa. The IRBA Codes are consistent with the corresponding sections of the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants and the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (including International Independence Standards) respectively.
- 5. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of matters

6. We draw attention to the matters below. Our opinion is not modified in respect of these matters.

Restatement of corresponding figures

7. As disclosed in note 41 to the financial statements, the corresponding figures for 31 March 2018 have been restated as a result of errors in the financial statements of the entity for the year ended, 31 March 2019.

Material impairments - trade debtors

8. As disclosed in note 4 to the financial statements, material impairments to the amount of R3 531 479 were incurred as a result of doubt in recovering the amounts owed by these debtors.

Other matter

9. The supplementary information set out on pages 277 to 278 does not form part of the financial statements and is presented as additional information. I have not audited this schedule and, accordingly, I do not express an opinion thereon.

Responsibilities of accounting authority for the financial statements

- 10. The board of directors, which constitutes the accounting authority is responsible for the preparation and fair presentation of the consolidated and separate financial statements in accordance with GRAP and the requirements of the PFMA and the requirements of the GRAP and the requirements of the PFMA and for such internal control as the accounting authority determines is necessary to enable the preparation of consolidated and separate financial statements that are free from material misstatement, whether due to fraud or error.
- 11. In preparing the consolidated and separate financial statements, the accounting authority is responsible for assessing the National Health Laboratory Service's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting unless the appropriate governance structure either intends to liquidate the entity or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the consolidated and separate financial statements

- 12. Our objectives are to obtain reasonable assurance about whether the consolidated and separate financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated and separate financial statements.
- 13. As part of an audit in accordance with the ISAs, we exercise professional judgement and maintain professional scepticism throughout our audit of the consolidated and separate financial statements, and the procedures performed on reported performance information for selected programmes and on the public entity's compliance with respect to the selected subject matters.

Financial statements

- 14. In addition to our responsibility for the audit of the consolidated and separate financial statements as described in this auditor's report, we also:
- Identify and assess the risks of material misstatement of the consolidated and separate financial statements whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the public entity's internal control
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors, which constitutes the accounting authority
- Conclude on the appropriateness of the board of directors, which constitutes the accounting authority's use of the going concern basis of accounting in the preparation of the financial statements. We also conclude, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the National Health Laboratory Service and its subsidiary's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements about the material uncertainty or, if such disclosures are inadequate, to modify the opinion on the financial statements. Our conclusions are based on the information available to me at the date of this auditor's report. However, future events or conditions may cause a public entity to cease continuing as a going concern

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

Communication with those charged with governance

- 15. We communicate with the accounting authority regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.
- 16. We also confirm to the accounting authority that we have complied with relevant ethical requirements regarding independence, and communicate all relationships and other matters that may reasonably be thought to have a bearing on our independence and, where applicable, related safeguards.

Report on the audit of the annual performance report

Introduction and scope

- 17. In accordance with the Public Audit Act of South Africa, 2004 (Act No. 25 of 2004) (PAA) and the general notice issued in terms thereof, we have a responsibility to report material findings on the reported performance information against predetermined objectives for selected programmes presented in the annual performance report. We performed procedures to identify findings but not to gather evidence to express assurance.
- 18. Our procedures address the reported performance information, which must be based on the approved performance planning documents of the entity. We have not evaluated the completeness and appropriateness of the performance indicators/ measures included in the planning documents. Our procedures also did not extend to any disclosures or assertions relating to planned performance strategies and information in respect of future periods that may be included as part of the reported performance information. Accordingly, our findings do not extend to these matters.
- 19. We evaluated the usefulness and reliability of the reported performance information in accordance with the criteria developed from the performance management and reporting framework, as defined in the general notice, for the following selected programmes presented in the annual performance report of the entity for the year ended 31 March 2019:

Programmes	Pages in the annual performance report
Programme 2 - Surveillance of Communicable Diseases	42 - 43
Programme 4 - Academic affairs, Research and Quality assurance objective	45 - 48
Programme 5 - Laboratory services	49 - 50

- 20. We performed procedures to determine whether the reported performance information was properly presented and whether performance was consistent with the approved performance planning documents. We performed further procedures to determine whether the indicators and related targets were measurable and relevant, and assessed the reliability of the reported performance information to determine whether it was valid, accurate and complete.
- 21. The material findings in respect of the usefulness and reliability of the selected programmes are as follows:



22. The description and method of calculation of the achievement of the planned indicator was not well-defined as required by the Framework for Managing Programme Performance Information (FMPPI) as the reported achievement relates to a report whose data was collated in 2017 but only reported in 2019 financial year end.

Other matters

23. We draw attention to the matters below. Our opinions are not modified in respect of these matters.

Achievement of planned targets

24. Refer to the annual performance report on pages 36 to 51 for information on the achievement of planned targets for the year and explanations provided for the under/ over achievement of a significant number of targets. This information should be considered in the context of the material findings on the usefulness and reliability of the reported performance information in paragraph 21 of this report.

Adjustment of material misstatements

25. We identified material misstatements in the annual performance report submitted for auditing. These material misstatements were on the reported performance information of Surveillance of Communicable Diseases, Academic affairs, Research and Quality assurance objective and Laboratory services. Although management subsequently corrected some of the misstatements, we raised material findings on the usefulness and reliability of the reported performance information. Those that were not corrected are reported above in paragraph 21.

Report on the audit of compliance with legislation

Introduction and scope

- 26. In accordance with the PAA and the general notice issued in terms thereof, we have a responsibility to report material findings on the compliance of the entity with specific matters in key legislation. We performed procedures to identify findings but not to gather evidence to express assurance.
- 27. The material findings on compliance with specific matters in key legislations are as follows:

Annual financial statements

- 28. The financial statements submitted for auditing were not prepared in accordance with the prescribed financial reporting framework and/or supported by full and proper records as required by section 55(1) (a).
- 29. Financial statements were not submitted for auditing within two months after the end of financial year, as required by section 55(1) (c) (i) of the PFMA.

Expenditure management

30. Effective steps were not taken to prevent irregular expenditure, amounting to R5 132 billion as disclosed in note 40 of the AFS, as required by section 51(1) (b) (ii) of the PFMA.



- 31. Some of the goods and services with a transaction value below R500 000 were procured without obtaining the required price quotations, as required by Treasury Regulation 16A6.1.
- 32. Sufficient appropriate audit evidence could not be obtained that competitive bids were adjudicated by a bid adjudication committee that was composed in accordance with the client's policies as required by Treasury Regulation 16A6.2 (a), (b) and (c).
- 33. Sufficient appropriate audit evidence could not be obtained that contracts were awarded only to bidders who submitted a declaration on whether they are employed by the state or connected to any person employed by the state, which is prescribed in order to comply with Treasury Regulation 16A8.3.
- 34. Sufficient appropriate audit evidence could not be obtained that contracts were awarded to bidders based on points given for criteria that were stipulated in the original invitation for bidding, as required by treasury regulations 16A6.3 (a).
- 35. Some of the construction contracts were awarded to contractors that were not registered with the Construction Industry Development Board in accordance with section 18(1) of the CIDB Act and CIDB regulations 17 and 25(7A).
- 36. In some instances persons in service of the public entity who had a private or business interest in contracts awarded by the public entity failed to disclose such interest, as required by treasury regulation 16A8.4.
- 37. In some instances persons in service of the public entity whose close family members, partners or associates had a private or business interest in contracts awarded by the public entity failed to disclose such interest, as required by treasury regulation 16A8.4.
- 38. In some instances persons in service of the public entity and other role players in the supply chain management system whose close family members/ partners/ associates had a private or business interest in contracts awarded by the public entity participated in the process relating to that contract in contravention of treasury regulation 16A8.4.
- 39. In some instances persons in service of other state institutions who had a private or business interest in contracts awarded by the public entity participated in the process relating to that contract in contravention of treasury regulation 16A8.4

Other information

- 40. The accounting authority is responsible for the other information. The other information comprises the information included in the annual report, which includes the Foreword by the Chairperson of the Board, Chief Executive Officer's overview, Chief Financial Officer's report, Accounting Authority's Responsibility and Approval and Report of the Audit and Risk Committee. The other information does not include the consolidated and separate financial statements, the auditor's report and those selected programmes presented in the annual performance report that have been specifically reported in this auditor's report.
- 41. Our opinion on the financial statements and findings on the reported performance informationi and compliance with legislation do not cover the other information and we do not express an audit opinion or any form of assurance conclusion thereon.
- 42. In connection with our audit, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated and separate financial statements and the selected programmes presented in the annual performance report, or our knowledge obtained in the audit, or otherwise appears to be materially misstated.
- 43. We did not receive the other information prior to the date of this auditor's report. After we receive and read this information, and if we conclude that there is a material misstatement, we are required to communicate the matter to those charged with governance and request that the other information be corrected. If the other information is not corrected, we may have to retract this auditor's report and re-issue an amended report as appropriate. However, if it is corrected this will not be necessary.

Internal control deficiencies

44. We considered internal control relevant to our audit of the consolidated and separate financial statements. reported performance information and compliance with applicable legislation; however, our objective was not to express any form of assurance on it. The matters reported below are limited to the significant internal control deficiencies that resulted in the basis for the opinion, the findings on the annual performance report and the findings on compliance with legislation included in this report.

Financial and performance management

- 45. Management did not implement proper record keeping in a timely manner to ensure that complete, relevant and accurate information is accessible and available to support financial and performance reporting.
- 46. Management did not prepare regular, accurate and complete financial and performance reports that are supported and evidenced by reliable information.
- 47. Management did not review and monitor compliance with applicable laws and regulations

Neridha Moodley

Sizwe Ntsaluba Gobodo Grant Thornton Inc.

Director

Registered Auditor

06 August 2019

20 Morris Street East Woodmead

2191



Statement of Financial Position as at 31 March 2019

Economic entity Controlling entity

	Note(s)	2019 R'000	2018 Restated* R'000	2019 R'000	2018 Restated* R'000
Assets					
Current Assets					
Inventories	3	159,990	124,412	151,101	118,172
Receivables from exchange transactions	4	2,003,613	2,219,090	2,001,139	2,217,101
Receivables from non-exchange transactions*	6	431,468	327,626	431,468	327,626
Cash and cash equivalents	7	2,208,093	1,119,144	2,201,737	1,114,456
		4,803,164	3,790,272	4,785,445	3,777,355
Non-Current Assets					
Property, plant and equipment	8	1,125,355	1,222,649	1,124,033	1,221,160
Intangible assets	9	964	34,582	964	34,582
Deferred tax*	18	5	15	-	-
		1,126,324	1,257,246	1,124,997	1,255,742
Total Assets		5,929,488	5,047,518	5,910,442	5,033,097
Liabilities					
Current Liabilities					
Other financial liabilities	12	4,228	23,306	4,228	23,306
Current tax payable		1,924	821	-	-
Finance lease obligation	13	16,933	15,197	16,933	15,197
Payables from exchange transactions	14	541,634	703,527	539,608	701,740
Employee benefit obligation	15	30,879	26,480	30,879	26,480
Unspent conditional grants and receipts	16	28,669	20,316	28,669	20,316
Provisions	17	941,958	853,841	941,958	853,841
		1,566,225	1,643,488	1,562,275	1,640,880
Non-Current Liabilities					
Other financial liabilities	12	9,712	13,940	9,712	13,940
Finance lease obligation	13	38,191	55,124	38,191	55,124
Employee benefit obligation	15	957,536	973,554	957,536	973,554
		1,005,439	1,042,618	1,005,439	1,042,618
Total Liabilities		2,571,664	2,686,106	2,567,714	2,683,498
Net Assets		3,357,824	2,361,412	3,342,728	2,349,599
Share capital / contributed capital	19	332	332	332	332
Reserves					
Revaluation reserve	20	688,072	688,072	688,072	688,072
Accumulated surplus		2,669,420	1,673,008	2,654,324	1,661,195
Total Net Assets		3,357,824	2,361,412	3,342,728	2,349,599

Statement of Financial Performance

		Econom	Economic entity		ng entity
	Note(s)	2019 R'000	2018 Restated* R'000	2019 R'000	2018 Restated* R'000
Revenue	21	8,502,008	7,915,877	8,475,253	7,894,314
Cost of sales	22	(6,746,379)	(6,277,601)	(6,727,641)	(6,259,766)
Gross surplus		1,755,629	1,638,276	1,747,612	1,634,548
Other income	23	288,863	420,319	288,860	420,318
Operating expenses (by function)	29	(1,252,619)	(748,158)	(1,249,885)	(747,921)
Operating surplus	24	791,873	1,310,437	786,587	1,306,945
Investment income	25	194,717	102,936	194,256	102,595
Fair value adjustments		22,665	22	22,665	-
Finance costs	26	(10,753)	(16,098)	(10,379)	(15,973)
Surplus before taxation		998,502	1,397,297	993,129	1,393,567
Taxation	27	(2,090)	(693)	-	-
Surplus for the year		996,412	1,396,604	993,129	1,393,567

Statement of Changes in Net Assets

		Share capital / contributed capital R'000	Revaluation reserve R'000	Accumulated surplus R'000	Total net assets R'000
Economic entity					
Opening balance as previously reported Adjustments Correction of errors*		332	597,297	(365)	597,264
Driver years adjustments*		-	-	(37,612)	(37,612)
Prior year adjustments* Balance at 01 April 2017 as restated*		332	597,297	10,178	10,178 569,830
Changes in net assets Revaluation of land and buildings		-	90,775	-	90,775
Correction of errors*		-	-	304,204	304,204
Net income (losses) recognised directly in net assets		-	90,775	304,204	394,979
Restated Surplus for the year *		-	-	1,396,604	1,396,604
Total recognised income and expenses for the year		-	90,775	1,700,808	1,791,583
Total changes		-	90,775	1,700,808	1,791,583
Opening balance as previously reported Adjustments Correction of errors		332	688,072	1,264,598	1,953,002
		-	-	304,204	304,204
Prior year adjustments		-	-	104,206	104,206
Restated* Balance at 01 April 2018 Changes in net assets Surplus for the year		332	688,072	1,673,008	2,361,412
		-	-	996,412	996,412
Total changes		-	-	996,412	996,412
Balance at 31 March 2019		332	688,072	2,669,420	3,357,824
Note(s)	19		20		
Controlling entity					
Opening balance as previously reported Adjustments		332	560,947	729	562,008
Correction of errors*		-	36,350	(37,615)	(1,265)
Prior year adjustments		-	-	310	310
Balance at 01 April 2017 as restated* Changes in net assets Revaluation of Land and Buildings		332	597,297 87,379	(36,576)	561,053 87,379
Correction of errors*			3,396		3,396
			90.775	-	90,775
Net income (losses) recognised directly in net assets Restated surplus for the year *			90,773	1,393,567	1,393,567
Total recognised income and expenses for the year			90,775		1,484,342
Correction of errors*			90,773	1,393,567 304,204	304,204
Total changes			90,775	1,697,771	1,788,546
Opening balance as previously reported		332	648,326	1,264,394	1,913,052
Adjustments Correction of errors*		_	39,746	304,204	343,950
Prior year adjustments		_	-	92,597	92,597
Restated* Balance at 01 April 2018		332	688,072	1,661,195	2,349,599
Changes in net assets Surplus for the year		-	-	993,129	993,129
Total changes		_	-	993,129	993,129
Balance at 31 March 2019		332	688,072	2,654,324	3,342,728
Note(s)	19		20	, = = -, = = -	-,,

^{*} The restated surplus comprises of grant revenue not recognised and recognition of the building previously in SAVP.

Cash Flow Statement

		Econom	ic entity	Controllir	ng entity
	Note(s)	2019 R'000	2018 Restated* R'000	2019 R'000	2018 Restated* R'000
Cash flows from operating activities					
Receipts					
Sale of goods and services		8,229,686	7,186,241	8,203,268	7,163,939
Grants		694,270	746,464	694,270	746,464
Interest income		186,577	97,645	186,116	97,304
		9,110,533	8,030,350	9,083,654	8,007,707
Payments					
Employee costs		(3,623,644)	(3,358,469)	(3,608,543)	(3,344,510)
Suppliers		(4,245,251)	(3,740,237)	(4,236,749)	(3,735,156)
Finance costs		(377)	(142)	(3)	(17)
Taxes on surpluses	33	(977)	(618)	-	-
		(7,870,249)	(7,099,466)	(7,845,295)	(7,079,683)
Net cash flows from operating activities	32	1,240,284	930,884	1,238,359	928,024
Cash flows from investing activities					
Purchase of property, plant and equipment	8	(102,450)	(128,060)	(102,166)	(127,831)
Proceeds from sale of property, plant and equipment	8	39	-	12	-
Purchase of other intangible assets	9	(45)	(390)	(45)	(390)
Net cash flows from investing activities		(102,456)	(128,450)	(102,199)	(128,221)
Cash flows from financing activities					
Repayment of other financial liabilities		(25,353)	(53,506)	(25,353)	(53,506)
Finance lease payments		(23,526)	(21,760)	(23,526)	(21,760)
Net cash flows from financing activities		(48,879)	(75,266)	(48,879)	(75,266)
Net increase in cash and cash equivalents		1,088,949	727,168	1,087,281	724,537
Cash and cash equivalents at the beginning of the year		1,119,144	391,976	1,114,456	389,919
Cash and cash equivalents at the end of the year	7	2,208,093	1,119,144	2,201,737	1,114,456

Statement of Comparison of Budget and Actual Amounts

	Approved budget R'000	Adjustments R'000	Final Budget R'000	Actual amounts on comparable basis R'000	Difference between final budget and actual R'000	Reference
Economic entity						
Statement of Financial						
Performance						
Revenue						
Revenue from exchange						
transactions						
Sale of goods	-	-	-	26,755	26,755	
Rendering of services	7,544,234	-	7,544,234	7,679,047	134,813	43
Miscellaneous other revenue	9,940	-	9,940	6,447	(3,493)	43.
Grant income recognised	-	-	-	226,885	226,885	43.
Royalties received	428	-	428	804	376	
Discount received	1,330	-	1,330	1,193	(137)	
Recoveries	6,903	-	6,903	13,938	7,035	43.
Teaching Income	61,602	-	61,602	45,905	(15,697)	43.
Sundry income	4,887	-	4,887	138	(4,749)	43.
nterest received	81,200	-	81,200	194,717	113,517	43.
Total revenue from exchange	7,710,524	-	7,710,524	8,195,829	485,305	
transactions						
Revenue from non-exchange transactions						
Transfer revenue	007.157		007 157	700 750	(17.70.4)	
Government grants & subsidies	807,153	-	807,153	789,759	(17,394)	
Fotal revenue	8,517,677	-	8,517,677	8,985,588	467,911	
Expenditure Personnel	(3,994,213)	-	(3,994,213)	(3,660,540)	333,673	43.
Depreciation and amortisation	(201,174)	-	(201,174)	(250,899)	(49,725)	43.
- Finance costs	(6,299)	-	(6,299)	(10,753)	(4,454)	43.1
_ease rentals on operating lease	(44,383)	-	(44,383)	(50,500)	(6,117)	43.1
Debt Impairment	(11,800)	-	(11,800)	(188,296)	(176,496)	43.1
General Expenses	(4,027,679)	-	(4,027,679)	(3,839,973)	187,706	43.1
Total expenditure	(8,285,548)	-	(8,285,548)	(8,000,961)	284,587	
Operating surplus	232,129	-	232,129	984,627	752,498	
Loss on disposal of assets and	(1)	1	_	(4,814)	(4,814)	43.1
iabilities Loss on foreign exchange	-	-		(3,976)	(3,976)	43.1
Fair value adjustments	-	-	-	22,665	22,665	
	(1)	1	-	13,875	13,875	
Surplus before taxation	232,128	1	232,129	998,502	766,373	
Taxation	-	-	_	2,090	2,090	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	232,128	1	232,129	996,412	764,283	

1. Presentation of Audited Group Annual Financial Statements

The audited group annual financial statements have been prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP), issued by the Accounting Standards Board in accordance with Section 91(1) of the Public Finance Management Act (Act 1 of 1999).

These audited group annual financial statements have been prepared on an accrual basis of accounting and are in accordance with historical cost convention as the basis of measurement, unless specified otherwise.

A summary of the significant accounting policies, which have been consistently applied in the preparation of these audited group annual financial statements, are disclosed below.

These accounting policies are consistent with the previous period, except for the changes set out in the Changes in accounting policy note.

1.1 Presentation currency

These audited group annual financial statements are presented in South African Rand, which is the functional currency of the economic entity and all values are rounded to the nearest thousand (R000), except when otherwise indicated.

1.2 Going concern assumption

These audited group annual financial statements have been prepared based on the expectation that the economic entity will continue to operate as a going concern for at least the next 12 months.

1.3 Consolidation Basis of consolidation

Consolidated audited group annual financial statements are the audited group annual financial statements of the economic entity presented as those of a single entity.

The consolidated audited group annual financial statements incorporate the audited separate annual financial statements of the National Health Laboratory Service (NHLS) as the controlling entity and those of controlled entity, the South African Vaccine Producers (Pty) Ltd (SAVP).

Consolidated audited group annual financial statements are prepared using uniform accounting policies for like transactions and other events in similar circumstances.

Control exists when the controlling entity has the power to govern the financial and operating policies of another entity so as to obtain benefits from its activities.

The revenue and expenses of the SAVP are included in the consolidated audited group annual financial statements from the transfer date or acquisition date as defined in the Standards of GRAP on Transfer of functions between entities under common control. The revenue and expenses of the SAVP are based on the values of the assets and liabilities recognised in the controlling entity's audited group annual financial statements at the acquisition date.

The seperate annual financial statements of the NHLS and those of the SAVP used in the preparation of the consolidated audited group annual financial statements are prepared as of the same date.

All intra-entity transactions, balances, revenues and expenses are eliminated in full on consolidation.

1.4 Significant judgements and sources of estimation uncertainty

In preparing the audited group annual financial statements, management is required to make estimates and assumptions that affect the amounts represented in the audited group annual financial statements and related disclosures. Use of available information and the application of judgement is inherent in the formation of estimates. Actual results in the future could differ from these estimates which may be material to the audited group annual financial statements. Significant judgements include:

Trade and other receivables

The economic entity assesses its trade and other receivables for impairment at the end of each reporting period. In determining whether an impairment loss should be recorded in surplus or deficit, the economic entity makes judgements as to whether there is observable data indicating a measurable decrease in the estimated future cash flows from a financial asset.

The impairment for trade and other receivables is calculated on a individual basis for major customers (others are grouped on a portfolio basis), based on historical loss ratios, adjusted for national and industry-specific economic conditions and other indicators present at the reporting date that correlate with defaults on the customer. These annual loss ratios are applied to loan balance of the customer or the portfolio and scaled to the estimated loss emergence period.

The impairment is measured as the difference between the debtors carrying amount and the present value of estimated future cash flows discounted at the effective interest rate, computed at initial recognition.

Allowance for slow moving, damaged and obsolete stock

An allowance is raised to write stock down to the lower of cost or net realisable value. Management have made estimates of the selling price and direct cost to sell on certain inventory items.

Impairment testing

The recoverable amounts of cash-generating units and individual assets are determined based on the higher of value-in-use calculations and fair values less costs to sell. These calculations require the use of estimates and assumptions. It is reasonably possible that the key assumptions may change which may then impact our estimations and may then require a material adjustment to the carrying value of tangible assets.

The economic entity reviews and tests the carrying value of assets when events or changes in circumstances suggest that the carrying amount may not be recoverable. Assets are grouped at the lowest level for which identifiable cash flows are largely independent of cash flows of other assets and liabilities. If there are indications that impairment may have occurred, estimates are prepared of expected future cash flows for each group of assets. Expected future cash flows used to determine the value in use of tangible assets are inherently uncertain and could materially change over time. They are significantly affected by a number of factors including including production estimates, together with economic factors such as exchange rates, inflation rates and interest rates.

Provisions

Provisions were raised and management determined an estimate based on the information available. Additional disclosure of these estimates of provisions are included in note 17 - Provisions.

1.4 Significant judgements and sources of estimation uncertainty (continued)

Useful lives of property, plant and equipment

The economic entity's management determines the estimated useful lives and related depreciation charges for property, plant and equipment. This estimate is based on industry norm. Management will increase the depreciation charge where useful lives are less than previously estimated useful lives.

Post-retirement benefits

The present value of the post retirement obligation depends on a number of factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost (income) include the discount rate, healthcare cost inflation, expected retirement age and withdrawal rate. Any changes in these assumptions will impact on the carrying amount of post retirement obligations.

The economic entity determines the appropriate discount rate at the end of each year. This is the interest rate that should be used to determine the present value of estimated future cash outflows expected to be required to settle the medical obligations. In determining the appropriate discount rate, the economic entity considers the interest rates of high-quality government bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating the terms of the related medical liability.

Other key assumptions for medical obligations are based on current market conditions. Additional information is disclosed in Note 15.

1.5 Property, plant and equipment

Property, plant and equipment are tangible non-current assets (including infrastructure assets) that are held for use in the production or supply of goods or services, rental to others, or for administrative purposes, and are expected to be used during more than one period.

The cost of an item of property, plant and equipment is recognised as an asset when:

- it is probable that future economic benefits or service potential associated with the item will flow to the economic entity; and
- the cost of the item can be measured reliably. Property, plant and equipment is initially measured at cost.

The cost of an item of property, plant and equipment is the purchase price and other costs attributable to bring the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Trade discounts and rebates are deducted in arriving at the cost.

Where an asset is acquired through a non-exchange transaction, its cost is its fair value as at date of acquisition.

Where an item of property, plant and equipment is acquired in exchange for a non-monetary asset or monetary assets, or a combination of monetary and non-monetary assets, the asset acquired is initially measured at fair value (the cost). If the acquired item's fair value was not determinable, it's deemed cost is the carrying amount of the asset(s) given up.

When significant components of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

1.5 Property, plant and equipment (continued)

Costs include costs incurred initially to acquire an item of property, plant and equipment and costs incurred subsequently to add to, replace part of, or service it. If a replacement cost is recognised in the carrying amount of an item of property, plant and equipment, the carrying amount of the replaced part is derecognised.

Recognition of costs in the carrying amount of an item of property, plant and equipment ceases when the item is in the location and condition necessary for it to be capable of operating in the manner intended by management.

Items such as spare parts, standby equipment and servicing equipment are recognised when they meet the definition of property, plant and equipment.

Major inspection costs which are a condition of continuing use of an item of property, plant and equipment and which meet the recognition criteria above are included as a replacement in the cost of the item of property, plant and equipment. Any remaining inspection costs from the previous inspection are derecognised.

Property, plant and equipment is subsequently carried at cost less accumulated depreciation and any impairment losses except for Land and Buildings. Buildings is carried at revalued amount being the fair value at the date of revaluation less any subsequent accumulated depreciation and subsequent accumulated impairment losses. Land is not depreciated but carried at revalued amount less accumulated impairment losses.

Revaluations are made with sufficient regularity such that the carrying amount does not differ materially from that which would be determined using fair value at the end of the reporting period.

When an item of property, plant and equipment is revalued, any accumulated depreciation at the date of the revaluation is eliminated against the gross carrying amount of the asset and the net amount restated to the revalued amount of the asset.

Any increase in an asset's carrying amount, as a result of a revaluation, is credited directly to a revaluation surplus. The increase is recognised in surplus or deficit to the extent that it reverses a revaluation decrease of the same asset previously recognised in surplus or deficit.

Any decrease in an asset's carrying amount, as a result of a revaluation, is recognised in surplus or deficit in the current period. The decrease is debited directly to a revaluation surplus to the extent of any credit balance existing in the revaluation surplus in respect of that asset.

The revaluation surplus in equity related to a specific item of property, plant and equipment is transferred directly to retained earnings when the asset is derecognised.

Property, plant and equipment are depreciated on the straight line basis over their expected useful lives to their estimated residual value.

Sheep and horses that are used for research purposes are initially measured at cost and subsequently carried at cost less any accumulated depreciation and any accumulated impairment losses.

The useful lives of items of property, plant and equipment have been assessed as follows:



1.5 Property, plant and equipment (continued)

Item	Depreciation method	Average useful life
Buildings	Straight line	30 - 52 years
Laboratory equipment	Straight line	4 - 10 years
Plant and machinery	Straight line	5 years
Furniture and fixtures	Straight line	10 - 20 years
Motor vehicles	Straight line	5 years
Office equipment	Straight line	3 - 10 years
Computer equipment	Straight line	3 - 5 years
Leasehold improvements	Straight line	5 - 8 years
Mobile units	Straight line	6 - 10 years
Buildings - air systems	Straight line	5 years
Sheep	Straight line	5 years
Horses	Straight line	15 years

The depreciable amount of an asset is allocated on a systematic basis over its useful life.

Each part of an item of property, plant and equipment with a cost that is significant in relation to the total cost of the item is depreciated separately.

The depreciation method used reflects the pattern in which the asset's future economic benefits or service potential are expected to be consumed by the economic entity. The depreciation method applied to an asset is reviewed at least at each reporting date and, if there has been a significant change in the expected pattern of consumption of the future economic benefits or service potential embodied in the asset, the method is changed to reflect the changed pattern. Such a change is accounted for as a change in an accounting estimate.

The economic entity assesses at each reporting date whether there is any indication that the economic entity expectations about the residual value and the useful life of an asset have changed since the preceding reporting date. If any such indication exists, the economic entity revises the expected useful life and/or residual value accordingly. The change is accounted for as a change in an accounting estimate.

The depreciation charge for each period is recognised in surplus or deficit unless it is included in the carrying amount of inventory.

Items of property, plant and equipment are derecognised when the asset is disposed of or when there are no further economic benefits or service potential expected from the use of the asset.

The gain or loss arising from the derecognition of an item of property, plant and equipment is included in surplus or deficit when the item is derecognised. The gain or loss arising from the derecognition of an item of property, plant and equipment is determined as the difference between the net disposal proceeds, if any, and the carrying amount of the item.

The economic entity separately discloses expenditure to repair and maintain property, plant and equipment in the notes to the financial statements (see note 8).

1.6 Intangible assets

An intangible asset is identifiable if it either:

- is separable, i.e. is capable of being separated or divided from an entity and sold, transferred, licensed, rented or exchanged, either individually or together with a related contract, identifiable assets or liability, regardless of whether the entity intends to do so; or
- arises from binding arrangements (including rights from contracts), regardless of whether those rights are transferable or separable from the economic entity or from other rights and obligations.

A binding arrangement describes an arrangement that confers similar rights and obligations on the parties to it as if it were in the form of a contract.

An intangible asset is recognised when:

- it is probable that the expected future economic benefits or service potential that are attributable to the asset will flow to the economic entity; and
- the cost or fair value of the asset can be measured reliably.

The economic entity assesses the probability of expected future economic benefits or service potential using reasonable and supportable assumptions that represent management's best estimate of the set of economic conditions that will exist over the useful life of the asset.

Where an intangible asset is acquired through a non-exchange transaction, its initial cost at the date of acquisition is measured at its fair value as at that date.

Intangible assets are carried at cost less any accumulated amortisation and any impairment losses.

The amortisation period and the amortisation method for intangible assets are reviewed at each reporting date. Amortisation is provided to write down the intangible assets, on a straight line basis, to their residual values as follows:

Item	Depreciation method	Average useful life
Patents	Straight line	20 years
Computer software	Straight line	5 - 10 years

Intangible assets are derecognised:

- on disposal; or
- · when no future economic benefits or service potential are expected from its use or disposal.

The gain or loss arising from the derecognition of intangible assets is included in surplus or deficit when the asset is derecognised.

1.7 Investments in controlled entities

Economic entity audited group annual financial statements

Investments in controlled entities are consolidated in the economic entity audited group annual financial statements. Refer to the accounting policy on Consolidations (Note 1.3).

Controlling entity audited group annual financial statements

In the entity's separate audited group annual financial statements, investments in controlled entities are carried at cost.

1.8 Financial instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or a residual interest of another entity.

The amortised cost of a financial asset or financial liability is the amount at which the financial asset or financial liability is measured at initial recognition minus principal repayments, plus or minus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount, and minus any reduction (directly or through the use of an allowance account) for impairment or uncollectibility.

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation.

Currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates.

Derecognition is the removal of a previously recognised financial asset or financial liability from an entity's statement of financial position.

The effective interest method is a method of calculating the amortised cost of a financial asset or a financial liability (or group of financial assets or financial liabilities) and of allocating the interest income or interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments or receipts through the expected life of the financial instrument or, when appropriate, a shorter period to the net carrying amount of the financial asset or financial liability. When calculating the effective interest rate, an entity estimates cash flows considering all contractual terms of the financial instrument but does not consider future credit losses. The calculation includes all fees and points paid or received between parties to the contract that are an integral part of the effective interest rate, transaction costs, and all other premiums or discounts. In cases when it is not possible to reliably estimate the cash flows or the expected life of a financial instrument (or group of financial instruments), the entity uses the contractual cash flows over the full contractual term of the financial instrument (or group of financial instruments).

Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable willing parties in an arm's length transaction.

A financial asset is:

- cash;
- a residual interest of another entity; or
- a contractual right to:
 - receive cash or another financial asset from another entity; or
 - exchange financial assets or financial liabilities with another entity under conditions that are potentially favourable to the entity.

A financial liability is any liability that is a contractual obligation to:

- deliver cash or another financial asset to another entity; or
- exchange financial assets or financial liabilities under conditions that are potentially unfavourable to the entity.

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

1.8 Financial instruments (continued)

Liquidity risk is the risk encountered by an entity in the event of difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset.

Loans payable are financial liabilities, other than short-term payables on normal credit terms.

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

Other price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices (other than those arising from interest rate risk or currency risk), whether those changes are caused by factors specific to the individual financial instrument or its issuer, or factors affecting all similar financial instruments traded in the market.

A financial asset is past due when a counterparty has failed to make a payment when contractually due.

Transaction costs are incremental costs that are directly attributable to the acquisition, issue or disposal of a financial asset or financial liability. An incremental cost is one that would not have been incurred if the entity had not acquired, issued or disposed of the financial instrument.

Financial instruments at amortised cost are non-derivative financial assets or non-derivative financial liabilities that have fixed or determinable payments, excluding those instruments that:

- the entity designates at fair value at initial recognition; or
- are held for trading.

Financial instruments at cost are investments in residual interests that do not have a quoted market price in an active market, and whose fair value cannot be reliably measured.

1.8 Financial instruments (continued) Classification

The entity has the following types of financial assets (classes and category) as reflected on the face of the statement of financial position or in the notes thereto:

Class	Category
Trade and other receivables	Financial asset measured at amortised cost
Cash and cash equivalents	Financial asset measured at amortised cost

The entity has the following types of financial liabilities (classes and category) as reflected on the face of the statement of financial position or in the notes thereto:

Class	Category
Trade and other payables	Financial liability measured at amortised cost
Other financial liabilities	Financial liability measured at amortised cost

Initial recognition

The economic entity recognises a financial asset or a financial liability in its statement of financial position when the entity becomes a party to the contractual provisions of the instrument.

1.8 Financial instruments (continued)

The economic entity recognises financial assets using trade date accounting.

Initial measurement of financial assets and financial liabilities

The economic entity measures a financial asset and financial liability initially at its fair value plus transaction costs that are directly attributable to the acquisition or issue of the financial asset or financial liability.

Subsequent measurement of financial assets and financial liabilities

The entity measures all financial assets and financial liabilities after initial recognition using the following categories:

- Financial instruments at amortised cost.
- Financial instruments at cost.

All financial assets measured at amortised cost, or cost, are subject to an impairment review.

Gains and losses

For financial assets and financial liabilities measured at amortised cost or cost, a gain or loss is recognised in surplus or deficit when the financial asset or financial liability is derecognised or impaired, or through the amortisation process.

Impairment and uncollectibility of financial assets

The entity assesses at the end of each reporting period whether there is any objective evidence that a financial asset or group of financial assets is impaired.

Financial assets measured at amortised cost:

If there is objective evidence that an impairment loss on financial assets measured at amortised cost has been incurred, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset's original effective interest rate. The carrying amount of the asset is reduced through the use of an allowance account. The amount of the loss is recognised in surplus or deficit.

If, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognised, the previously recognised impairment loss is reversed by adjusting an allowance account. The reversal does not result in a carrying amount of the financial asset that exceeds what the amortised cost would have been had the impairment not been recognised at the date the impairment is reversed. The amount of the reversal is recognised in surplus or deficit.

Financial assets measured at cost:

If there is objective evidence that an impairment loss has been incurred on an investment in a residual interest that is not measured at fair value because its fair value cannot be measured reliably, the amount of the impairment loss is measured as the difference between the carrying amount of the financial asset and the present value of estimated future cash flows discounted at the current market rate of return for a similar financial asset. Such impairment losses are not reversed.

1.8 Financial instruments (continued) Derecognition

Financial assets

The entity derecognises financial assets using trade date accounting. The entity derecognises a financial asset only when:

- the contractual rights to the cash flows from the financial asset expire, are settled or waived;
- the entity transfers to another party substantially all of the risks and rewards of ownership of the financial asset; or
- the entity, despite having retained some significant risks and rewards of ownership of the financial asset, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party, and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer. In this case, the entity:
 - derecognise the asset; and
 - recognise separately any rights and obligations created or retained in the transfer.

The carrying amounts of the transferred asset are allocated between the rights or obligations retained and those transferred on the basis of their relative fair values at the transfer date. Newly created rights and obligations are measured at their fair values—at that date. Any difference between the consideration received and the amounts recognised and derecognised is recognised—in surplus or deficit in the period of the transfer.

If the entity transfers a financial asset in a transfer that qualifies for derecognition in its entirety and retains the right to service — the financial asset for a fee, it recognise either a servicing asset or a servicing liability for that servicing contract. If the fee to be received is not expected to compensate the entity adequately for performing the servicing, a servicing liability for the servicing obligation is recognised at its fair value. If the fee to be received is expected to be more than adequate compensation for the servicing, a servicing asset is recognised for the servicing right at an amount determined on the basis of an allocation of the carrying amount of the larger financial asset.

If, as a result of a transfer, a financial asset is derecognised in its entirety but the transfer results in the entity obtaining a new financial asset or assuming a new financial liability, or a servicing liability, the entity recognise the new financial asset, financial liability or servicing liability at fair value.

On derecognition of a financial asset in its entirety, the difference between the carrying amount and the sum of the consideration received is recognised in surplus or deficit.

If the transferred asset is part of a larger financial asset and the part transferred qualifies for derecognition in its entirety, the previous carrying amount of the larger financial asset is allocated between the part that continues to be recognised and the part that is derecognised, based on the relative fair values of those parts, on the date of the transfer. For this purpose, a retained servicing asset is treated as a part that continues to be recognised. The difference between the carrying amount allocated to the part derecognised and the sum of the consideration received for the part derecognised is recognised in surplus or deficit.

If a transfer does not result in derecognition because the entity has retained substantially all the risks and rewards of ownership of the transferred asset, the entity continues to recognise the transferred asset in its entirety and recognise a financial liability for the consideration received. In subsequent periods, the entity recognises any revenue on the transferred asset and any expense incurred on the financial liability. Neither the asset, and the associated liability nor the revenue, and the associated expenses are offset.

1.8 Financial instruments (continued)

Financial liabilities

The entity removes a financial liability (or a part of a financial liability) from its statement of financial position when it is extinguished - i.e. when the obligation specified in the contract is discharged, cancelled, expires or waived

An exchange between an existing borrower and lender of debt instruments with substantially different terms is accounted for as having extinguished the original financial liability and a new financial liability is recognised. Similarly, a substantial modification of the terms of an existing financial liability or a part of it is accounted for as having extinguished the original financial liability and having recognised a new financial liability.

The difference between the carrying amount of a financial liability (or part of a financial liability) extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognised in surplus or deficit. Any liabilities that are waived, forgiven or assumed by another entity by way of a non-exchange transaction are accounted for in accordance with the Standard of GRAP on Revenue from Non-exchange Transactions (Taxes and Transfers).

Presentation

Interest relating to a financial instrument or a component that is a financial liability is recognised as revenue or expense in surplus or deficit.

Losses and gains relating to a financial instrument or a component that is a financial liability is recognised as revenue or expense in surplus or deficit.

A financial asset and a financial liability are only offset and the net amount presented in the statement of financial position when the entity currently has a legally enforceable right to set off the recognised amounts and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

In accounting for a transfer of a financial asset that does not qualify for derecognition, the entity does not offset the transferred asset and the associated liability.

Loans from economic entities

These include loans to and from controlling entities and controlled entity, are recognised initially at fair value plus direct transaction costs.

Loans from economic entities are classified as financial liabilities measured at amortised cost.

Receivables from exchange transactions

Trade receivables are measured at initially measured at fair value plus or minus transaction costs, and are subsequently measured at amortised cost using the effective interest rate method. Appropriate allowances for debt for estimated irrecoverable amounts are recognised in surplus or deficit when there is objective evidence that the asset is impaired. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganisation, and default or delinquency in payments (more than 30 days overdue) are considered indicators that the trade receivable is impaired. The allowance recognised is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the effective interest rate computed at initial recognition.

1.8 Financial instruments (continued)

The carrying amount of the asset is reduced through the use of an allowance account, and the amount of the deficit is recognised in surplus or deficit within operating expenses. When a trade receivable is uncollectible, it is written off against the allowance account for trade receivables. Subsequent recoveries of amounts previously written off are credited against operating expenses in surplus or deficit.

Payables from exchange transactions

Trade payables are initially measured at fair value added to or subtracted from transaction costs, and are subsequently measured at amortised cost, using the effective interest rate method.

Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits, and other short-term highly liquid investments that are readily convertible to a known amount of cash and are subject to an insignificant risk of changes in value. These are initially measured at fair value and subsequently recognised at amortised cost.

Other financial liabilities and finance lease obligations

Financial liabilities are measured at initial recognition at fair value, and are subsequently measured at amortised cost using the effective interest rate method.

1.9 Tax

Current tax assets and liabilities

Current tax for current and prior periods is, to the extent unpaid, recognised as a liability. If the amount already paid in respect of current and prior periods exceeds the amount due for those periods, the excess is recognised as an asset.

Current tax liabilities (assets) for the current and prior periods are measured at the amount expected to be paid to (recovered from) the tax authorities, using the tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax assets and liabilities

A deferred tax liability is recognised for all taxable temporary differences, except to the extent that the deferred tax liability arises from the initial recognition of an asset or liability in a transaction which at the time of the transaction, affects neither accounting surplus nor taxable profit (tax loss).

A deferred tax asset is recognised for all deductible temporary differences to the extent that it is probable that taxable surplus will be available against which the deductible temporary difference can be utilised. A deferred tax asset is not recognised when it arises from the initial recognition of an asset or liability in a transaction at the time of the transaction, affects neither accounting surplus nor taxable profit (tax loss).

A deferred tax asset is recognised for the carry forward of unused tax losses to the extent that it is probable that future taxable surplus will be available against which the unused tax losses.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

1.9 Tax (continued)

Tax expenses

Current and deferred taxes are recognised as income or an expense and included in surplus or deficit for the period, except to the extent that the tax arises from:

- a transaction or event which is recognised, in the same or a different period, to net assets; or
- a business combination.

Current tax and deferred taxes are charged or credited to net assets if the tax relates to items that are credited or charged, in the same or a different period, to net assets.

1.10 Leases

A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership. A lease is classified as an operating lease if it does not transfer substantially all the risks and rewards incidental to ownership.

When a lease includes both land and buildings elements, the entity assesses the classification of each element separately.

Finance leases - lessee

Finance leases are recognised as assets and liabilities in the statement of financial position at amounts equal to the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding liability to the lessor is included in the statement of financial position as a finance lease obligation.

The discount rate used in calculating the present value of the minimum lease payments is the interest rate implicit in the lease.

Minimum lease payments are apportioned between the finance charge and reduction of the outstanding liability. The finance charge is allocated to each period during the lease term so as to produce a constant periodic rate on the remaining balance of the liability.

Any contingent rents are expensed in the period in which they are incurred.

Operating leases - lessee

Operating lease payments are recognised as an expense on a straight-line basis over the lease term. The difference between the amounts recognised as an expense and the contractual payments are recognised as an operating lease asset or liability.

1.11 Inventories

Inventories comprise of raw materials, work in progress, finished goods and consumable stores. These are initially measured at cost except where inventories are acquired through a non-exchange transaction, then their costs are their fair value as at the date of acquisition.

Subsequently inventories are measured at the lower of cost and net realisable value.

Net realisable value is the estimated selling price in the ordinary course of operations less the estimated costs of completion and the estimated costs necessary to make the sale, exchange or distribution.

1.11 Inventories (continued)

The cost of inventories comprises of all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

The cost of inventories is assigned using the weighted average cost formula. The same cost formula is used for all inventories having a similar nature and use to the economic entity.

When inventories are sold, the carrying amounts of those inventories are recognised as an expense in the period in which the related revenue is recognised. If there is no related revenue, the expenses are recognised when the goods are distributed, or related services are rendered. The amount of any write-down of inventories to net realisable value or current replacement cost and all losses of inventories are recognised as an expense in the period the write-down or loss occurs. The amount of any reversal of any write-down of inventories, arising from an increase in net realisable value or current replacement cost, are recognised as a reduction in the amount of inventories recognised as an expense in the period in which the reversal occurs.

1.12 Impairment of cash-generating assets

Cash-generating assets are assets used with the objective of generating a commercial return. Commercial return means that positive cash flows are expected to be significantly higher than the cost of the asset.

Impairment is a loss in the future economic benefits or service potential of an asset, over and above the systematic recognition of the loss of the asset's future economic benefits or service potential through depreciation (amortisation).

Carrying amount is the amount at which an asset is recognised in the statement of financial position after deducting any accumulated depreciation and accumulated impairment losses thereon.

A cash-generating unit is the smallest identifiable group of assets used with the objective of generating a commercial return that generates cash inflows from continuing use that are largely independent of the cash inflows from other assets or groups of assets.

Costs of disposal are incremental costs directly attributable to the disposal of an asset, excluding finance costs and income tax expense.

Depreciation (Amortisation) is the systematic allocation of the depreciable amount of an asset over its useful life.

Fair value less costs to sell is the amount obtainable from the sale of an asset in an arm's length transaction between knowledgeable, willing parties, less the costs of disposal.

Recoverable amount of an asset or a cash-generating unit is the higher its fair value less costs to sell and its value in use.

Useful life is the period of time over which an asset is expected to be used by the economic enty. Judgements made by management in applying the criteria to designate assets as cash-generating assets or non-cash-generating assets, are as follows:

1.12 Impairment of cash-generating assets (continued) Designation

At initial recognition, the economic entity designates an asset as non-cash-generating, or an asset or cashgenerating unit as cash-generating. The designation is made on the basis of an economic entity's objective of using the asset.

The economic entity designates an asset or a cash-generating unit as cash-generating when:

- its objective is to use the asset or a cash-generating unit in a manner that generates a commercial return; such that
- the asset or cash-generating unit will generate positive cash flows, from continuing use and its ultimate disposal, that are expected to be significantly higher than the cost of the asset.

An asset used with the objective of generating a commercial return and service delivery, is designated either as a cash- generating asset or non-cash-generating asset based on whether the economic entity expects to use that asset to generate a commercial return. When it is not clear whether the objective is to use the asset to generate commercial return, the economic entity designates the asset as a non-cash-generating asset and applies the accounting policy on Impairment of Non-cash- generating assets, rather than this accounting policy.

Identification

When the carrying amount of a cash-generating asset exceeds its recoverable amount, it is impaired.

The economic entity assesses at each reporting date whether there is any indication that a cash-generating asset may be impaired. If any such indication exists, the economic entity estimates the recoverable amount of the asset.

Value in use

Value in use of a cash-generating asset is the present value of the estimated future cash flows expected to be derived from the continuing use of an asset and from its disposal at the end of its useful life.

When estimating the value in use of an asset, the economic entity estimates the future cash inflows and outflows to be derived from continuing use of the asset and from its ultimate disposal and the economic entity applies the appropriate discount rate to those future cash flows.

Basis for estimates of future cash flows

In measuring value in use the economic entity:

- base cash flow projections on reasonable and supportable assumptions that represent management's best estimate of the range of economic conditions that will exist over the remaining useful life of the asset. Greater weight is given to external evidence;
- base cash flow projections on the most recent approved financial budgets, but excludes any estimated future cash inflows or outflows expected to arise from future restructuring's or from improving or enhancing the asset's performance. Projections based on these budgets covers a maximum period of five years; and
- estimate cash flow projections beyond the period covered by the most recent budgets by extrapolating the projections based on the budgets using a steady growth rate for subsequent years. This growth rate does not exceed the long-term average growth rate for the products, industries in which the NHLS operates, or for the market in which the asset is used.

1.12 Impairment of cash-generating assets (continued) Composition of estimates of future cash flows

Estimates of future cash flows include:

- projections of cash inflows from the continuing use of the asset;
- projections of cash outflows that are necessarily incurred to generate the cash inflows from continuing use of the asset (including cash outflows to prepare the asset for use) and can be directly attributed, or allocated on a reasonable and consistent basis, to the asset; and
- net cash flows, if any, to be received (or paid) for the disposal of the asset at the end of its useful life.

Estimates of future cash flows exclude:

- · cash inflows or outflows from financing activities; and
- income tax receipts or payments.

The estimate of net cash flows to be received (or paid) for the disposal of an asset at the end of its useful life is the amount that the economic entity expects to obtain from the disposal of the asset in an arm's length transaction between knowledgeable, willing parties, after deducting the estimated costs of disposal.

Discount rate

The discount rate is a pre-tax rate that reflects current market assessments of the time value of money, represented by the current risk-free rate of interest and the risks specific to the asset for which the future cash flow estimates have not been adjusted.

Recognition and measurement (individual asset)

If the recoverable amount of a cash-generating asset is less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. This reduction is an impairment loss.

An impairment loss is recognised immediately in surplus or deficit.

Any impairment loss of a revalued cash-generating asset is treated as a revaluation decrease.

When the amount estimated for an impairment loss is greater than the carrying amount of the cash-generating asset to which it relates, the economic entity recognises a liability only to the extent that is a requirement in the Standard of GRAP.

After the recognition of an impairment loss, the depreciation (amortisation) charge for the cash-generating asset is adjusted in future periods to allocate the cash-generating asset's revised carrying amount, less its residual value (if any), on a systematic basis over its remaining useful life.

1.13 Impairment of cash-generating assets (continued) Cash-generating units

If there is any indication that an asset may be impaired, the recoverable amount is estimated for the individual asset. If it is not possible to estimate the recoverable amount of the individual asset, the economic entity determines the recoverable amount of the cash-generating unit to which the asset belongs (the asset's cash-generating unit).

1.12 Impairment of cash-generating assets (continued) Cash-generating units

If an active market exists for the output produced by an asset or group of assets, that asset or group of assets is identified as a cash-generating unit, even if some or all of the output is used internally. If the cash inflows generated by any asset or cash-generating unit are affected by internal transfer pricing, the economic entity use management's best estimate of future price(s) that could be achieved in arm's length transactions in estimating:

- the future cash inflows used to determine the asset's or cash-generating unit's value in use; and
- the future cash outflows used to determine the value in use of any other assets or cash-generating units that are affected by the internal transfer pricing.

Cash-generating units are identified consistently from period to period for the same asset or types of assets, unless a change is justified.

The carrying amount of a cash-generating unit is determined on a basis consistent with the way the recoverable amount of the cash-generating unit is determined.

An impairment loss is recognised for a cash-generating unit if the recoverable amount of the unit is less than the carrying amount of the unit. The impairment is allocated to reduce the carrying amount of the cash-generating assets of the unit on a pro rata basis, based on the carrying amount of each asset in the unit. These reductions in carrying amounts are treated as impairment losses on individual assets.

In allocating an impairment loss, the entity does not reduce the carrying amount of an asset below the highest of:

- its fair value less costs to sell (if determinable);
- its value in use (if determinable); and
- zero.

The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other cash-generating assets of the unit.

Where a non-cash-generating asset contributes to a cash-generating unit, a proportion of the carrying amount of that non- cash-generating asset is allocated to the carrying amount of the cash-generating unit prior to estimation of the recoverable amount of the cash-generating unit.

1.12 Impairment of cash-generating assets (continued) Reversal of impairment loss

The economic entity assesses at each reporting date whether there is any indication that an impairment loss recognised in prior periods for a cash-generating asset may no longer exist or may have decreased. If any such indication exists, the entity estimates the recoverable amount of that asset.

An impairment loss recognised in prior periods for a cash-generating asset is reversed if there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognised. The carrying amount of the asset is increased to its recoverable amount. The increase is a reversal of an impairment loss. The increased carrying amount of an asset attributable to a reversal of an impairment loss does not exceed the carrying amount that would have been determined (net of depreciation or amortisation) had no impairment loss been recognised for the asset in prior periods.

A reversal of an impairment loss for a cash-generating asset is recognised immediately in surplus or deficit. Any reversal of an impairment loss of a revalued cash-generating asset is treated as a revaluation increase.

1.12 Impairment of cash-generating assets (continued) Reversal of impairment loss

After a reversal of an impairment loss is recognised, the depreciation (amortisation) charge for the cash-generating asset is adjusted in future periods to allocate the cash-generating asset's revised carrying amount, less its residual value (if any), on a systematic basis over its remaining useful life.

A reversal of an impairment loss for a cash-generating unit is allocated to the cash-generating assets of the unit pro rata with the carrying amounts of those assets. These increases in carrying amounts are treated as reversals of impairment losses for individual assets. No part of the amount of such a reversal is allocated to a non-cash-generating asset contributing service potential to a cash-generating unit.

In allocating a reversal of an impairment loss for a cash-generating unit, the carrying amount of an asset is not increased above the lower of:

- its recoverable amount (if determinable); and
- the carrying amount that would have been determined (net of amortisation or depreciation) had no impairment loss been recognised for the asset in prior periods.

The amount of the reversal of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit.

Redesignation

The redesignation of assets from a cash-generating asset to a non-cash-generating asset or from a non-cash-generating asset to a cash-generating asset only occur when there is clear evidence that such a redesignation is appropriate.

1.13 Share capital / contributed capital

Contributed capital is the initial funding received from the shareholder upon establishment of the National Health Laboratory Service.

Contributed capital is stated at par value.

1.14 Employee benefits

Employee benefits are all forms of consideration given by an entity in exchange for service rendered by employees.

A qualifying insurance policy is an insurance policy issued by an insurer that is not a related party (as defined in the Standard of GRAP on Related Party Disclosures) of the reporting entity, if the proceeds of the policy can be used only to pay or fund employee benefits under a defined benefit plan and are not available to the reporting entity's own creditors (even in liquidation) and cannot be paid to the reporting entity, unless either:

- the proceeds represent surplus assets that are not needed for the policy to meet all the related employee benefit obligations; or
- the proceeds are returned to the reporting entity to reimburse it for employee benefits already paid.

Termination benefits are employee benefits payable as a result of either:

an entity's decision to terminate an employee's employment before the normal retirement date; or

Employee benefits (continued)

an employee's decision to accept voluntary redundancy in exchange for those benefits.

Other long-term employee benefits are employee benefits (other than post-employment benefits and termination benefits) that are not due to be settled within twelve months after the end of the period in which the employees render the related service.

Vested employee benefits are employee benefits that are not conditional on future employment.

A constructive obligation is an obligation that derives from an entity's actions where by an established pattern of past practice, published policies or a sufficiently specific current statement, the entity has indicated to other parties that it will accept certain responsibilities and as a result, the entity has created a valid expectation on the part of those other parties that it will discharge those responsibilities.

Short-term employee benefits

Short-term employee benefits are employee benefits (other than termination benefits) that are due to be settled within twelve months after the end of the period in which the employees render the related service.

Short-term employee benefits include items such as:

- wages, salaries and social security contributions;
- short-term compensated absences (such as paid annual leave and paid sick leave) where the compensation for the absences is due to be settled within twelve months after the end of the reporting period in which the employees render the related employee service;
- bonus, incentive and performance related payments payable within twelve months after the end of the reporting period in which the employees render the related service; and
- non-monetary benefits (for example, medical care, and free or subsidised goods or services such as housing, cars and cellphones) for current employees.

When an employee has rendered service to the entity during a reporting period, the entity recognise the undiscounted amount of short-term employee benefits expected to be paid in exchange for that service:

- as a liability (accrued expense), after deducting any amount already paid. If the amount already paid exceeds the undiscounted amount of the benefits, the entity recognise that excess as an asset (prepaid expense) to the extent that the prepayment will lead to, for example, a reduction in future payments or a cash refund; and
- as an expense, unless another Standard requires or permits the inclusion of the benefits in the cost of an asset.

The expected cost of compensated absences is recognised as an expense as the employees render services that increase their entitlement or, in the case of non-accumulating absences, when the absence occurs. The entity measures the expected cost of accumulating compensated absences as the additional amount that the entity expects to pay as a result of the unused entitlement that has accumulated at the reporting date.

The entity recognise the expected cost of bonus, incentive and performance related payments when the entity has a present legal or constructive obligation to make such payments as a result of past events and a reliable estimate of the obligation can be made. A present obligation exists when the entity has no realistic alternative but to make the payments.

1.14 Employee benefits (continued)

Post-employment benefits

Post-employment benefits are employee benefits (other than termination benefits) which are payable after the completion of employment.

Post-employment benefit plans are formal or informal arrangements under which an entity provides post-employment benefits for one or more employees.

Multi-employer plans are defined contribution plans (other than state plans) or defined benefit plans (other than state plans) that pool the assets contributed by various entities that are not under common control and use those assets to provide benefits to employees of more than one entity, on the basis that contribution and benefit levels are determined without regard to the identity of the entity that employs the employees concerned.

Multi-employer plans and/or State plans

Where a plan is a defined contribution plan, the entity accounts for in the same way as for any other defined contribution plan.

Post-employment benefits: Defined contribution plans

Defined contribution plans are post-employment benefit plans under which an entity pays fixed contributions into a separate entity (a fund) and will have no legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employee benefits relating to employee service in the current and prior periods.

When an employee has rendered service to the entity during a reporting period, the entity recognise the contribution payable to a defined contribution plan in exchange for that service:

- as a liability (accrued expense), after deducting any contribution already paid. If the contribution already paid exceeds the contribution due for service before the reporting date, the entity recognise that excess as an asset (prepaid expense) to the extent that the prepayment will lead to, for example, a reduction in future payments or a cash refund; and
- as an expense, unless another Standard requires or permits the inclusion of the contribution in the cost of an asset.

Where contributions to a defined contribution plan do not fall due wholly within twelve months after the end of the reporting period in which the employees render the related service, they are discounted. The rate used to discount reflects the time value of money. The currency and term of the financial instrument selected to reflect the time value of money is consistent with the currency and estimated term of the obligation.

Post-employment benefits: Defined benefit plans

Defined benefit plans are post-employment benefit plans other than defined contribution plans.

Actuarial gains and losses comprise experience adjustments (the effects of differences between the previous actuarial assumptions and what has actually occurred) and the effects of changes in actuarial assumptions. In measuring its defined benefit liability the entity recognise actuarial gains and losses in surplus or deficit in the reporting period in which they occur.

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Employee benefits (continued)

Current service cost is the increase in the present value of the defined benefit obligation resulting from employee service in the current period.

Interest cost is the increase during a period in the present value of a defined benefit obligation which arises because the benefits are one period closer to settlement.

Past service cost is the change in the present value of the defined benefit obligation for employee service in prior periods, resulting in the current period from the introduction of, or changes to, post-employment benefits or other long-term employee benefits. Past service cost may be either positive (when benefits are introduced or changed so that the present value of the defined benefit obligation increases) or negative (when existing benefits are changed so that the present value of the defined benefit obligation decreases). In measuring its defined benefit liability the entity recognise past service cost as an expense in the reporting period in which the plan is amended.

The present value of a defined benefit obligation is the present value of expected future payments required to settle the obligation resulting from employee service in the current and prior periods.

The economic entity account not only for its legal obligation under the formal terms of a defined benefit plan, but also for any constructive obligation that arises from the entity's informal practices. Informal practices give rise to a constructive obligation where the entity has no realistic alternative but to pay employee benefits. An example of a constructive obligation is where a change in the entity's informal practices would cause unacceptable damage to its relationship with employees.

The amount recognised as a defined benefit liability is the net total of the following amounts:

- the present value of the defined benefit obligation at the reporting date;
- plus any liability that may arise as a result of a minimum funding requirement

The entity determines the present value of defined benefit obligations with sufficient regularity such that the amounts recognised in the audited group annual financial statements do not differ materially from the amounts that would be determined at the reporting date.

The entity recognises the net total of the following amounts in surplus or deficit, except to the extent that another Standard requires or permits their inclusion in the cost of an asset:

- current service cost;
- interest cost:
- actuarial gains and losses;
- past service cost;
- the effect of any curtailments or settlements; and
- the effect of applying the limit on a defined benefit asset (negative defined benefit liability).

The entity uses the Projected Unit Credit Method to determine the present value of its defined benefit obligations and the related current service cost and, where applicable, past service cost. The Projected Unit Credit Method (sometimes known as the accrued benefit method pro-rated on service or as the benefit/ years of service method) sees each period of service as giving rise to an additional unit of benefit entitlement and measures each unit separately to build up the final obligation.

In determining the present value of its defined benefit obligations and the related current service cost and, where applicable, past service cost, entity attributes benefit to periods of service under the plan's benefit formula. However, if an employee's service in later years will lead to a materially higher level of benefit than in earlier years, an entity attributes benefit on a straight-line basis from:

1.14 Employee benefits (continued)

- the date when service by the employee first leads to benefits under the plan (whether or not the benefits are conditional on further service); until
- the date when further service by the employee will lead to no material amount of further benefits under the plan, other than from further salary increases.

Actuarial valuations are conducted on an annual basis by independent actuaries separately for each plan. The results of the valuation are updated for any material transactions and other material changes in circumstances (including changes in market prices and interest rates) up to the reporting date.

The entity recognises gains or losses on the curtailment or settlement of a defined benefit plan when the curtailment or settlement occurs. The gain or loss on a curtailment or settlement comprises of any resulting change in the present value of the defined benefit obligation.

Before determining the effect of a curtailment or settlement, the entity re-measure the obligation (and the related plan assets, if any) using current actuarial assumptions (including current market interest rates and other current market prices).

The entity offsets an asset relating to one plan against a liability relating to another plan when the entity has a legally enforceable right to use a surplus in one plan to settle obligations under the other plan and intends either to settle the obligations on a net basis, or to realise the surplus in one plan and settle its obligation under the other plan simultaneously.

Actuarial assumptions

Actuarial assumptions are unbiased and mutually compatible.

Financial assumptions are based on market expectations, at the reporting date, for the period over which the obligations are to be settled.

The rate used to discount post-employment benefit obligations reflect the time value of money. The currency and term of the financial instrument selected to reflect the time value of money is consistent with the currency and estimated term of the post- employment benefit obligations.

Post-employment benefit obligations are measured on a basis that reflects:

- estimated future salary increases;
- the benefits set out in the terms of the plan (or resulting from any constructive obligation that goes beyond those terms) at the reporting date; and
- estimated future changes in the level of any state benefits that affect the benefits payable under a defined benefit plan, if, and only if, either:
- those changes were enacted before the reporting date; or
- past history, or other reliable evidence, indicates that those state benefits will change in some predictable manner, for example, in line with future changes in general price levels or general salary levels.

Assumptions about medical costs take account of estimated future changes in the cost of medical services, resulting from both inflation and specific changes in medical costs.



1.14 Employee benefits (continued)

Termination benefits

The entity recognises termination benefits as a liability and an expense when the entity is demonstrably committed to either:

- terminate the employment of an employee or group of employees before the normal retirement date; or
- provide termination benefits as a result of an offer made in order to encourage voluntary redundancy.

The entity is demonstrably committed to a termination when the entity has a detailed formal plan for the termination and is without realistic possibility of withdrawal. The detailed plan includes [as a minimum]:

- the location, function, and approximate number of employees whose services are to be terminated;
- the termination benefits for each job classification or function; and
- the time at which the plan will be implemented.

Implementation begins as soon as possible and the period of time to complete implementation is such that material changes to the plan are not likely.

Where termination benefits fall due more than 12 months after the reporting date, they are discounted using an appropriate discount rate. The rate used to discount the benefit reflects the time value of money. The currency and term of the financial instrument selected to reflect the time value of money is consistent with the currency and estimated term of the benefit.

In the case of an offer made to encourage voluntary redundancy, the measurement of termination benefits shall be based on the number of employees expected to accept the offer.

1.15 Provisions and contingencies

Provisions are recognised when:

- the economic entity has a present obligation as a result of a past event;
- it is probable that an outflow of resources embodying economic benefits or service potential will be required to settle the obligation; and
- a reliable estimate can be made of the obligation.

The amount of a provision is the best estimate of the expenditure expected to be required to settle the present obligation at the reporting date.

Where the effect of time value of money is material, the amount of a provision is the present value of the expenditures expected to be required to settle the obligation.

The discount rate is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability.

Where some or all of the expenditure required to settle a provision is expected to be reimbursed by another party, the reimbursement is recognised when, and only when, it is virtually certain that reimbursement will be received if the economic entity settles the obligation. The reimbursement is treated as a separate asset. The amount recognised for the reimbursement does not exceed the amount of the provision.

Provisions are reviewed at each reporting date and adjusted to reflect the current best estimate. Provisions are reversed if it is no longer probable that an outflow of resources embodying economic benefits or service potential will be required, to settle the obligation.

1.14 Provisions and contingencies (continued)

Where discounting is used, the carrying amount of a provision increases in each period to reflect the passage of time. This increase is recognised as an interest expense.

A provision is used only for expenditures for which the provision was originally recognised. Provisions are not recognised for future operating write offs.

For onerous contracts, the economic entity recognises and measures the present obligation (net of recoveries) under the contract as a provision.

Contingent assets and contingent liabilities are not recognised. Contingencies are disclosed in note 36.

1.16 Commitments

Items are classified as commitments when the economic entity has committed itself to future transactions that will normally result in the outflow of cash.

Disclosures are provided for unrecognised contractual commitments.

Commitments for which disclosure is necessary to achieve a fair presentation are disclosed in a note to the financial statements, if both the following criteria are met:

- Contracts are non-cancellable or only cancellable at significant cost; and
- Contracts relate to something other than the routine, steady, state business of the entity therefore salary commitments relating to employment contracts or social security benefit commitments are excluded.

1.17 Revenue from exchange transactions

Revenue is the gross inflow of economic benefits or service potential during the reporting period when those inflows result in an increase in net assets, other than increases relating to contributions from owners.

An exchange transaction is one in which the economic entity receives assets or services, or has liabilities extinguished, and directly gives approximately equal value (primarily in the form of goods, services or use of assets) to the other party in exchange.

Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable, willing parties in an arm's length transaction.

1.17 Revenue from exchange transactions (continued) Measurement

Revenue is measured at the fair value of the consideration received or receivable, net of trade discounts and volume rebates.

Sale of goods

Revenue from the sale of goods is recognised when all the following conditions have been satisfied:

- the economic entity has transferred to the purchaser the significant risks and rewards of ownership of the goods:
- the economic entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
- the amount of revenue can be measured reliably;
- it is probable that the economic benefits or service potential associated with the transaction will flow to the economic entity; and
- the costs incurred or to be incurred in respect of the transaction can be measured reliably.

Rendering of services

When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction is recognised by reference to the stage of completion of the transaction at the reporting date. The outcome of a transaction can be estimated reliably when all the following conditions are satisfied:

- the amount of revenue can be measured reliably;
- it is probable that the economic benefits or service potential associated with the transaction will flow to the economic entity;
- · the stage of completion of the transaction at the reporting date can be measured reliably; and
- the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

When services are performed by an indeterminate number of acts over a specified time frame, revenue is recognised on a straight line basis over the specified time frame unless there is evidence that some other method better represents the stage of completion. When a specific act is much more significant than any other acts, the recognition of revenue is postponed until the significant act is executed.

When the outcome of the transaction involving the rendering of services cannot be estimated reliably, revenue is recognised only to the extent of the expenses recognised that are recoverable.

Service revenue is recognised by reference to the stage of completion of the transaction at the reporting date. Stage of completion is determined by services performed to date as a percentage of total services to be performed.

Interest and royalties

Revenue arising from the use by others of entity assets yielding interest is recognised when:

- It is probable that the economic benefits or service potential associated with the transaction will flow to the entity, and
- The amount of the revenue can be measured reliably.

Interest is recognised, in surplus or deficit, using the effective interest rate method.

Royalties are recognised as they are earned in accordance with the substance of the relevant agreements.

1.18 Revenue from non-exchange transactions

Revenue comprises gross inflows of economic benefits or service potential received and receivable by an entity, which represents an increase in net assets, other than increases relating to contributions from owners.

Conditions on transferred assets are stipulations that specify that the future economic benefits or service potential embodied in the asset is required to be consumed by the recipient as specified or future economic benefits or service potential must be returned to the transferor.

Control of an asset arise when the entity can use or otherwise benefit from the asset in pursuit of its objectives and can exclude or otherwise regulate the access of others to that benefit.

Exchange transactions are transactions in which one entity receives assets or services, or has liabilities extinguished, and directly gives approximately equal value (primarily in the form of cash, goods, services, or use of assets) to another entity in exchange.

Non-exchange transactions are transactions that are not exchange transactions. In a non-exchange transaction, an entity either receives value from another entity without directly giving approximately equal value in exchange, or gives value to another entity without directly receiving approximately equal value in exchange.

Restrictions on transferred assets are stipulations that limit or direct the purposes for which a transferred asset may be used, but do not specify that future economic benefits or service potential is required to be returned to the transferor if not deployed as specified.

Stipulations on transferred assets are terms in laws or regulation, or a binding arrangement, imposed upon the use of a transferred asset by entities external to the reporting entity.

Transfers are inflows of future economic benefits or service potential from non-exchange transactions, other than taxes.

Recognition

An inflow of resources from a non-exchange transaction recognised as an asset is recognised as revenue, except to the extent that a liability is also recognised in respect of the same inflow.

As the entity satisfies a present obligation recognised as a liability in respect of an inflow of resources from a non-exchange transaction recognised as an asset, it reduces the carrying amount of the liability recognised and recognises an amount of revenue equal to that reduction.

Measurement

Revenue from a non-exchange transaction is measured at the amount of the increase in net assets recognised by the entity.

When, as a result of a non-exchange transaction, the entity recognises an asset, it also recognises revenue equivalent to the amount of the asset measured at its fair value as at the date of acquisition, unless it is also required to recognise a liability. Where a liability is required to be recognised it will be measured as the best estimate of the amount required to settle the obligation at the reporting date, and the amount of the increase in net assets, if any, recognised as revenue. When a liability is subsequently reduced, because the taxable event occurs or a condition is satisfied, the amount of the reduction in the liability is recognised as revenue.

1.18 Revenue from non-exchange transactions (continued)

Transfers

Apart from Services in kind, which are not recognised, the entity recognises an asset in respect of transfers when the transferred resources meet the definition of an asset and satisfy the criteria for recognition as an asset

The entity recognises an asset in respect of transfers when the transferred resources meet the definition of an asset and satisfy the criteria for recognition as an asset.

Transferred assets are measured at their fair value as at the date of acquisition.

1.19 Turnover

Turnover comprises of sales to customers and service rendered to customers. Turnover is stated at the invoice amount and is exclusive of value added taxation.

1.20 Cost of sales

When inventories are sold, the carrying amount of those inventories is recognised as an expense in the period in which the related revenue is recognised. The amount of any write-down of inventories to net realisable value and all write offs of inventories are recognised as an expense in the period the write-down or loss occurs. The amount of any reversal of any write- down of inventories, arising from an increase in net realisable value, is recognised as a reduction in the amount of inventories recognised as an expense in the period in which the reversal occurs.

The related cost of providing services recognised as revenue in the current period is included in cost of sales.

1.21 Investment income

Investment income is recognised on a time-proportion basis using the effective interest method.

1.22 Borrowing costs

Borrowing costs are interest and other expenses incurred by an entity in connection with the borrowing of funds. Borrowing costs are recognised as an expense in the period in which they are incurred.

1.23 Translation of foreign currencies Foreign currency transactions

A foreign currency transaction is recorded, on initial recognition in Rands, by applying to the foreign currency amount the spot exchange rate between the functional currency and the foreign currency at the date of the transaction.

At each reporting date:

- foreign currency monetary items are translated using the closing rate;
- non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction; and
- non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

Exchange differences arising on the settlement of monetary items or on translating monetary items at rates different from those at which they were translated on initial recognition during the period or in previous audited group annual financial statements are recognised in surplus or deficit in the period in which they arise.

1.23 Translation of foreign currencies Foreign currency transactions (continued)

Cash flows arising from transactions in a foreign currency are recorded in Rands by applying to the foreign currency amount the exchange rate between the Rand and the foreign currency at the date of the cash flow.

1.24 Comparative figures

Where necessary, comparative figures have been reclassified to conform to changes in presentation in the current year.

1.25 Fruitless and wasteful expenditure

Fruitless expenditure means expenditure which was made in vain and would have been avoided had reasonable care been exercised.

All expenditure relating to fruitless and wasteful expenditure is recognised as an expense in the statement of financial performance in the year that the expenditure was incurred. The expenditure is classified in accordance with the nature of the expense, and where recovered, it is subsequently accounted for as revenue in the statement of financial performance.

1.26 Irregular expenditure

Irregular expenditure as defined in section 1 of the PFMA is expenditure other than unauthorised expenditure, incurred in contravention of or that is not in accordance with a requirement of any applicable legislation, including -

- a. this Act; or
- b. the State Tender Board Act, 1968 (Act No. 86 of 1968), or any regulations made in terms of the Act; or
- c. any provincial legislation providing for procurement procedures in that provincial government.

National Treasury practice note no. 4 of 2008/2009 which was issued in terms of sections 76(1) to 76(4) of the PFMA requires the following (effective from 1 April 2008):

Irregular expenditure that was incurred and identified during the current financial and which was condoned before year end and/or before finalisation of the financial statements must also be recorded appropriately in the irregular expenditure register. In such an instance, no further action is also required with the exception of updating the note to the financial statements.

Irregular expenditure that was incurred and identified during the current financial year and for which condonement is being awaited at year end must be recorded in the irregular expenditure register. No further action is required with the exception of updating the note to the financial statements.

Where irregular expenditure was incurred in the previous financial year and is only condoned in the following financial year, the register and the disclosure note to the financial statements must be updated with the amount condoned.

Irregular expenditure that was incurred and identified during the current financial year and which was not condoned by the National Treasury or the relevant authority must be recorded appropriately in the irregular expenditure register. If liability for the irregular expenditure can be attributed to a person, a debt account must be created if such a person is liable in law. Immediate—steps must thereafter be taken to recover the amount from the person concerned. If recovery is not possible, the accounting officer or Accounting Authority may write off the amount as debt impairment and disclose such in the relevant note to the financial statements. The irregular expenditure register must also be updated accordingly. If the irregular expenditure has not been condoned and no person is liable in law, the expenditure related thereto must remain against the relevant programme/expenditure item, be disclosed as such in the note to the financial statements and updated accordingly in the irregular expenditure register.

1.27 Segment information

A segment is an activity of an entity:

- that generates economic benefits or service potential (including economic benefits or service potential relating to transactions between activities of the same entity);
- whose results are regularly reviewed by management to make decisions about resources to be allocated to that activity and in assessing its performance; and
- for which separate financial information is available.

Reportable segments are the actual segments which are reported on in the segment report. They are the segments identified above or alternatively an aggregation of two or more of those segments where the aggregation criteria are met.

Measurement

The amount of each segment item reported is the measure reported to management for the purposes of making decisions about allocating resources to the segment and assessing its performance. Adjustments and eliminations made in preparing the entity's financial statements and allocations of revenues and expenses are included in determining reported segment surplus or deficit only if they are included in the measure of the segment's surplus or deficit that is used by management. Similarly, only those assets and liabilities that are included in the measures of the segment's assets and segment's liabilities that are used by management are reported for that segment. If amounts are allocated to reported segment surplus or deficit, assets or liabilities, those amounts are allocated on a reasonable basis.

If management uses only one measure of a segment's surplus or deficit, the segment's assets or the segment's liabilities in assessing segment performance and deciding how to allocate resources, segment surplus or deficit, assets and liabilities are reported in terms of that measure. If management uses more than one measure of a segment's surplus or deficit, the segment's assets or the segment's liabilities, the reported measures are those that management believes are determined in accordance with the measurement principles most consistent with those used in measuring the corresponding amounts in the entity's financial statements.

1.28 Research and development expenditure

Expenditure on research is recognised as an expense when it is incurred. An asset arising from development is recognised when:

- it is technically feasible to complete the asset so that it will be available for use or sale.
- there is an intention to complete and use or sell it.
- there is an ability to use or sell it.
- it will generate probable future economic benefits or service potential.
- there are available technical, financial and other resources to complete the development and to use or sell the asset.
- the expenditure attributable to the asset during its development can be measured reliably.

1.29 Budget information

The economic entity is typically subject to budgetary limits in the form of appropriations or budget authorisations (or equivalent), which is given effect through authorising legislation, appropriation or similar.

General purpose financial reporting by economic entity provides information on whether resources were obtained and used in accordance with the legally adopted budget.

1.29 Budget information (continued)

The approved budget is prepared on a accrual basis and presented by functional classification. The approved budget covers the fiscal period from 01/04/2018 to 31/03/2019.

The budget for the economic entity includes all the entities approved budgets under its control.

The audited group annual financial statements and the budget are on the same basis of accounting therefore a comparison with the budgeted amounts for the reporting period have been included in the Statement of comparison of budget and actual amounts.

1.30 Related parties

A related party is a person or an entity with the ability to control or jointly control the other party, or exercise significant influence over the other party, or vice versa, or an entity that is subject to common control, or joint control

Control is the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities

Joint control is the agreed sharing of control over an activity by a binding arrangement, and exists only when the strategic financial and operating decisions relating to the activity require the unanimous consent of the parties sharing control (the venturers).

Related party transaction is a transfer of resources, services or obligations between the reporting entity and a related party, regardless of whether a price is charged.

Significant influence is the power to participate in the financial and operating policy decisions of an entity, but is not control over those policies.

Management are those persons responsible for planning, directing and controlling the activities of the economic entity, including those charged with the governance of the economic entity in accordance with legislation, in instances where they are required to perform such functions.

Close members of the family of a person are considered to be those family members who may be expected to influence, or be influenced by, that management in their dealings with the economic entity.

The economic entity is exempt from disclosure requirements in relation to related party transactions if that transaction occurs within normal supplier and/or client/recipient relationships on terms and conditions no more or less favourable than those which it is reasonable to expect the economic entity to have adopted if dealing with that individual entity or person in the same circumstances and terms and conditions are within the normal operating parameters established by that reporting entity's legal mandate.

Where the economic entity is exempt from the disclosures in accordance with the above, the economic entity discloses narrative information about the nature of the transactions and the related outstanding balances, to enable users of the entity's financial statements to understand the effect of related party transactions on its audited group annual financial statements.



1.31 Events after reporting date

Events after reporting date are those events, both favourable and unfavourable, that occur between the reporting date and the date when the financial statements are authorised for issue. Two types of events can be identified:

- those that provide evidence of conditions that existed at the reporting date (adjusting events after the reporting date); and
- those that are indicative of conditions that arose after the reporting date (non-adjusting events after the reporting date).

The economic entity adjusts the amount recognised in the financial statements to reflect adjusting events after the reporting date once the event occurred.

The economic entity discloses the nature of the event and an estimate of its financial effect or a statement that such estimate cannot be made in respect of all material non-adjusting events, where non-disclosure could influence the economic decisions of users taken on the basis of the financial statements.

1.32 Sundry income Teaching income

Teaching Income is recognised on the accrual basis. This policy decision is attributable to the uncertainty associated with the flow of economic benefits arising from teaching-related transactions to the entity. The management decision taken complies with the requirements of the statement on revenue recognition.

Miscellaneous income

Miscellaneous sales are generated when the NHLS recovers funds for rental lease agreements, hosts conferences and other charges which need to be recovered from the use of its own facilities such as those used by Contract Laboratory Services.

2. New standards and interpretations

2.1 Standards and interpretations issued, but not yet effective

The economic entity has not applied the following standards and interpretations, which have been published and are mandatory for the economic entity's accounting periods beginning on or after 01 April 2019 or later periods:

GRAP 34: Separate Financial Statements

The objective of this Standard is to prescribe the accounting and disclosure requirements for investments in controlled entities, joint ventures and associates when an entity prepares separate financial statements.

It furthermore covers Definitions, Preparation of separate financial statements, Disclosure, Transitional provisions and Effective date.

The effective date of the amendment is for years beginning on or after 01/04/2020.

The economic entity expects to adopt the standard for the first time in the financial year 2020.

It is unlikely that the standard will have a material impact on the economic entity's audited group annual financial statements.

GRAP 35: Consolidated Financial Statements

The objective of this Standard is to establish principles for the presentation and preparation of consolidated financial statements when an entity controls one or more other entities.

- requires an entity (the controlling entity) that controls one or more other entities (controlled entities) to present consolidated financial statements;
- defines the principle of control, and establishes control as the basis for consolidation;
- sets out how to apply the principle of control to identify whether an entity controls another entity and therefore must consolidate that entity;
- sets out the accounting requirements for the preparation of consolidated financial statements; and
- defines an investment entity and sets out an exception to consolidating particular controlled entities of an investment entity.

It furthermore covers Definitions, Control, Accounting requirements, Investment entities: Fair value requirement, Transitional provisions and Effective date.

The effective date of the amendment is for years beginning on or after 01/04/2020.

The economic entity expects to adopt the standard for the first time in the financial year 2020.

It is unlikely that the standard will have a material impact on the economic entity's audited group annual financial statements.

GRAP 110: Living and Non-living Resources

The objective of this Standard is to prescribe the:

- recognition, measurement, presentation and disclosure requirements for living resources; and
- disclosure requirements for non-living resources



2. New standards and interpretations (continued)

It furthermore covers Definitions, Recognition, Measurement, Depreciation, Impairment, Compensation for impairment, Transfers, Derecognition, Disclosure, Transitional provisions and Effective date.

The effective date of the standard is not yet set by the Minister of Finance.

The economic entity expects to adopt the standard for the first time when the Minister sets the effective date for the standard.

It is unlikely that the standard will have a material impact on the economic entity's audited group annual financial statements.

GRAP 110 (as amended 2016): Living and Non-living Resources

Amendments to the Standard of GRAP on Living and Non-living Resources resulted from editorial changes to the original text and inconsistencies in measurement requirements in GRAP 23 and other asset-related Standards of GRAP in relation to the treatment of transaction costs. Other changes resulted from changes made to IPSAS 17 on Property, Plant and Equipment (IPSAS 17) as a result of the IPSASB's Improvements to IPSASs 2014 issued in January 2015 and Improvements to IPSASs 2015 issued in March 2016.

The most significant changes to the Standard are:

- General improvements: To clarify the treatment of transaction costs and other costs incurred on assets
 acquired in non-exchange transactions to be in line with the principle in GRAP 23; and To clarify the
 measurement principle when assets may be acquired in exchange for a non-monetary asset or assets, or
 a combination of monetary and non-monetary assets
- IPSASB amendments: To clarify the revaluation methodology of the carrying amount and accumulated depreciation when a living resource is revalued; To clarify acceptable methods of depreciating assets; and To define a bearer plant and include bearer plants within the scope of GRAP 17 or GRAP 110, while the produce growing on bearer plants will remain within the scope of GRAP 27

The effective date of the amendment is for years beginning on or after 01 April 2020.

The economic entity expects to adopt the amendment for the first time in the 2021 audited group annual financial statements.

It is unlikely that the amendment will have a material impact on the economic entity's audited group annual financial statements.

GRAP 6 (as revised 2010): Consolidated and Separate Financial Statements

The definition of 'minority interest' has been amended to 'non-controlling interest', and paragraph .60 was added by the Improvements to the Standards of GRAP issued in November 2010. An entity shall apply these amendments prospectively for annual financial periods beginning on or after the effective date [in conjunction with the effective date to be determined by the Minister of Finance for GRAP 105, 106 and 107]. If an entity elects to apply these amendments earlier, it shall disclose this fact.

2. New standards and interpretations (continued)

Paragraph .59 was amended by Improvements to the Standards of GRAP issued in November 2010. An entity shall apply these amendments prospectively for annual financial periods beginning on or after the effective date [in conjunction with the effective date to be determined by the Minister of Finance for GRAP 105, 106 and 107] from the date at which it first applied the Standard of GRAP on Non-current Assets Held for Sale and Discontinued Operations. If an entity elects to apply these amendments earlier, it shall disclose this fact.

The Standards of GRAP on Transfer of Functions Between Entities Under Common Control, Transfer of Functions Between Entities Not Under Common Control and Mergers amended paragraphs .03, .39, .47 to .50 and added paragraphs .51 to .58 and .61 to .62. An entity shall apply these amendments when it applies the Standards of GRAP on Transfer of Functions Between Entities Under Common Control, Transfer of Functions Between Entities Not Under Common Control and Mergers.

An entity shall apply this amendment for audited group annual financial statements covering periods beginning on or after the effective date [in conjunction with the effective date to be determined by the Minister of Finance for GRAP 105, 106 and 107].

The economic entity expects to adopt the amendment for the first time in the 2020 audited group annual financial statements.

It is unlikely that the amendment will have a material impact on the economic entity's audited group annual financial statements.

GRAP 18 (as amended 2016): Segment Reporting

Amendments to the Standard of GRAP on Segment Reporting resulted from editorial and other changes to the original text have been made to ensure consistency with other Standards of GRAP.

The most significant changes to the Standard are:

• General improvements: An appendix with illustrative segment disclosures has been deleted from the Standard as the National Treasury has issued complete examples as part of its implementation guidance.

The effective date of the amendment is for years beginning on or after 01 April 2019

The economic entity expects to adopt the amendment for the first time when the Minister sets the effective date for the amendment.

It is unlikely that the amendment will have a material impact on the economic entity's audited group annual financial statements.

GRAP 20: Related parties

The objective of this standard is to ensure that a reporting entity's audited group annual financial statements contain the disclosures necessary to draw attention to the possibility that its financial position and surplus or deficit may have been affected by the existence of related parties and by transactions and outstanding balances with such parties.



2. New standards and interpretations (continued)

An entity that prepares and presents financial statements under the accrual basis of accounting (in this standard referred to as the reporting entity) shall apply this standard in:

- identifying related party relationships and transactions;
- · identifying outstanding balances, including commitments, between an entity and its related parties;
- identifying the circumstances in which disclosure of the items in (a) and (b) is required; and
- determining the disclosures to be made about those items.

This standard requires disclosure of related party relationships, transactions and outstanding balances, including commitments, in the consolidated and separate financial statements of the reporting entity in accordance with the Standard of GRAP on Consolidated and Separate Financial Statements. This standard also applies to individual audited group annual financial statements.

Disclosure of related party transactions, outstanding balances, including commitments, and relationships with related parties may affect users' assessments of the financial position and performance of the reporting entity and its ability to deliver agreed services, including assessments of the risks and opportunities facing the entity. This disclosure also ensures that the reporting entity is transparent about its dealings with related parties.

The standard states that a related party is a person or an entity with the ability to control or jointly control the other party, or exercise significant influence over the other party, or vice versa, or an entity that is subject to common control, or joint control. As a minimum, the following are regarded as related parties of the reporting entity:

- A person or a close member of that person's family is related to the reporting entity if that person:
 - has control or joint control over the reporting entity;
 - has significant influence over the reporting entity;
 - is a member of the management of the entity or its controlling entity.
- An entity is related to the reporting entity if any of the following conditions apply:
 - the entity is a member of the same economic entity (which means that each controlling entity, controlled entity and fellow controlled entity is related to the others);
 - one entity is an associate or joint venture of the other entity (or an associate or joint venture of a member of an economic entity of which the other entity is a member);
 - both entities are joint ventures of the same third party;
 - one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
 - the entity is a post-employment benefit plan for the benefit of employees of either the entity or an entity related to the entity. If the reporting entity is itself such a plan, the sponsoring employers are related to the entity;
 - the entity is controlled or jointly controlled by a person identified in (a); and
 - a person identified in (a)(i) has significant influence over that entity or is a member of the management of that entity (or its controlling entity).

2. New standards and interpretations (continued)

The standard furthermore states that related party transaction is a transfer of resources, services or obligations between the reporting entity and a related party, regardless of whether a price is charged.

The standard elaborates on the definitions and identification of:

- Close member of the family of a person;
- Management;
- Related parties;
- Remuneration; and
- Significant influence

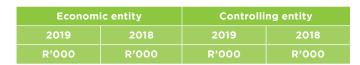
The standard sets out the requirements, inter alia, for the disclosure of:

- Control:
- Related party transactions; and
- Remuneration of management

The effective date of the standard is not yet set by the Minister of Finance.

The economic entity expects to adopt the standard for the first time when the Minister sets the effective date for the standard.

It is unlikely that the standard will have a material impact on the economic entity's audited group annual financial statements.



3. Inventories

Raw materials, components
Work in progress
Finished goods
Consumable stores

8,182 5,468 - 516 863 14 151,086 117,781 151,087 159,990 124,412 151,101	387 117,785 118,172
516 863 14	387
8,182 5,468 -	_
	_
206 300 -	-

It is the economic entity's policy to make inventory write-downs for obsolete and expired stock. During the current year, the assessment of inventory for impairment did not result in any write downs.

4. Receivables from exchange transactions

Trade debtors

Prepayments

Other receivables

Less: Allowance for impairment on trade receivables*

Interest receivable

Teaching Services

2,003,613	2,219,090	2,001,139	2,217,101
112,783	97,993	112,783	97,993
13,772	5,632	13,772	5,632
(3,531,479)	(3,355,380)	(3,531,479)	(3,355,380)
3,979	10,745	3,931	10,726
5,031	74	5,031	74
5,399,527	5,460,026	5,397,101	5,458,056

* The economic entity raises a doubtful debt provision on private debtors (Medical Aid debtors and private individuals) and State Debtors.

Outstanding debt from KwaZulu-Natal Department of Health

Included in the receivables above is R2.805bn (2018: R2.952bn) owed by the KwaZulu-Natal Department of Health of which R2.637bn (2018: R2.639bn) has been impaired. For the receivables of R2.805bn, the Accountant General performed an audit of R2.8bn relating to pathology services rendered to KwaZulu-Natal DoH which was queried for the period from 01 March 2010 to 31 March 2014. It was confirmed that R1.8bn is payable to the NHLS.

Outstanding debt from Gauteng Department of Health

The balance in receivables also includes an amount owed by Gauteng Department of Health amounting to R1.455bn (2018: R1.595bn) of which R548m (2018: R452m) has been impaired.

Trade and other receivables past due but not impaired

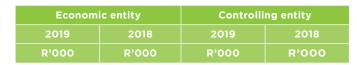
Trade and other receivables which are less than 3 months past due are not considered to be impaired. At 31 March 2019, R1,226,348 (2018: R 1,395,004) were past due but not impaired.

The ageing of amounts past due but not impaired is as follows:

1 month past due 2 months past due 3 months past due

707,747	667,149	706,760	667,149
314,437	393,382	313,605	393,382
204,164	334,473	203,734	334,473
1,226,348	1,395,004	1,224,099	1,395,004





4. Receivables from exchange transactions (continued)

Trade and other receivables impaired

As of 31 March 2019, trade and other receivables of 3.531bn (2018: R3.355bn) were provided for impairment.

The ageing of these loans is as follows.				
Over 6 months	3,531,479	3,355,380	3,531,479	3,355,380
Reconciliation of provision for impairment of trade and	other receival	oles		
Opening balance	3,355,380	4,682,645	3,355,380	4,682,645
Provision for impairment	188,306	(272,603)	188,306	(272,603)
Amounts written off as uncollectible	(12,207)	(1,054,662)	(12,207)	(1,054,662)
	3,531,479	3,355,380	3,531,479	3,355,380

The creation and release of provision for impaired receivables have been included in operating expenses in surplus or deficit. Amounts charged to the allowance account are generally written off when there is no expectation of recovering additional cash.

5. Debt impairment

	188,296	(270,688)	187,131	(269,619)
Bad debts written off [2]	12,207	1,054,662	12,207	1,054,662
Contributions to debt impairment provision [1]	176,089	(1,325,350)	174,924	(1,324,281)

- [1] Contributions to debt impairment provision are made up of provision for doubtful debt in the Controlling entity and provision for the loss in the controlled entity, SAVP.
- [2] Debt written off consists of stale medical aid claims due to late billing as well as write offs due to data-capturing errors, debt that is uneconomical to pursue, death of patients, uncontactable patients, uncollectable debt and debt which falls over the prescribed period.

6. Receivables from non-exchange transactions

Other receivables from non-exchange revenue	431,468	327,626	431,468	327,626
7. Cash and cash equivalents				
Cash and cash equivalents consist of:				
Cash on hand	308	526	296	515
Bank balances	30,184	36,719	29,632	36,328
Short-term deposits	2,177,601	1,081,899	2,171,809	1,077,613
	2,208,093	1,119,144	2,201,737	1,114,456
Cash and cash equivalents held by the entity that are not available for use by the economic entity - Grant donor funds	446,328	365,772	446,328	365,772

The interest earned on cash at bank and short term deposits ranged from 8.49% to 8.53% (2018: 8.45% to 9.85%) and these deposits had an average maturity of 30 days.

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Notes to the Audited Group Annual Financial Statements

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Figures in Rand thousand

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	2019			2018	
Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
710,474	(19,741)	690,733	710,474	ı	710,474
437	(45)	392	7,165	(6,302)	863
350,164	(264,136)	86,028	337,107	(227,738)	109,369
9,955	(6,455)	3,500	10,228	(6,853)	3,375
755,794	(582,656)	173,138	690,142	(533,881)	156,261
95,552	1	95,552	95,552	ı	95,552
101,351	(100,040)	1,311	112,812	(57,043)	55,769
35,971	(27,410)	8,561	37,381	(25,428)	11,953
95,802	(46,075)	49,727	96,551	(30,415)	66,136
40,716	(25,965)	14,751	32,026	(20,648)	11,378
7,916	(6,276)	1,640	7,292	(5,795)	1,497
22	1	22	22	1	22
2,204,154	(1,078,799)	1,125,355	2,136,752	(914,103)	1,222,649

_easehold improvements

Office equipment

Motor vehicles

Sheep and horses

Laboratory equipment Furniture and fixtures Computer equipment

Buildings - air systems

Figures in Rand thousand 3. Property, plant and equipment (continued)

Controlling entity

Buildings Buildings - air systems Computer equipment Furniture and fixtures Laboratory equipment Land Leasehold improvements	Mobile units Motor vehicles Office equipment
--	--

		2019			2018	
Cost / Valuation	u o	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
1	710,474	(19,741)	690,733	710,474	ı	710,474
	437	(45)	392	7,165	(6,302)	863
[2]	349,919	(263,953)	85,966	336,866	(227,572)	109,294
	9,840	(6,358)	3,482	10,113	(6,745)	3,368
1	751,684	(579,766)	171,918	686,103	(531,206)	154,897
	95,552	ı	95,552	95,552	1	95,552
	101,351	(100,040)	1,311	112,812	(57,043)	55,769
	35,971	(27,410)	8,561	37,381	(25,428)	11,953
	95,802	(46,075)	49,727	96,551	(30,415)	66,136
•	40,654	(25,903)	14,751	31,951	(20,594)	11,357
	7,916	(6,276)	1,640	7,292	(5,795)	1,497
2,19	2,199,600	(1,075,567)	1,124,033	2,132,260	(911,100)	1,221,160

Figures in Rand thousand

Property, plant and equipment (continued)

Reconciliation of property, plant and equipment - Economic entity - 2019

		•					
	Opening balance	Additions	Recognition of grants asset	Disposals	Reclassificati on *	Depreciation	Total
Buildings	710,474	1	1	1	ı	(19,741)	690,733
Buildings - air systems	863	1	386	(228)	(511)	(118)	392
Computer equipment	109,369	19,720	440	(268)	(46)	(43,187)	86,028
Furniture and fixtures	3,375	579	36	(105)	(125)	(260)	3,500
Laboratory equipment	156,261	73,696	21,600	(2,879)	(1,093)	(74,447)	173,138
Land	95,552	ı	ı	ı	Γ	ı	95,552
Leasehold improvements	55,769	I	1	(300)	511	(54,669)	1,311
Mobile units	11,953	269	ı	(355)	r	(3,306)	8,561
Motor vehicles	66,136	096	ı	(342)	(295)	(16,732)	49,727
Office equipment	11,378	5,844	202	(149)	1,159	(3,683)	14,751
Plant and machinery	1,497	1,383	ı	(244)	(535)	(461)	1,640
Sheep and horses	22	I	ı	ı	Г	ı	22
	1,222,649	102,451	22,664	(4,870)	(935)	(216,604)	1,125,355

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	Opening balance	Additions	Disposals	Revaluations	Reclassificati on *	Depreciation	Total
Buildings	639,124	1	1	90,774	1	(19,424)	710,474
Buildings - air systems	4,104	73	(3,451)	1	1,635	(1,498)	863
Computer equipment	123,453	35,974	(575)	1	(253)	(49,230)	109,369
Furniture and fixtures	3,768	6,318	(267)	1	(6,101)	(343)	3,375
Laboratory equipment	134,388	72,588	(1,594)	1	(1,344)	(47,777)	156,261
Land	95,552	ı	ſ	1	ı	ı	95,552
Leasehold improvements	64,246	1	(145)	1	2	(8,334)	55,769
Mobile units	10,351	3,754	ſ	1	ı	(2,152)	11,953
Motor vehicles	79,292	3,375	ſ	1	ı	(16,531)	66,136
Office equipment	8,014	6,881	(522)	1	277	(3,272)	11,378
Plant and machinery	101	1,496	ı	1	1	(100)	1,497
Sheep and horses	1	22	ı	1	1	ı	22
	1,162,393	130,481	(6,554)	90,774	(5,784)	(148,661)	1,222,649

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Notes to the Audited Group Annual Financial Statements

Property, plant and equipment (continued)

Figures in Rand thousand

Reconciliation of property, plant and equipment - Controlling entity - 2019

	Opening balance	Additions	Recognition of grant assets	Disposals	Reclassificati on *	Depreciation	Total
Buildings	710,474	ı	T	ı	1	(19,741)	690,733
Buildings - air systems	863	ı	386	(228)	(511)	(118)	392
Computer equipment	109,294	19,682	440	(268)	(46)	(43,136)	85,966
Furniture and fixtures	3,368	579	36	(105)	(125)	(271)	3,482
Laboratory equipment	154,897	73,450	21,600	(2,852)	(1,101)	(74,076)	171,918
Land	95,552	ı	Γ	ı	ſ	ı	95,552
Leasehold improvements	55,769	ı	Γ	(300)	511	(54,669)	1,311
Mobile units	11,953	269	Γ	(355)	ſ	(3,306)	8,561
Motor vehicles	66,136	096	Γ	(342)	(295)	(16,732)	49,727
Office equipment	11,357	5,844	202	(149)	1,159	(3,662)	14,751
Plant and machinery	1,497	1,383	ľ	(244)	(535)	(461)	1,640
	1,221,160	102,167	22,664	(4,843)	(943)	(216,172)	1,124,033

Reconciliation of property, plant and equipment - Controlling entity - 2018

Total	710,474	863	109,294	3,368	154,897	95,552	55,769	11,953	66,136	11,357	1,497	1,221,160
Depreciation	(19,424)	(1,497)	(49,183)	(337)	(47,489)	ı	(8,334)	(2,152)	(16,531)	(3,270)	(100)	(148,317)
Reclassificati on *	ı	1,627	(253)	(6,101)	(1,325)	ı	2	ı	ı	266	ı	(5,784)
Revaluations	90,774	ı	ı	ı	ı	ı	ı	ı	ı	ı	ı	90,774
Disposals	1	(3,435)	(575)	(267)	(1,593)	ı	(145)	1	1	(522)	1	(6,537)
Additions	1	73	35,959	6,318	72,374	ı	ı	3,754	3,375	6,881	1,496	130,230
Opening balance	639,124	4,095	123,346	3,755	132,930	95,552	64,246	10,351	79,292	8,002	101	1,160,794

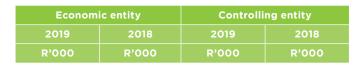
Plant and machinery Office equipment

_easehold improvements

Mobile units

_aboratory equipment Furniture and fixtures Computer equipment

Buildings - air systems



08. Property, plant and equipment (continued)

Reclassification * represent corrections made in the current year in relation to assets incorrectly classified.

Assets subject to finance lease (Net carrying amount)

Included in property, plant and equipment above are the following finance leased assets.

Laboratory equipment	
Motor vehicles	

47,844	66,871	47,844	66,871
47,844	64,396	47,844	64,396
-	2,475	-	2,475

Revaluations

The effective date of the revaluations was Saturday, 31 March 2018. Revaluations were performed by independent valuers, T. Mokhuwa (Professional Associated Valuer) and R.A. Rakau (Professional Valuer), of Black Dot Property Consultants (Pty) Ltd. Mokhuwa and Rakau are not connected to the economic entity.

Land and buildings are re-valued independently every five years.

The valuation was performed using the Depreciated Replacement Cost Method, and the following assumptions were used:

- **Effective Age:-** Effective age is the age indicated by the condition and utility of a building and was based on a valuer's judgment and interpretation of market perceptions. Actual age is the number of years that have elapsed since building construction was completed. Actual age is the initial element analysed in the estimation of effective age.
- **Remaining Economic Life:-** This is the estimated period over which existing improvements / buildings are expected to continue to contribute to property value. The remaining economic life extends from the date of the opinion of value to the end of the improvement's economic life.
- **Depreciation Percentages:-** The improvements were assumed to be depreciated by an amount regarded as applicable to that improvement, based on current condition and expected remaining lifespan. Where buildings / improvements are well maintained, the buildings were basically be regarded to have a 50 year remaining lifespan.

These assumptions were based on current market conditions.

Had land and buildings been carried at their historical cost, the carrying amounts would have been:

Category Land Buildings

129,598	133,488	129,304	133,186
126,390	130,280	126,096	129,978
3,208	3,208	3,208	3,208

Economi	ic entity	Controlli	ng entity
2019	2018	2019	2018
R'000	R'000	R'000	R'000

8. Property, plant and equipment (continued)

Other information

Property, plant and equipment fully depreciated and still in use (Gross carrying amount)

Buildings - air systems
Computer equipment
Computer software
Furniture and fixtures
Laboratory equipment
Leasehold improvements
Mobile units
Motor vehicles
Office equipment
Plant and machinery

7,717	5,176	7,717	5,176
165,583	145,414	165,556	145,362
141,577	24,287	141,577	24,287
4,792	5,548	4,707	5,463
447,798	407,705	446,511	406,584
88,579	16,151	88,579	16,151
12,080	8,585	12,080	8,585
11,925	12,788	11,925	12,788
17,328	13,334	17,266	13,301
5,823	5,611	5,823	5,611
903,202	644,599	901,741	643,308

At the end of the year, the economic entity had 18,652 assets with a total cost of R903,202 (2018: 11,132 assets with a total cost of R644,599) which had been fully depreciated and are recorded at a carrying amount of Rnil. Due to severe cash constraints experienced by the NHLS during previous years, old equipment across a number of fixed asset categories have been retained and are currently in full use. The NHLS has a policy to replace assets at specified intervals. However, due to cash flow an constraints problems and budget cuts, the NHLS was not able to replace these assets. The NHLS has not entered into accelerated capital replacement programme to replace old and outdated equipment.

Expenditure incurred to repair and maintain property, plant and equipment included in the Statement of Financial Performance

Office equipment	
Buildings	
Motor vehicles	
Laboratory equipm	ent

4,110	980	4,110	980
43,853	38,239	43,779	38,228
547	1,131	547	1,131
45,032	38,808	43,936	38,340
93,542	79,158	92,372	78,679

Sheep and horses

As at 31 March 2019, the economic entity owns 61 horses (2018: 67) and 51 sheep (2018: 71). The horses are used for the production of antivenom. Sheep blood is used for the testing of antivenom. The horses and sheep meet the definition of an asset and they have been classified as property, plant and equipment in terms of GRAP 17.

A register of all assets containing the information required by section 63 of the Public Finance Management Act is available for inspection at the registered office of the entity.



Computer software Patents **Total**

2019			2018			
Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value	
143,547	(142,610)	937	148,870	(114,318)	34,552	
60	(33)	27	60	(30)	30	
143,607	(142,643)	964	148,930	(114,348)	34,582	

Controlling entity

Computer software Patents **Total**

2019			2018		
Cost / Valuation	Accumulat ed amortisation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value
143,547	(142,610)	937	148,870	(114,318)	34,552
60	(33)	27	60	(30)	30
143,607	(142,643)	964	148,930	(114,348)	34,582

Reconciliation of intangible assets - Economic entity - 2019

Computer software Patents

Opening balance	Additions	Reclassification	Amortisation	Total
34,552	45	650	(34,310)	937
30	-	-	(3)	27
34,582	45	650	(34,313)	964

Reconciliation of intangible assets - Economic entity - 2018

Computer software
Patents

Opening balance	Additions	Disposals	Reclassification	Amortisation	Total
77,976	390	(12)	307	(44,109)	34,552
33	-	-	-	(3)	30
78,009	390	(12)	307	(44,112)	34,582

Reconciliation of intangible assets - Controlling entity - 2019

Computer software
Patents

Opening balance	Additions	Reclassification	Amortisation	Total
34,552	45	650	(34,310)	937
30	-	-	(3)	27
34,582	45	650	(34,313)	964

Reconciliation of intangible assets - Controlling entity - 2018

Computer software
Patents

Opening balance	Additions	Disposals	Reclassification	Amortisation	Total
77,976	390	(12)	307	(44,109)	34,552
33	-	-	-	(3)	30
78,009	390	(12)	307	(44,112)	34,582

Reclasses represent corrections made in current year of intangible assets incorrectly classified as property, plant and equipment.

Economic entity		Controlling entity		
2019	2018	2019	2018	
R'000	R'000	R'000	R'000	

10. Investment in controlled entity

Name of company	Held by	% holding 2019	% holding 2018	Carrying amount 2019	Carrying amount 2018
South African Vaccine Producers (Pty) Limited	National Health Laboratory Service	100.00 %	100.00 %	10	10
				10	10
Impairment of investment in controlled entity		100.00 %	100.00 %	(10)	(10)
				-	-

The carrying amounts of controlled entity is shown net of impairment losses.

11. Loans to economic entity

Controlled entities

South African Vaccine Producers (Pty) Ltd	-	-	35,207	36,382
	-	-	35,207	36,382
Impairment of loans to controlled entity	-	-	(35,207)	(36,382)
	-	-	-	-

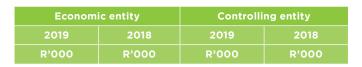
The Controlling entity has subordinated it's rights to claim payments of debts of R35,207m (2018: R36,382m) owing to it by South African Vaccine Producers (Pty) Limited until the assets of the subsidiary, fairly valued, exceeds its liabilities. The report of the Accounting Authority contains further details of the subsidiary.

Loan to SAVP impaired

As of 31 March 2019, loans to economic entities of 35,207m - (2018: 36,382m) were provided for impairment.

The ageing of these loans is as follows:

Over 6 months	-	-	35,207	36,382
12. Other financial liabilities				
At amortised cost				
Other financial liabilities [1]	-	19,497	-	19,497
Onerous contract [2]	13,940	17,749	13,940	17,749
	13,940	37,246	13,940	37,246



12. Other financial liabilities (continued)

Total other financial liabilitie	S
Non-current liabilities	
At amortised cost	

Current linkilities

Current	liab	ilities
At amort	ised	cost

13,940	37,246	13,940	37,246
9,712	13,940	9,712	13,940
4,228	23,306	4,228	23,306

- [1] Other financial liabilities comprise of amounts owed to suppliers for the acquisition of laboratory equipment, IT equipment and IT software. The liabilities are interest-free and are payable within the next 24 months.
- [2] Onerous contract relates to the amount committed by the economic entity on certain lease contracts over and above the fair value of the assets obtained therefrom.

13. Finance lease obligation

Minimum lease payments due

- within	one	Vear	

- in second to fifth year inclusive

less: future finance charges

Present value of minimum lease payments

Present value of minimum lease payments due

- within one year

- in second to fifth year inclusive

Non-current liabilities Current liabilities

21,942	21,863	21,942	21,863
42,634	64,342	42,634	64,342
64,576	86,205	64,576	86,205
(9,252)	(15,884)	(9,252)	(15,884)
55,324	70,321	55,324	70,321
16,933	15,197	16,933	15,197
38,191	55,124	38,191	55,124
55,124	70,321	55,124	70,321
38,191	55,124	38,191	55,124
16,933	15,197	16,933	15,197
55,124	70,321	55,124	70,321

It is economic entity's policy to lease certain motor vehicles and equipment under finance leases.

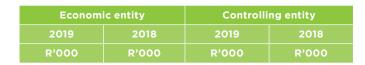
The average lease term was 5 years and the average effective borrowing rate was 10.50% (2018:10.5%).

Interest rates are fixed at the contract date. All leases have fixed repayments and no arrangements have been entered into for contingent rent.

The depreciation on leased assets amounts to R32.7 million (2018: R16.7 million).

The economic entity's obligations under finance leases are secured by the lessor's charge over the leased assets. Refer note 8





14. Payables from exchange transactions

Trade payables "
Accrued expenses
Other payables **

Opening balance

541,634	703,527	539,608	701,740
312,131	99,085	311,845	98,897
67,055	87,653	65,525	86,406
162,448	516,789	162,238	516,437

1,022,679 1,000,034

15. Employee benefit obligations Defined benefit plan

The plan is a post employment medical benefit plan.

Post retirement medical aid plan

NHLS provides post-employment healthcare benefits. Members who joined NHLS before 1 January 2003, and KwaZulu-Natal members who joined NHLS before 1 October 2006 are eligible for a subsidy of medical scheme contributions in retirement.

The amounts recognised in the statement of financial position are as follows:

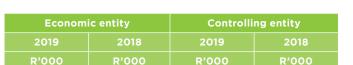
-				
	(988,415)	(1,000,034)	(988,415)	(1,000,034)
Current liabilities	(30,879)	(26,480)	(30,879)	(26,480)
Non-current liabilities	(957,536)	(973,554)	(957,536)	(973,554)
unfunded				
Present value of the defined benefit obligation-wholly	(988,415)	(1,000,034)	(988,415)	(1,000,034)
Carrying value				

Changes in the present value of the defined benefit obligation are as follows:

	112,381	135,983	112,381	135,983
including changes in members in members' benefit options Unexpected changes in memberships	(1,096)	8,859	(1,096)	8,859
(Higher)/Lower than expected healthcare cost inflation	1,080	22,598	1,080	22,598
Change in real discount rate	112,397	104,526	112,397	104,526
Calculation of actuarial gains and losses				
	16,142	2,094	16,142	2,094
Actuarial (gains) losses	(112,381)	(135,983)	(112,381)	(135,983)
Interest cost	103,504	110,088	103,504	110,088
Current service cost	25,019	27,989	25,019	27,989
Net expense recognised in the statement of financial performance				
	988,415	1,000,034	988,415	1,000,034
Net expense recognised in the statement of financial performance	16,142	2,094	16,142	2,094
Benefits paid	(27,761)	(24,739)	(27,761)	(24,739)
opening balance	1,000,001	1,022,073	1,000,001	1,022,073

^{*} Trade payables are non-interest bearing and are normally settled on 30-day payment terms.

^{**} Other payables are made up of employee cost related liabilities, debtors with credit balances and other sundry payables.



15. **Employee benefit obligations (continued)**

Key assumptions used

For practical reasons, these assumptions are determined before the valuation date. The economic assumptions used in this valuation are based on the market information as at end February 2019. The economic assumptions have been set in relation to the duration of the liability as at 31 March 2019. At that date, the duration of the liability was 18.6 years and thus a duration of 17.2 years was used to set economic assumptions. Assumptions used at the reporting date:

Discount rates used	11.00 %	10.50 %	11.00 %	10.50 %
CPI inflation rate	7.10 %	7.30 %	7.10 %	7.30 %
Salary inflation	8.60 %	8.80 %	8.60 %	8.80 %
Expected increase in healthcare costs Discount rate:	9.80 %	9.30 %	9.80 %	9.30 %

The discount rate of 11% per annum is primarily determined by reference to current market yields on government

Consumer Price Index inflation:

While not used explicitly in the valuation, the actuaries have assumed the underlying future rate of consumer price index inflation (CPI inflation) to be 7.10% per annum. This assumption has been based on the relationship between the nominal bond curve and the real bond yield.

Income at Retirement:

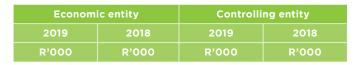
Income at retirement is relevant to the extent that the contribution tables are based on income. The actuaries have assumed that an individual member's income would increase by 8.60% per annum, based on the underlying assumption that individual remuneration increase including merit and promotional increases would exceed CPI inflation by an average of 1.5% per annum over the long term. The actuarial assumption is that income at retirement would be 65% of final salary.

Healthcare cost inflation:

The current contribution tables of the medical schemes would continue to apply in the future, with allowances of inflationary increases of 9.80% per annum. In consultation with the NHLS, assumptions made by the actuaries state that healthcare cost inflation exceed CPI inflation by an average of 2.00% per annum over the long term.

Sensitivity analysis

Assumed healthcare cost trends rates have a significant effect on the amounts recognised in surplus or deficit. A one percentage point change in assumed healthcare cost trends rates would have the following effects:



15. Employee benefit obligations (continued)

2019 One percentage point increase	2019 One percentage point decrease	2018 One percentage point increase	2018 One percentage point decrease
23,435	(18,764)	25,337	(20,028)
166.037	(142,961)	182.610	(145.542)

Effect on the aggregate of the service cost and interest cost Effect on defined benefit obligation

Amounts for the current and previous four years are as follows:

	2019	2018	2017	2016	2015
	R'000	R'000	R'000	R'000	R'000
Defined benefit obligation	988,415	1,000,034	1,022,679	954,223	876,457

Defined contribution plan

It is the policy of the economic entity to provide retirement benefits to all its employees. A number of defined contribution provident funds, all of which are subject to the Pensions Fund Act exist for this purpose.

The economic entity is under no obligation to cover any unfunded benefits.

The total economic entity contribution to such schemes

	2E1 717	219 700	250 200	217 727
Recognised as general expenses	47,835	30,100	47,832	30,100
Recognised as cost of sales	203,482	188,609	202,448	187,627

16. Unspent conditional grants and receipts

Conditional grant funds are recognised only when grant conditions are met.

Unspent conditional grants and receipts comprises of:

Research grants
Movement during the year
Balance at the beginning of the year
Additions during the year
Income recognition during the year

28,669	20,316	28,669	20,316
(18,594)	(11,226)	(18,594)	(11,226)
26,947	19,290	26,947	19,290
20,316	12,252	20,316	12,252
28,669	20,316	28,669	20,316



Reconciliation of provisions - Economic entity - 2019

	Opening Balance R'000	Additions R'000	Utilised during the year R'000	Reversed during the year R'000	Total R'000
Bonus provision [1]	492	1,761	(1,724)	-	529
DoH utility charges provision [2]	505,277	72,162	(16,672)	(15,888)	544,879
Leave pay provision [3]	202,485	46,346	(16,732)	-	232,099
Salaries provision [4]	139,087	24,584	-	-	163,671
Student bursary provision [5]	6,500	780	(6,500)	-	780
	853,841	145,633	(41,628)	(15,888)	941,958

Reconciliation of provisions - Economic entity - 2018

	Opening Balance R'000	Additions R'000	Utilised during the year R'000	Reversed during the year R'000	Total R'000
Bonus provision [1]	544	126,415	(126,467)	-	492
DoH utility charges provision [2]	405,357	113,038	(13,118)	-	505,277
Leave pay provision [3]	185,789	30,048	(13,352)	-	202,485
Salaries provision [4]	116,197	22,890	-	-	139,087
Student bursary provision [5]	6,059	2,750	-	(2,309)	6,500
	713,946	295,141	(152,937)	(2,309)	853,841

Reconciliation of provisions - Controlling entity - 2019

	Opening Balance R'000	Additions R'000	Utilised during the year R'000	Reversed during the year R'000	Total R'000
Bonus provision [1]	492	1,761	(1,724)	-	529
DoH utility charges provision [2]	505,277	72,162	(16,672)	(15,888)	544,879
Leave pay provision [3]	202,485	46,346	(16,732)	-	232,099
Salaries provision [4]	139,087	24,584	-	-	163,671
Student bursary provision [5]	6,500	780	(6,500)	-	780
	853,841	145,633	(41,628)	(15,888)	941,958

Reconciliation of provisions - Controlling entity - 2018

	Opening Balance R'000	Additions R'000	Utilised during the year R'000	Reversed during the year R'000	Total R'000
Bonus provision [1]	544	126,415	(126,467)	-	492
DoH utility charges provision [2]	405,357	113,038	(13,118)	-	505,277
Leave pay provision [3]	185,789	30,048	(13,352)	-	202,485
Salaries provision [4]	116,197	22,890	-	-	139,087
Student bursary provision [5]	6,059	2,750	-	(2,309)	6,500
	713,946	295,141	(152,937)	(2,309)	853,841



Economic entity		Controlli	ng entity
2019	2018	2019	2018
R'000	R'000	R'000	R'000

17. **Provisions (continued)**

- [1] The bonus provision is made up of the following:
 - Certain employees in bands D and above who are on the cost to company package and elect to structure part of their package as a 13th cheque. The provision is utilised when employees become entitled to and are paid for their services to the entity. The bonus payable is determined by applying a specific formula based on the employees' total cost to company; and
 - A 13th cheque for employees in bands A to C which is payable in December each year.
- [2] The DoH utility charges provision relates to utilities and maintenance fees owing to the DoH for various provincial hospital facilities around the country.
- [3] The leave pay provision relates to vesting leave pay to which employees may become entitled upon leaving the employment of the economic entity. The provision arises as employees render a service that increases their entitlement to future compensated leave and is calculated based on an employee's total cost of employment. The provision is utilised when employees become entitled to and are paid for the accumulated leave pay or utilise compensated leave due to them.
- [4] The economic entity has an agreement with Walter Sisulu University wherein the NHLS is required to pay part of the salaries for pathological academic staff. The amount has been estimated in the absence of actual figures and invoices.
- [5] Student bursary provisions relate to contractual commitments made by the economic entity by year end to fund student education for which the amount cannot yet be determined. The economic entity makes a provision based of the number of students awarded bursaries and amounts estimated using historical experiences.

18. **Deferred tax**

5	215	-	-
15	215	-	
(10)	(200)	-	-
5	15	-	
		15 215 (10) (200)	15 215 - (10) (200) -

19. Share capital / contributed capital

Issued				
Initial capital contribution	332	332	332	332

The economic entity's sole shareholder is the South African government. There have been no shares issued since the incorporation of NHLS.

Economic entity		Controlli	ng entity
2019	2018	2019	2018
R'000	R'000	R'000	R'000
R*000	R*000	R 000	R'000

20. Revaluation reserve

Opening balance	688,072	597,297	688,072	597,297
Change during the year	-	90,775	-	90,775
	688,072	688,072	688,072	688,072
Revaluation surplus relating to property, plant and equipment				
Revaluation surplus beginning of period	688,072	597,297	688,072	597,297
Movements in the reserve for the year	-	90,775	-	90,775
	688,072	688,072	688,072	688,072

21. Revenue

Sale of goods	26,755	21,563	-	-
Rendering of services	7,679,047	7,076,656	7,679,047	7,076,656
Miscellaneous other revenue *	6,447	71,194	6,447	71,194
Government grants & subsidies	789,759	746,464	789,759	746,464
	8,502,008	7,915,877	8,475,253	7,894,314
The amount included in revenue arising from exchanges of goods or services are as follows:				
Sale of goods	26,755	21,563	-	-
Rendering of services	7,679,047	7,076,656	7,679,047	7,076,656
Miscellaneous other revenue*	6,447	71,194	6,447	71,194
	7,712,249	7,169,413	7,685,494	7,147,850

^{*} Miscellaneous other revenue constitutes other income from other activities of the NHLS.

The amount included in revenue arising from non- exchange transactions is as follows:

Transfer revenue				
Government grants & subsidies	789,759	746,464	789,759	746,464
22. Cost of sales				
Direct employee costs	3,359,636	3,078,817	3,344,691	3,064,860
Direct depreciation and impairments	220,792	172,387	220,445	172,100
Direct material expenses	3,165,951	3,026,397	3,162,505	3,022,806
	6 7 46 770	6 277 601	C 707 C 41	6 250 766
23. Other income	6,746,379	6,277,601	6,727,641	6,259,766
23. Other income	6,/46,5/9	6,277,601	6,/2/,641	6,259,766
23. Other income Bad debts recovered	1,414	671	1,414	671
Bad debts recovered				
	1,414	671	1,414	671
Bad debts recovered Discount received	1,414	671 1,134	1,414	671 1,133
Bad debts recovered Discount received Exchange gains	1,414 1,193	671 1,134 3,376	1,414 1,190	671 1,133 3,376
Bad debts recovered Discount received Exchange gains Grant income recognised	1,414 1,193 - 226,885	671 1,134 3,376 357,832	1,414 1,190 - 226,885	671 1,133 3,376 357,832
Bad debts recovered Discount received Exchange gains Grant income recognised Internal recoveries	1,414 1,193 - 226,885 12,524	671 1,134 3,376 357,832 11,036	1,414 1,190 - 226,885 12,524	671 1,133 3,376 357,832 11,036
Bad debts recovered Discount received Exchange gains Grant income recognised Internal recoveries Royalties received	1,414 1,193 - 226,885 12,524 804	671 1,134 3,376 357,832 11,036 408	1,414 1,190 - 226,885 12,524 804	671 1,133 3,376 357,832 11,036 408

Economi	ic entity	Controlli	ng entity
2019	2018	2019	2018
R'000	R'000	R'000	R'000

24. Operating surplus

Operating surplus for the year is stated after accounting for the following:

Operating lease charges				
Premises				
Straight-lined	3,654	3,624	3,654	3,624
Motor vehicles				
Straight-lined	2,110	-	2,110	-
Equipment				
Straight-lined	44,736	64,796	44,589	64,657
	50,500	68,420	50,353	68,281
Loss on sale of property, plant and equipment	(4,814)	(6,579)	(4,831)	(6,562)
Amortisation on intangible assets	1,395	4,254	1,395	4,254
Depreciation on property, plant and equipment	249,504	188,515	249,091	188,171
Employee costs	3,660,540	3,326,192	3,645,439	3,312,233
25. Investment income				
Interest revenue Bank	170,961	87,850	170,500	87,509
Interest received - debtors	23,756	15,085	23,756	15,085

26	- 61	2	nce	-	ctc

Loans to directors managers and employees

	10,753	16,098	10,379	
te payment of tax [2]	377	140	3	
Finance leases	8,329	8,132	8,329	
Bank	-	2	-	
Amortisation of liabilities [1]	2,047	7,824	2,047	

194,717

102,936

194,256

102,595

^[1] Finance costs relate mainly to the amortisation charges of onerous contract liability whose payments are deferred over 24 to 60 months.

^[2] Other interest relate mainly to notional interest on creditors.

Economic entity Controlling entity 2019 2018 2019 2018 R'000 R'000 R'000 R'000

27. Taxation

Major components of the tax expense

Current

Local income tax - current period

Local income tax - recognised in current tax for prior periods

Deferred

Originating and reversing temporary differences

Reconciliation of the tax expense

Reconciliation between applicable tax rate and average effective tax

Applicable tax rate

Prior year

Pacio

Non-deductable expenses

1,876	974	-	-
204	(10)	-	-
2,080	964	-	-
10	(271)	-	-
2,090	693	-	-
28.00 %	28.00 %	- %	- %
3.20 %	- %	- %	- %
1.65 %	(0.10)%	- %	- %
32.85 %	27.90 %	- %	- %

28. Employee related costs

Basic
Bonus
Defined contribution plans
External bursaries
Leave pay provision charge
Long-term benefits - incentive scheme
Medical aid - company contributions
Other allowances
Other short term costs
SDL
Training
UIF
WCA

Employee	costs	are	split	into	cost	of	sales	and	general	expenses	as
follows:											

Cost of sales - employee costs General expenses - employee costs

3,660,540	3,326,192	3,645,439	3,312,233
11,686	6,657	11,626	6,600
12,692	12,098	12,624	12,029
126	171	28	27
22,533	26,619	22,401	26,497
117,195	104,906	116,506	104,224
176,384	166,634	176,384	166,634
200,384	186,266	199,383	185,312
2,860	3,159	2,838	3,117
45,956	29,956	45,736	29,949
(31)	9,406	(46)	9,406
251,317	218,709	250,280	217,727
140,427	127,359	139,686	126,639
2,679,011	2,434,252	2,667,993	2,424,072

3,359,636	3,078,817	3,344,691	3,064,860
300,904	247,375	300,748	247,373
3,660,540	3,326,192	3,645,439	3,312,233

Economic entity		Controlling entity		
2019	2018	2019	2018	
R'000	R'000	R'000	R'000	

29. General expenses (by function)

Advertising Archiving and Storage Auditors remuneration Bank charges Bad debts written off Cleaning Computer expenses Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection Delivery expenses	2,092 7,033 15,870 7,654 12,207 8,223 8,043 835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904 119 3,976	777 7,974 8,096 4,062 1,054,662 36,238 747 494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	2,092 7,033 15,567 7,615 12,207 8,179 8,043 795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	777 7,974 7,770 4,028 1,054,662 36,131 747 440 52,663 14,174 (1,324,281) 1,670 1,727 20,325 10,967
Auditors remuneration Bank charges Bad debts written off Cleaning Computer expenses Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	15,870 7,654 12,207 8,223 8,043 835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904	8,096 4,062 1,054,662 36,238 747 494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	15,567 7,615 12,207 8,179 8,043 795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	7,770 4,028 1,054,662 36,131 747 440 52,663 14,174 (1,324,281) 1,670 1,727 20,325
Bank charges Bad debts written off Cleaning Computer expenses Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	7,654 12,207 8,223 8,043 835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904 119	4,062 1,054,662 36,238 747 494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	7,615 12,207 8,179 8,043 795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	4,028 1,054,662 36,131 747 440 52,663 14,174 (1,324,281) 1,670 1,727 20,325
Bad debts written off Cleaning Computer expenses Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	12,207 8,223 8,043 835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904	1,054,662 36,238 747 494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	12,207 8,179 8,043 795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	1,054,662 36,131 747 440 52,663 14,174 (1,324,281) 1,670 1,727 20,325
Cleaning Computer expenses Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	8,223 8,043 835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904	36,238 747 494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	8,179 8,043 795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	36,131 747 440 52,663 14,174 (1,324,281) 1,670 1,727 20,325
Computer expenses Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	8,043 835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904	747 494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	8,043 795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	747 440 52,663 14,174 (1,324,281) 1,670 1,727 20,325
Conferences and seminars Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	835 69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904	494 52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	795 69,319 17,657 174,924 1,275 1,057 30,041 15,366	440 52,663 14,174 (1,324,281) 1,670 1,727 20,325
Consulting and professional fees Consumables Contributions to debt impairment provision Debt collection	69,362 17,694 176,089 1,275 1,059 30,107 15,366 300,904	52,844 14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	69,319 17,657 174,924 1,275 1,057 30,041 15,366	52,663 14,174 (1,324,281) 1,670 1,727 20,325
Consumables Contributions to debt impairment provision Debt collection	17,694 176,089 1,275 1,059 30,107 15,366 300,904	14,205 (1,325,350) 1,670 1,728 20,382 10,967 247,375	17,657 174,924 1,275 1,057 30,041 15,366	14,174 (1,324,281) 1,670 1,727 20,325
Contributions to debt impairment provision Debt collection	176,089 1,275 1,059 30,107 15,366 300,904	(1,325,350) 1,670 1,728 20,382 10,967 247,375	174,924 1,275 1,057 30,041 15,366	(1,324,281) 1,670 1,727 20,325
Debt collection	1,275 1,059 30,107 15,366 300,904 119	1,670 1,728 20,382 10,967 247,375	1,275 1,057 30,041 15,366	1,670 1,727 20,325
	1,059 30,107 15,366 300,904 119	1,728 20,382 10,967 247,375	1,057 30,041 15,366	1,727 20,325
Delivery expenses	30,107 15,366 300,904 119	20,382 10,967 247,375	30,041 15,366	20,325
B I I I I I I I I I I I I I I I I I I I	15,366 300,904 119	10,967 247,375	15,366	
Depreciation, amortisation and impairments	300,904 119	247,375		I() 9h/
Discount allowed	119			
Employee costs			300,748	247,373
Entertainment	3,976	116	119	116
Exchange losses		-	3,976	-
Lease rentals on operating lease	43,518	60,266	43,389	60,140
Loss on disposal of assets and liabilities	4,814	6,579	4,831	6,562
Insurance	4,857	4,706	4,857	4,706
Legal expenses	10,822	7,697	10,796	7,672
Medical expenses	1,721	45	1,721	45
Minor assets	173	3,534	132	3,498
Motor vehicle expenses	1,090	4,000	1,090	4,000
Other expenses	2,477	11,367	2,466	11,367
Packaging	8,483	7,845	8,341	7,790
Petrol and oil	6,105	5,197	6,105	5,197
Postage and courier	18	189	18	188
Printing and stationery	40,114	37,598	40,028	37,493
Project Management expenses	677	1,269	677	1,269
Promotions	289	365	289	365
Promotions and sponsorships	40	2	40	2
Repairs and maintenance	48,510	40,350	48,436	40,339
Research Trust	22	-	22	-
Royalties and license fees	794	-	794	-
Security	996	15,413	996	15,413
Software development expenses	10,076	7,635	10,076	7,635
Software expenses	105,981	93,364	105,984	93,364
Staff welfare	9,567	9,302	9,432	9,253
Subscriptions and membership fees	4,916	6,674	4,916	6,674
Telephone and fax	85,655	83,497	85,441	83,409
Training	21,109	16,011	21,109	16,011
Travel - local	48,533	48,741	48,532	48,741
Travel - overseas	307	124	307	124
Utilities	113,047	139,401	113,047	139,401
	1,252,619	748,158	1,249,885	747,921



30. Auditors' remuneration

Audit Fees - current year

Adjustment for previous year
Fees for other services

Expenses

Auditors' remuneration consists of external and internal audit remuneration. Internal audit services are co-sourced.

31. Depreciation and amortisation

Depreciation and amortisation - Cost of sales	
Depreciation and amortisation - General expenses	

250,899	192,769	250,486	192,425
30,107	20,382	30,041	20,325
220,792	172,387	220,445	172,100

32. Cash generated from operations

Surplus (deficit) for the year	996,412	1,396,604	993,129	1,393,567
Adjustments for:				
Depreciation and amortisation	250,917	192,769	250,486	192,425
Loss (gain) on sale of assets and liabilities	4,831	6,579	4,831	6,562
Loss (gain) on foreign exchange	-	(3,376)	-	(3,376)
Fair value adjustments	(22,665)	(22)	(22,665)	-
Finance costs	10,376	15,973	10,376	15,973
Debt impairment	188,296	(270,688)	187,131	(269,619)
Movements in operating lease assets and accruals	-	201	-	(2)
Movements in retirement benefit assets and liabilities	(11,619)	(22,645)	(11,619)	(22,645)
Movements in provisions	88,117	139,895	88,117	139,895
Movement in tax receivable and payable	1,103	346	-	-
Annual charge for deferred tax	10	(271)	-	-
Prior period adjustments	-	266,589	-	266,589
Other non-cash items	285	5,925	291	5,925
Changes in working capital:				
Inventories	(35,578)	(7,569)	(32,929)	(5,615)
Receivables from exchange transactions	27,181	(308,752)	28,831	(310,559)
Other receivables from non-exchange transactions	(103,842)	(230,373)	(103,842)	(230,373)
Payables from exchange transactions	(161,893)	(258,365)	(162,131)	(258,787)
Unspent conditional grants and receipts	8,353	8,064	8,353	8,064
	1,240,284	930,884	1,238,359	928,024

33. Tax paid

Balance at beginning of the year
Current tax for the year recognised in surplus or deficit
Balance at end of the year

(977)	(618)	-	-
1,924	821	-	-
(2,080)	(964)	-	-
(821)	(475)	-	-

Financial instruments disclosure 34.

Categories of financial instruments

Economic entity - 2019

Financial assets

Trade and other receivables from exchange transactions Other receivables from non-exchange transactions Cash and cash equivalents

lotal	At amortised cost
2,003,613	2,003,613
431,468	431,468
2,208,088	2,208,088
4,643,169	4,643,169

Financial liabilities

Other financial liabilities Trade and other payables from exchange transactions Finance lease liability

At amortised cost	Total
13,940	13,940
541,634	541,634
55,324	55,324
610,898	610,898

Economic entity - 2018

Financial assets

Trade and other receivables from exchange transactions Other receivables from non-exchange transactions Cash and cash equivalents

At amortised cost	Total
2,219,090	2,219,090
327,626	327,626
1,119,144	1,119,144
3,665,860	3,665,860

Financial liabilities

Other financial liabilities Trade and other payables from exchange transactions Finance lease liability

At amortised cost	Total
37,246	37,246
703,527	703,527
70,321	70,321
811,094	811,094



Controlling entity - 2019

Financial assets

Trade and other receivables from exchange transactions Other receivables from non-exchange transactions Cash and cash equivalents

Financial liabilities

Other financial liabilities

Trade and other payables from exchange transactions

Finance lease liability

Controlling entity - 2018

Financial assets

Trade and other receivables from exchange transactions
Other receivables from non-exchange transactions
Cash and cash equivalents

Financial liabilities

Other financial liabilities

Trade and other payables from exchange transactions
Finance lease liability

Financial instruments in Statement of financial performance Economic entity - 2019

Interest income Interest expense

Economic entity - 2018

Interest income Interest expense

Controlling entity - 2019

Interest income
Interest expense

At amortised cost	Total
2,001,139	2,001,139
431,468	431,468
2,208,088	2,208,088
4,640,695	4,640,695

At amortised cost	Total	
13,940	13,940	
539,608	539,608	
55,324	55,324	
608,872	608,872	

Total	At amortised cost	
2,217,10	2,217,101	
327,62	327,626	
1,119,14	1,119,144	
3,663,87	3,663,871	

At amortised cost	Total
37,246	37,246
701,740	701,740
70,321	70,321
809,307	809,307

At amortised cost	Total	
194,717	194,717	
(10,379)	(10,379)	
184,338	184,338	

At amortised cost	Total	
102,936	102,936	
(16,098)	(16,098)	
86,838	86,838	

At amortised cost	Total	
102,595	102,595	
(15,973)	(15,973)	
86,622	86,622	

Economic entity		Controlling entity	
2019	2018	2019	2018
R'000	R'000	R'000	R'000

Financial instruments disclosure (continued) 34.

Controlling entity - 2018 Interest income

Interest expense (calculated using effective interest method) for financial instruments at amortised cost

At amortised cost	Total	
194,256	194,256	
(10,379)	(10,379)	
183,877	183,877	

35. Commitments

Authorised capital expenditure

Already contracted for but not provided for

- Property, plant and equipment
- Intangible assets

Total	capital	commitments

Already contracted for but not provided for

5 60,857	62,885
0 262,252	336,500
0 262 252	336,500

Authorised operational expenditure

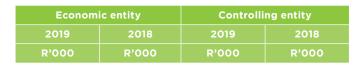
This committed expenditure relates to property, plant and equipment and will be financed by retained surpluses,, existing cash resources and funds internally generated.

Minimum lease payments due

- within one year
- in second to fifth year inclusive

48,053	51,753	48,053	51,753
28,943	35,221	28,943	35,221
19,110	16,532	19,110	16,532

Operating lease payments represent rentals payable by the economic entity for certain of its office equipment. Leases are negotiated for an average term of five years and rentals are fixed for an average of three years. No contingent rent is payable.



36. Contingencies

The WSU has claimed that the salaries of HODs, Medical Scientists and Technologists are owed by the NHLS for the period 2007 - 2013. The amount is disputed by the NHLS as the staff for which the claim is being made are not the employees of the NHLS.

The intention of the NHLS is to defend all other cases and the legal opinion is of the view that the NHLS is in a favourable legal position to succeed.

The economic entity is facing litigation from former employees citing unfair termination of employment contracts. The economic entity's lawyers consider the likelihood of the action against the entity being successful as unlikely.

Claims lodged for damages:
WSU salaries dispute
605 Consulting matter
Drive Control Corporation matter
Ms B Mnguni
Mr W P Msimanga
Ms S Fortuin
Diana Mabasa Incorporated
South African Medical Association on behalf of Dr Z
Moorad and Dr A Jali Ms L Gqwetha

15,309	15,309	15,309	15,309
17,383	-	17,383	-
37,505	-	37,505	-
4,800	-	4,800	-
3,000	-	3,000	-
328	-	328	-
235	-	235	-
178	-	178	-
50	-	50	-
78,788	15,309	78,788	15,309

There is a matter between 605 Consulting and NHLS, where the NHLS is being sued for an amount of R17.4 million.

There is another matter between Drive Control and the NHLS, where the NHLS is being sued for an amount of R37.5 million.

There is also another matter between Ms B Mnguni and the NHLS, where the NHLS is being sued for personal injury against the NHLS which amount to R4.8 million.

There is also another labour matter between Mr W P Msimanga and the NHLS, where the NHLS is being sued for an amount of R3.0 million

There is also another matter between Mr S Fortuin and the NHLS, where the NHLS is being sued for personal injury against the NHLS which amounts to R0.328 million.

There is also another matter between Diana Mabasa Inc and the NHLS, where the NHLS is being sued for damages for legal fees by the law firm which amounts to R0.235 million.

There is also a dispute before the Labour court on the deduction of monies that were allegedly overpaid to the Dr Z Moorad and Dr A Jali which amounts to R0.178 million.

There is also another labour matter between Ms L Gqwetha and the NHLS, where the NHLS is being sued for an amount of R0.050 million.

▶ ≥ 259

Notes to the Audited Group Annual Financial Statements

Econom	ic entity	Controlling entity			
2019	2018	2019	2018		
R'000	R'000	R'000	R'000		

36. Contingencies (continued)

Contingent assets

An employee and a vendor are alleged to have committed fraud and/or theft against the NHLS for a period of about 13 years from 2002 until June 2013. The NHLS conducted a disciplinary process and the employee was dismissed. The matter was reported to the Commercial Crimes Unit and a civil process has been instituted against the employee and the vendor.

Amount claimed	18,290	18,290	18,290	18,290

NHLS is in the process of registering all its foreign donor funded projects for VAT in order to be able to claim VAT input, which is not recoverable from donors. Once registrations have been finalised and the VAT input is determined this will result in the assets being recognised by NHLS.

37. Related parties

Relationships

Board Members

Controlling entity

Controlled entity

Universities

Limited Provincial Departments of Health

Prof Erich Buch

Dr Balekile E Mzangwa

Dr Gerhard Goosen

Dr Monde Tom

Dr Sibongile Zungu

Dr Tim Tucker

Dr Zwelibanzi Abie Mavuso

Mr Michael Shingange

Mr Ben Durham

Mr Ian van der Merwe

Ms Nelisiwe Mkhize

Ms Sphiwe Mayinga

Prof Haroon Saloojee

Prof Mary Ross

Prof Obi Chikwelu Lawrence

Ms Nicolene van der Westhuizen

National Department of Health

South African Vaccine Producers (Pty)

Gauteng Department of Health Limpopo

Department of Health North West

Department of Health

Kwazulu-Natal Department of Health

Western Cape Department of Health

Eastern Cape Department of Health

Northern Cape Department of Health

Mpumalanga Department of Health

Free State Department of Health

University of Cape Town

University of Stellenbosch

University of Western Cape

University of Free State

University of Witwatersrand

University of Pretoria

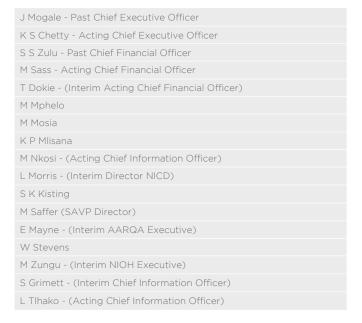
University of Limpopo

University of Kwazulu-Natal

Walter Sisulu University

37. Related parties (continued)

Members of key management



Sales to related parties' transactions relates to the provision of pathology, research and teaching services. Purchases from related parties are as a result of goods and services purchased in the ordinary course of business.



Economi	ic entity	Controlling entity			
2019	2018	2019	2018		
R'000	R'000	R'000	R'000		

37. Related parties (continued)

Related party balances

Amounts included in Trade receivable regarding related parties

By Region				
Eastern Cape	420,141	349,514	420,141	349,514
Free State	93,520	87,974	93,520	87,974
Gauteng	1,455,529	1,591,409	1,455,529	1,591,409
Kwazulu-Natal	2,804,805	2,989,865	2,804,805	2,989,865
Limpopo	118,346	99,145	118,346	99,145
Mpumalanga	84,340	117,990	84,340	117,990
National	770	1,473	770	1,473
North West	160,748	174,525	160,748	174,525
Northern Cape	79,246	58,530	79,246	58,530
Western Cape	31,602	43,210	31,602	43,210
	5,249,047	5,513,635	5,249,047	5,513,635
Provision for doubtful debts related to outstanding balances with related parties				
Gauteng	547,549	452,255	547,549	452,255
Kwazulu-Natal	2,637,049	2,639,227	2,637,049	2,639,227
	3,184,598	3,091,482	3,184,598	3,091,482
Amounts included in Trade receivable regarding related parties By Segment				
Anti-retroviral programmes	470,830	541,319	470,830	541,319
Correctional Services	7,603	7,845	7,603	7,845
Defense	4,950	4,378	4,950	4,378
Health Clinics	1,381,471	1,484,234	1,381,471	1,484,234
Hospitals	3,378,821	3,466,609	3,378,821	3,466,609
Municipalities	8,517	9,552	8,517	9,552
Other Public Entities	(3,144)	(302)	(3,144)	(302)
	5,249,048	5,513,635	5,249,048	5,513,635
Amounts included in Trade Payables regarding related parties By Region				
Eastern Cape	-	178	-	178
Gauteng	8,277	522	8,277	522
Kwazulu-Natal	2	10	2	10
Limpopo	48	1	48	1
North West	461	461	461	461
Western Cape	393	85	393	85
	9,181	1,257	9,181	1,257
Amounts included in Trade Payables regarding related parties By Segment				
Contract Laboratory Services	75	12	75	12
Municipalities	7,296	754	7,296	754
National Public Entities	1,485	458	1,485	458
Provincial Public Entities	1	2	1	2
Universities	324	31	324	31

Econom	ic entity	Controlling entity			
2019	2018	2019	2018		
R'000	R'000	R'000	R'000		

37. Related parties (continued)

Related party tra	nsactions
Services billed to	related parties By Region

Lasterri Cape	
Free State	
Gauteng	
Kwazulu-Natal	
Limpopo	
Mpumalanga	
National	
North West	
Northern Cape	
Western Cape	

Services	billed	to	related	parties	Bv	Seament

Anti-retroviral pro	grammes
Correctional Service	ces
Defense	
Health Clinics	
Hospitals	
Municipalities	
Other Public Entiti	es
Universities	

Purchases	from	related	parties	Ву	Region

Eastern Cape	
Free State	
Gauteng	
Kwazulu-Natal	
Limpopo	
North West	
Western Cape	

Purchases from related parties By Segment

Contract Laboratory Services
Municipalities
National Public Entities
Provincial Public Entities
Universities

815,215	718,776	815,215	718,776
368,199	332,105	368,199	332,105
2,004,181	1,874,543	2,004,181	1,874,543
2,014,428	1,834,872	2,014,428	1,834,872
509,202	477,211	509,202	477,211
469,200	451,940	469,200	451,940
13,038	15,912	13,038	15,912
412,419	375,511	412,419	375,511
149,087	137,815	149,087	137,815
794,791	729,715	794,791	729,715
7,549,760	6,948,400	7,549,760	6,948,400
2,886,122	2,664,609	2,886,122	2,664,609
24,940	22,677	24,940	22,677
34,128	29,223	34,128	29,223
842,534	785,133	842,534	785,133
3,687,900	3,377,682	3,687,900	3,377,682
16,059	15,682	16,059	15,682
26,261	30,165	26,261	30,165
31,816	23,229	31,816	23,229
7,549,760	6,948,400	7,549,760	6,948,400
3,451	3,370	3,451	3,370
3,695	11,885	3,695	11,885
76,823	75,401	76,823	75,401
1,299	1,643	1,299	1,643
277	367	277	367
128	443	128	443
27,766	27,078	27,766	27,078
113,439	120,187	113,439	120,187
36,198	33,028	36,198	33,028
	32,525	31,478	32,525
31,478			
31,478 14,648	14,726	14,648	14,726
		14,648 152	14,726 177
14,648	14,726		

Figures in Rand thousand

38. Prescribed Officers and Board members' emoluments - R'000s

Emoluments were paid to the board members or any individuals holding a prescribed office during the year.

Prescribed Officers							
2019							
	Salaries	Retirement contribution	Medical contribution	Expense allowance	Other**	Bonus	Total
J. Mogale (Past Chief Executive Officer)	2,457	215	ı	1	ı	ı	2,672
Dr K. Chetty (Acting Chief Executive Officer)	861	92	I	U	4	I	946
S.S. Zulu (Past Chief Financial Officer)	1,985	ı	1	11	ı	I	1,996
M. Sass (Acting Chief Financial Officer)	1,385	I	ı	ı	ı	ı	1,385
T. Dokie (Acting Chief Financial Officer up to 31 May 2018)	134	20	1	∞	31	ı	193
M. M. Mphelo	1,824	161	1	11	4	ı	2,000
M.S. Mosia	1,705	161	61	09	_	ı	1,988
K.P. Mlisana	1,920	180	117	21	41	ı	2,252
M. Nkosi	868	84	47	11	2	ı	1,042
L. Tlhako	1,114	86	I	11	ı	ı	1,223
L. Morris	1,677	200	34	1	2	13	1,926
S. K. Kisting	1,392	ı	l	0	2	ı	1,403
M. Saffer (SAVP Director)	781	69	l	10	4	ı	864
S. Grimett (Acting Chief Information Officer up to 31 May 2018)	154	23	10	ı	31	ı	218
W. Stevens	1,863	185	120	127	108	ı	2,403
Dr M. Zungu	333	34	12	ı	8	ı	382
Dr E. Mayne	249	24	10	-	31	1	314
	20,732	1,530	411	284	237	13	23,207

Figures in Rand thousand

Prescribed Officers and Board members' emoluments - R'000s (continued) 2018 38.

	Salaries	Other benefits*	Medical contribution	Expense allowance	Other**	Bonus	Leave paid out	Total
J. Mogale (Chief Executive Officer)	2,366	207	'	r	25	r	'	2,598
S. Madhi (Acting Chief Executive Officer)	958	1	42	9	13	ī	198	1,217
M. Mosia	1,560	149	09	09	18	Ī	1	1,847
M. Saffer (SAVP Director)	719	64	1	10	0	T	1	802
S. Kisting	434	ı	ı	1	16	r	1	450
S. Zulu (Chief Financial Officer)	1,844	ı	ı	11	20	r	1	1,875
M. Mphelo	1,695	149	ı	11	18	r	1	1,873
T. Shilowa	896	100	72	45	13	r	104	1,302
B. Wikner (Acting Chief Financial Officer *)	438	32	4	ΓU	Ŋ	r	1	494
T Dokie (Acting Chief Financial Officer)	510	40	1	30	10	18	ı	809
M. Shingange	696	86	28	11	14	r	ı	1,138
M. Tom	2,228	151	85	110	35	r	ı	2,609
N. Mapukata	1,291	150	32	1	25	13	ı	1,512
N. Mkhize	1,760	134	92	132	22	r	ı	2,140
	17,740	1,262	455	432	243	31	302	20,465

^{*} Amounts disclosed above only relates to the period of acting

Service contracts

Prescribed Officers are subject to written employment agreements. The employment agreements regulate duties, remuneration, allowances, restraints, leave and notice periods of these executives. None of these service contracts exceed 5 years.

^{**} Other payments include company contributions for skills development, UIF, expense recoveries and long service awards.

38. Prescribed Officers and Board members' emoluments - R'000s (continued)

Non-executive board members			
2019			
	Members' fees	Other fees (Consultancy fees to subsidiary)	Total
B. Schoub	7	-	7
B.E. Mzangwa	-	63	63
Prof. Eric Buch	336	-	336
G. Goosen	-	14	14
M. Ross	164	4	168
M. Shingange	71	16	87
N. Mkhize	-	24	24
C.L. Obi	176	11	187
S. Mayinga	130	1	131
S. Zungu	42	-	42
T. Tucker	118	5	123
Z.A. Mavuso	233	5	238
	1,277	143	1,420

2018			
	Members' fee	Other fees (Consultancy fees to subsidiary)	Total
B. Schoub	132	2	134
T. Stander	-	14	14
Prof. Eric Buch	441	5	446
G. Goosen	-	4	4
L. Ntshinga	63	12	75
M. Ross	204	7	211
M. Shingange	82	6	88
T. Mhlongo	136	20	156
G. Hussey	-	22	22
C.L. Obi	138	11	149
S. Harvey	152	2	154
S. Mayinga	109	2	111
S. Zungu	47	1	48
T. Tucker	170	1	171
W. Sturm	68	3	71
Z.A. Mavuso	95	5	100
	1,837	117	1,954

^{*}Other fees relate to travel re-imbursement, out-of-pocket expenses and other company contributions.

39. **Risk management**

Financial risk management

The economic entity's activities expose it to a variety of financial risks: market risk (including currency risk, fair value interest rate risk, cash flow interest rate risk and price risk), credit risk and liquidity risk.

The economic entity's overall risk management program focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the economic entity's financial performance. Risk management is carried out by a central treasury department under policies approved by the accounting authority. Economic Entity treasury identifies and evaluates financial risks in close co-operation with the economic entity's operating units. The accounting authority provides written principles for overall risk management, as well as written policies covering specific areas, such as interest rate risk, credit risk, and investment of excess liquidity.

Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and the availability of funding through an adequate amount of committed credit facilities and the ability to close out market positions. Due to the dynamic nature of the underlying businesses, economic entity treasury maintains flexibility in funding by maintaining availability of funds under short-term investments. At year end the investment in short-term deposits amounted to R2.177bn (2018: R1.087bn).

The economic entity's risk to liquidity is a result of the funds available to cover future commitments. The economic entity manages liquidity risk through an ongoing review of future commitments and credit facilities.

The table below analyses the economic entity's financial liabilities into relevant maturity groupings based on the remaining period at the statement of financial position to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows. Balances due within 12 months equal their carrying balances as the impact of discounting is not significant.

Economic entity At 31 March 2019

Pavables from exchange transactions Other financial liabilities Finance lease liabilities

At 31 March 2018

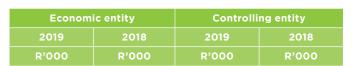
Payables from exchange transactions Other financial liabilities

Finance lease liabilities Controlling entity

At 31 March 2019

Trade and other payables Other financial liabilities Finance lease liabilities

Less than 1 year	Between 1 and 5 years
541,634	-
4,228	9,712
21,942	42,634
Less than 1 year	Between 1 and 5 years
703,527	-
27,036	16,284
21,787	64,102
Less than 1 year	Between 1 and 5 years
539,608	-
4,228	9,712
21,942	42,634



39. Risk management (continued) Credit risk

At 31 March 2018	Less than 1 year	Between 1 and 5 years
Trade and other payables	701,740	-
Other financial liabilities	27,036	16,284
Finance lease liabilities	21,787	64,102

Credit risk consists mainly of cash deposits, cash equivalents, and trade debtors. The entity only deposits cash with major banks with high quality credit standing and limits exposure to any one counter-party.

Concentrations of credit risk with respect to trade receivables are limited due to the majority of receivables being owned by government departments. However, due to the current payment disputes with the KwaZulu-Natal Provincial Department of Health and Gauteng Department of Health, a total doubtful debt allowance of R3.184bn (2018: R3.091bn) has been raised. Trade receivables are interest bearing and are generally on 30 day payment terms. All interest on overdue debt has been provided for in full due to various communications received from the relevant government departments indicating they will not be in a position to honour the the additional interest owed to NHLS.

Market risk Interest rate risk

As the economic entity has no significant interest-bearing assets, the economic entity's income and operating cash flows are substantially independent of changes in market interest rates.

Foreign exchange risk

The economic entity does not hedge foreign exchange fluctuations.

The economic entity has certain liabilities denominated in foreign currencies, whose carrying amounts are exposed to foreign currency translation risk.

Foreign currency exposure at statement of financial position date

Liabilities

Other financial liability USD 0 (2018: USD1 824) - 19,497 - 19,497

Econom	ic entity	Controlli	ng entity	
2019	2018	2019 2018		
R'000	R'000	R'000	R'000	

40. Irregular expenditure

Opening balance
Expired contracts (A)
Contracts that exceeded delegation of authority (C)
No tender procedures
Contract overspend
Tender no signed contract
Expenditure before contract
Quotation splitting
Less: Amount condoned

(2,310,258)	-	(2,310,258)	-
(2.710.2E0)			
1,707	-	1,707	-
18,282	218,077	18,282	218,077
19,470	18,702	19,470	18,702
361,810	730,310	361,810	730,310
800,671	794,091	800,671	794,091
104,770	118,710	104,770	118,710
1,690,132	675,805	1,690,132	675,805
4,445,560	1,889,865	4,445,560	1,889,865

41. Prior-year adjustments

Presented below are those items contained in the statement of financial position and statement of financial performance have been affected by prior-year adjustments, change in accounting policy and reclassifications:

Statement of financial position

Economic entity - 2017

Deferred tax	
Accumulated deficit	

Controlling entity - 2017

Property, plant and equipmen
Revaluation Reserve
Accumulated deficit

Economic entity - 2018

Controlling entity - 2018

Receivables from non-exchange transactions
Property, plant and equipment
Revaluation Reserve
Accumulated surplus
Payables from exchange transactions

Note	As previously reported	Correction of error	Restated
18	(10,234)	10,178	(56)
	37,977	(10,178)	27,799
	27,743	-	27,743

Note	As previously reported	Correction of error	Restated
8	1,124,134	36,660	1,160,794
20	(560,947)	(36,350)	(597,297)
	36,886	(310)	36,576
	600,073	-	600,073

Note	As previously reported	Correction of error	Restated
6	234,348	93,278	327,626
18	(10,914)	10,929	15
	(1,264,598)	(408,410)	(1,673,008)
14	(1,007,731)	304,204	(703,527)
	(2,048,895)	1	(2,048,894)

Note	As previously reported	Correction of error	Restated
6	234,348	93,278	327,626
8	1,182,095	39,065	1,221,160
20	(648,326)	(39,746)	(688,072)
	(1,264,394)	(396,801)	(1,661,195)
14	(1,005,944)	304,204	(701,740)
	(1,502,221)	-	(1,502,221)

- [1] During the year it was noted that income in relation to 2017/18 financial year was incorrectly recorded in the 2018/19 financial year. This had an impact on income and receivables from non exchange transactions where these were overstated in 2018/19 and understated in 2017/18. The error has been subsequently corrected in both financial years.
- [2] During the year it was also noted that the building belonging to the economic entity (NHLS) was incorrectly capitalised in SAVP books. This was corrected retrospectively in the current year. This had an impact on deferred tax on the revaluation recognised on the Economic Entity as SAVP is registered for tax. There is also an impact on revaluation reserve on the controlling entity (NHLS).
- [3] During the year it was noted that accruals related to prior year have been incorrectly credited to expenses and debited to payables from exchange transactions in the current year. This amount related to the prior period and were supposed to be debited to the payables from exchange transactions and credited accumulated surplus for the prior period. The error has been subsequently corrected, and prior year amounts restated.

41. Prior-year adjustments (continued)

Statement of financial performance

Economic entity - 2017

Taxation

Note	As previously reported	Correction of error	Restated
27	11,252	(10,178)	1,074

Economic entity - 2018

Other income
Taxation
Surplus for the year

Note	As previously reported	Correction of error	Restated
23	327,041	93,278	420,319
27	(1,444)	751	(693)
	325,597	94,029	419,626

The correction of error above resulted in the surplus for the year being restated from R1 301 280 to R1 393 567.

Controlling entity - 2018

Other income
Cost of Sales
(deficit) Surplus for the year

Note	As previously reported	Correction of error	Restated
23	327,040	93,278	420,318
22	(6,258,775)	(991)	(6,256,766)
	(5,931,735)	92,287	(5,836,448)

The correction of error above resulted in the surplus for the year being restated from R1 302 575 to R1 396 604.

- [1] During the year it was noted that income in relation to 2017/18 financial year was incorrectly recorded in the 2018/19 financial year. This had an impact on income and receivables from non exchange transactions where these were overstated in 2018/19 and understated in 2017/18. The error has been subsequently corrected in both financial years.
- [2] This adjustment is due to the tax implication of the removal of the building from the controlling entity NHLS to SAVP.
- [3] This adjustment is due the depreciation on the building moved to the controlling entity NHLS from SAVP.

Cash flow statement

Economic entity - 2018

Cash flow from operating activities Interest income Suppliers

Controlling entity - 2018

Cash flow from operating activities Interest income Suppliers

Note	As previously reported	Correction of error	Restated
	102,936	(5,291)	97,645
	(3,745,728)	5,491	(3,740,237)
	(418)	(200)	(618)
	(3,643,210)	-	(3,643,210)

Note	As previously reported	Correction of error	Restated
	102,595	(5,291)	97,304
	(3,740,447)	5,291	(3,735,156)
	(3,637,852)	-	(3,637,852)

Figures in Rand thousand

42. Segment information

General information

Identification of segments

around the the target market within the regions in the nine major provinces. Management uses these same segments for determining strategic The economic entity is organised and reports to management on the basis of nine major provinces within the country. The segments were organised objectives. Some regions were aggregated because of their size and proximity and alignment with provinces and viability. Information reported about these segments is used by management as a basis for evaluating the segments' performances and for making decisions about the allocation of resources. The disclosure of information about these segments is also considered appropriate for external reporting purposes.

Types services by segment

All the segments within the economic entity offer similar services namely laboratory testing, teaching and research services.

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Notes to the Audited Group Annual Financial Statements

Figures in Rand thousand

Segment information (continued) 42.

Segment surplus or deficit, assets and liabilities

Controlling entity - 2019

Revenue	Gauteng	Frees State-North West	Limpopo - Mpumalanga	Western Cape- Northern Cape	Eastern Cape	KwaZulu- Natal	NIOH &	Grants	Corporate	Total
Revenue from non-	'	1	1		1	1	528,433	1	,	528,433
exchange transact Revenue from exchange	2,440,436	723,662	853,076	1,087,468	791,268	2,044,756	ı	ı	6,154	7,946,820
transactions Other income	25,512	2,000	1,923	8,899	490	7,082	43	216,193	26,718	288,860
Interest received	1	1	1	1	1	1	33,973	227	160,056	194,256
Total segment revenue	2,465,948	725,662	854,999	1,096,367	791,758	2,051,838	562,449	216,420	6,154	8,475,253
Interest received										1
Expenditure Cost of sales	1,742,919	581,992	556,809	933,448	653,355	1,432,051	426,686	120,897	58,890	6,507,047
Operating expenses	115,112	19,492	1,969	32,117	28,986	70,769	80,681	104,067	766,506	1,219,699
Depreciation and amortisation	45,069	9,619	12,084	21,780	11,671	23,699	30,000	56	96,508	250,486
Total segment expenditure	1,903,100	611,103	570,862	987,345	3,904,822	3,904,822	3,904,822	3,904,822	3,904,822	7,977,232
Total segmental surplus/(deficit)										
Total revenue reconciling items										1
Interest expense										(10,379)
Unallocated assets										5,910,591
Unallocated liabilities										2,567,714

Figures in Rand thousand

Segment information (continued) 42.

Controlling entity - 2018

Revenue	Gauteng	Frees State-North West	Limpopo - Mpumalanga	Western Cape- Northern Cape	Eastern Cape	KwaZulu- Natal	NIOH &	Grants	Corporate	Total
Revenue from non-	1	1	T	1	1	ı	016,01	24,814	522,252	557,976
exchange transactions Revenue from exchange	2,283,698	656,131	820,444	1,005,321	699,540	1,871,204	ı	,	1	7,336,338
transactions Inter-segment transfers	(36,945)	11,322	19,744	2,798	2,411	1,616	(907)	(39)	ı	ı
Other income	24,316	1,961	1,885	10,067	480	6,459	815	355,408	18,927	420,318
Interest received	ı	1	ı	ı	ī	ı	4,036	19,376	79,183	102,595
Total segment revenue	2,271,069	669,414	842,073	1,018,186	702,431	1,879,279	14,854	399,559	620,362	8,417,227
Interest received										ı
Expenditure Cost of sales	1,662,540	536,136	548,952	897,968	598,166	1,322,861	361,717	124,581	34,745	6,087,666
Operating expenses	72,104	28,492	31,222	34,873	31,963	76,021	61,448	93,012	298,460	727,595
Depreciation and amortisation	24,381	5,549	6,717	10,888	9,342	13,372	25,011	3,884	93,281	192,425
Total segment expenditure	1,759,025	570,177	586,891	943,729	639,471	1,412,254	448,176	221,477	426,486	7,007,686
Total revenue reconciling items Interest expense										- (15,973)
Unallocated assets										5,033,097
Unallocated liabilities										2,683,498

Juallocated liabilities

43. Budget differences

Material differences between budget and actual amounts

The budget was prepared on an accruals basis covering the financial year ended 31 March 2019. The variances between budget and actual which are numerically 10% (R100m) above or below budget are explained below:

44. Rendering of services

The variance is caused by increase in test volumes beyond the levels anticipated during the budget period.

45. Miscellaneous other revenue

The increase was caused by once off conference revenue organised by the economic entity. This was not budgeted for.

46. Grant income

No amounts were budgeted for grants income.

47. Recoveries

The increase was caused by recoveries from pensoner's medical contributions beyond the amount budgeted.

48. Teaching Income

The shortfall relates to monies that we should have received from the TTR grant...

49. Sundry income

Included in the budget is an amont for NIOH (OHS) which was not charged by NHLS because the MOU was not signed..

50. Interest received

The variance was caused by higher interest rates realised on cash balances as well as more cash received from customers which was invested temporarily before being utilised.

51. Personnel

Personnel costs are underspent compared to budget by 5% due to vacancies which were budgeted for but were not filled. Year on year personnel costs increased by 10% from R3.3 billion to R3.6 billion/



52. Depreciation and amortisation

Actual amount of depreciation and amortisation expense is more than budgeted for due to asset acquisitions.

53. Finance costs

The economic entity incurred finance costs from finance lease liabilities, other financial liabilities and onerous contract obligations.

54. Lease rentals on operating lease

The variances were caused by increase in the number of equipment leased as well as the expenditure on leased vehicles and rental equipment not budgeted for.

55. Debt Impairment

The variance was caused by the reduction in impairment for Gauteng following settlement agreements.

56. General Expenses

The main drivers are research consumables for grants, external testing expenses, freight and courier as well as consumables all of which are related to the increase in volumes of tests performed. This resulted in more expenditure being incurred than budgeted for.

57. Loss on disposal of assets andliabilities

No amount was budgeted. The economic entity discovered more assets for scrapping during the year's physical verification than initially anticipated.

58. Gain on foreign exchange

No amount was budgeted. In current year the economic entity realised the gain on settling its foreign currency denominated obligations.

59. Fruitless and wasteful expenditure

The NHLS did not incure any fruitless and wasteful expenditure in current year (2018: R0).

Detailed Statement of Financial Performance

	Note(s)	2019 R'000	2018 Restated* R'000	2019 R'000	2018 Restated* R'000
Revenue					
Sale of goods		26,755	21,563	-	-
Rendering of services		7,679,047	7,076,656	7,679,047	7,076,656
Miscellaneous other revenue		6,447	71,194	6,447	71,194
Government grants & subsidies		789,759	746,464	789,759	746,464
		8,502,008	7,915,877	8,475,253	7,894,314
Cost of sales	22	(6,746,379)	(6,277,601)	(6,727,641)	(6,259,766)
Gross surplus		1,755,629	1,638,276	1,747,612	1,634,548
Other income					
Discount received		1,193	1,134	1,190	1,133
Fair value adjustments		22,665	22	22,665	-
Grant income recognised		226,885	357,832	226,885	357,832
Interest received	25	194,717	102,936	194,256	102,595
Exchange gains		-	3,376	-	3,376
Recoveries		13,938	11,707	13,938	11,707
Royalties received		804	408	804	408
Sundry Income		138	690	138	690
Teaching Income		45,905	45,172	45,905	45,172
		506,245	523,277	505,781	522,913
Expenses (Refer to page 99)		(1,252,619)	(748,158)	(1,249,885)	(747,921)
Operating surplus	24	1,009,255	1,413,395	1,003,508	1,409,540
Finance costs	26	(10,753)	(16,098)	(10,379)	(15,973)
Surplus before taxation		998,502	1,397,297	993,129	1,393,567
Taxation	27	2,090	693	-	-
Surplus for the year		996,412	1,396,604	993,129	1,393,567

Detailed Statement of Financial Performance

	Note(s)	2019 R'000	2018 Restated* R'000	2019 R'000	2018 Restated* R'000
Operating expenses (by function)					
Advertising		2,092	777	2,092	777
Archiving and Storage		7,033	7,974	7,033	7,974
Auditors remuneration	30	15,870	8,096	15,567	7,770
Bank charges		7,654	4,062	7,615	4,028
Cleaning		8,223	36,238	8,179	36,131
Computer expenses		8,043	747	8,043	747
Conferences and seminars		835	494	795	440
Consulting and professional fees		69,362	52,844	69,319	52,663
Consumables		17,694	14,205	17,657	14,174
Debt Impairment		188,296	(270,688)	187,131	(269,619)
Debt collection		1,275	1,670	1,275	1,670
Delivery expenses		1,059	1,728	1,057	1,727
Depreciation, amortisation and impairments		30,107	20,382	30,041	20,325
Discount allowed		15,366	10,967	15,366	10,967
Employee costs		300,904	247,375	300,748	247,373
Entertainment		119	116	119	116
Insurance		4,857	4,706	4,857	4,706
Lease rentals on operating lease		43,518	60,266	43,389	60,140
Legal expenses		10,822	7,697	10,796	7,672
Loss on disposal of assets		4,814	6,579	4,831	6,562
Loss on exchange differences		3,976	-	3,976	-
Medical expenses		1,721	45	1,721	45
Minor assets		173	3,534	132	3,498
Motor vehicle expenses		1,090	4,000	1,090	4,000
Other expenses		2,477	11,367	2,466	11,367
Packaging		8,483	7,845	8,341	7,790
Petrol and oil		6,105	5,197	6,105	5,197
Postage		18	189	18	188
Printing and stationery		40,114	37,598	40,028	37,493
Project Management expenses		677	1,269	677	1,269
Promotions		289	365	289	365
Promotions and sponsorships		40	2	40	2
Repairs and maintenance		48,510	40,350	48,436	40,339
Research Trust		22	-	22	-
Royalties and license fees		794	-	794	-
Security		996	15,413	996	15,413
Software development expenses		10,076	7,635	10,076	7,635
Software expenses		105,981	93,364	105,984	93,364
Staff welfare		9,567	9,302	9,432	9,253
Subscriptions		4,916	6,674	4,916	6,674
Telephone and fax		85,655	83,497	85,441	83,409
Training		21,109	16,011	21,109	16,011
Travel - local		48,533	48,741	48,532	48,741
Travel - overseas		307	124	307	124
Utilities		113,047	139,401	113,047	139,401
		1,252,619	748,158	1,249,885	747,921

Notes	

Notes	