Landscape Assessment of Health Technology Introduction in South Africa's Public Health Sector

- medicines, vaccines, diagnostics and devices

June 2026

ALIGN

CONSORTIUM

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Acknowledgements: We would like to thank Nalini Naidoo (Technical consultant), Khadija Jamaloodien (NDoH), Andrew G Parrish and Lumbwe Chola (PhD supervisors) for their technical support and guidance; and the study participants for their voluntary participation, time and responsiveness in the key informant interviews.

Funding acknowledgement: This work forms part of the ALIGN Consortium, funded by the Gates Foundation. The findings and conclusions presented here are those of the ALIGN Consortium South Africa team.

EXECUTIVE SUMMARY

This report examines how new medicines, vaccines, diagnostics and medical devices are introduced into South Africa's public health system. It draws on two linked components: a multi-case health policy analysis across the four technology categories, and four case studies: the retrospective introductions of the BPaL-L regimen for drug-resistant TB and GeneXpert MTB/RIF, and the prospective cases of adult TB vaccine preparedness and lenacapavir for HIV prevention. Findings from the multi-case analysis are synthesised through the ALIGN framework and tested against a stakeholder analysis.

South Africa has a formalised, rule-based system for introducing health technologies and makes good use of evidence. Adoption depends on alignment across regulation, financing, procurement, service readiness and monitoring not on evidence alone.

The multi-case analysis shows a formalised governance system that has repeatedly supported the introduction of complex innovations at national scale, particularly for medicines and vaccines. Across all four categories, introduction follows a broadly common policy-cycle pathway, from prioritisation and appraisal through regulatory approval, policy adoption, financing, procurement, implementation and monitoring. Adoption is shaped not by evidence alone, but by alignment across regulation, affordability, financing, procurement, service readiness, infrastructure, monitoring and stakeholder coordination. Where these functions are weakly aligned, the result is delays, uneven uptake and sustainability risks. These risks are greatest for medical devices, where pathways are more decentralised and procurement-driven and governance is less standardised, and where monitoring after introduction is less well developed.

This analysis also shows that introduction was smooth where a technology addressed a service-delivery need and could be carried by an existing delivery platform, such as the HIV, TB, immunisation, primary healthcare or laboratory networks, rather than requiring parallel systems. Early engagement with regulators, advisory committees and implementers before formal appraisal, together with adaptive pathways such as conditional or phased approval and pilots, helped manage uncertainty, while finance and procurement readiness reduced friction at scale-up. Engagement with civil society, professional bodies, donors and manufacturers was most catalytic when it supported government priorities and was tied to long-term sustainability.

Across 22 retrospective cases and 166 decision points, the system is strongest in using evidence (Pillar 1) and coordinating across government (Pillar 3), and more selective in portfolio optimisation (Pillar 2) and engagement with actors beyond government (Pillar 4).

The ALIGN framework assesses how health technologies are introduced across four governance dimensions: the use of market data and evidence, portfolio-based prioritisation, whole-of-government coordination, and engagement with actors across the market. Applying it across 22 retrospective cases and 166 documented decision points revealed a patterned but uneven distribution of governance activity across the four pillars. The system is strong in generating and using data for prioritisation (Pillar 1) and in coordinating across government structures (Pillar 3), more selective in deliberate portfolio optimisation (Pillar 2), and variably structured in its engagement with actors beyond government (Pillar 4). Rather than operating in sequence, the pillars overlap, with two or more often applied at once, for example, new epidemiological evidence triggering interdepartmental coordination. Portfolio logic is most visible in mature platforms such as antiretroviral therapy and immunisation, and least developed for devices and capital equipment, where workforce, maintenance and lifecycle costs are less consistently built into adoption decisions.

The stakeholder analysis locates the most profound coordination gap between national decision-making authorities and provincial implementation systems. National approval does not necessarily lead to rapid implementation: provincial departments, district offices, facility managers and frontline workers ultimately determine whether nationally approved innovations become routine service delivery, and financing and procurement are too often engaged only after policy is set.

The profound coordination gap is between national decision-making authorities and provincial implementation systems. National approval does not necessarily result in rapid implementation.

The two retrospective and two prospective case studies show both what the system does well and where it falls short. The BPaL-L regimen for drug-resistant TB moved from global recommendation to near-universal national use in roughly two years, built on existing programme strength rather than new institutions, and GeneXpert's early and ambitious rollout showed both the reach of decisive central action and the risks of moving faster than the system, including dependence on a single platform and supplier. The prospective cases show the system in a more anticipatory mode, preparing for a technology before it is licensed rather than responding once it arrives. South Africa is preparing for adult TB vaccines before licensure, where operational readiness and dedicated financing remain the largest gaps, while lenacapavir demonstrates how quickly the system can move when regulatory, financing, policy and procurement pathways align under time pressure although initial access rests on donor financing, with public-sector generics anticipated only from 2027.

The policy implications are consistent across the multi-case analysis, the ALIGN synthesis, the stakeholder analysis and the case studies. Adoption decisions should be linked explicitly to implementation readiness, with affordability, procurement feasibility, workforce and infrastructure capacity, monitoring and end-user needs assessed early rather than after a technology is adopted. Adaptive pathways, such as conditional approval or non-adoption, phased rollout, pilots and structured post-introduction review, help manage uncertainty about evidence maturity, safety, affordability and operational readiness. Sustainability should be planned from the outset, including domestic financing, procurement continuity, workforce training, maintenance and monitoring.

At system level, the ALIGN synthesis points to the same priorities: institutionalising portfolio review cycles aligned with medium-term expenditure and Treasury planning; formalising interdepartmental sequencing protocols, including procurement and tender-readiness checkpoints, to reduce the lag between policy adoption and implementation; and moving towards multi-year, portfolio-based budgeting and reinvestment so that savings from substitution or price reductions can support programme strengthening. The stakeholder analysis adds that provincial implementers should be brought into prioritisation and planning early, so that national decisions reflect facility-level constraints.

A more integrated introduction pathway would reduce delays, improve equity, and increase the likelihood that technologies adopted in policy are implemented effectively and sustained in routine service delivery.

ABBREVIATIONS

Acronym/ Abbreviation	Description
3HP	3-month Rifapentine + Isoniazid regimen for TB preventive therapy
ABHR	Alcohol-Based Hand Rub
AE	Adverse Event
AED	Automated External Defibrillator
AEFI	Adverse Event Following Immunisation – any untoward medical occurrence after vaccination, not necessarily causally related to the vaccine.
Ag-RDT	Antigen Rapid Diagnostic Test
ALIGN	Analytical framework assessing innovation introduction across four governance pillars (Market data & evidence; Portfolio logic; Whole-of-government coordination; Whole-of-market engagement)
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
BoD	Burden of Disease
BP	Blood Pressure
CHAI	Clinton Health Access Initiative
CIFF	Children's Investment Fund Foundation
CM	Cryptococcal Meningitis
COSUP	Community-Oriented Substance Use Programme
CPAP	Continuous Positive Airway Pressure
CrAg	Cryptococcal Antigen
CXR	Chest X-Ray
DG	Director-General – administrative head of the National Department of Health.
DHIS	District Health Information System
DMPA-SC	Depot-Medroxyprogesterone Acetate – Subcutaneous Injection
DPP	Diflucan Partnership Programme
DTG	Dolutegravir (antiretroviral medicine)
ECG	Electrocardiogram
EFV	Efavirenz
eGFR	Estimated Glomerular Filtration Rate
EHR	Electronic Health Record
ELBW	Extremely Low Birth Weight
EML	Essential Medicines List
E-MOTIVE	Early detection and Management of Obstetric haemorrhage with Tranexamic acid – an Intervention for real-world implementation
EMR	Electronic Medical Record
EPI	Expanded Programme on Immunisation
FDA	U.S. Food and Drug Administration
FDC	Fixed-Dose Combination
FP	Family Planning
FP2030	Family Planning 2030
FTE	Full-Time Equivalent
GERMS-SA	Group for Enteric, Respiratory and Meningeal Disease Surveillance in South Africa
Hb	Hemoglobin

Acronym/ Abbreviation	Description
HCV	Hepatitis C Virus
HFNO	High-Flow Nasal Oxygen
HHFNO	Heated High-Flow Nasal Oxygen
HHFNO	Heated Humidified High-Flow Nasal Oxygen
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus Vaccine – vaccine used to prevent HPV infection and cervical cancer.
HTA	Health Technology Assessment
HTN	Hypertension
ICU	Intensive Care Unit
IPC	Infection Prevention and Control
IPD	Invasive Pneumococcal Disease – severe infection caused by Streptococcus pneumoniae affecting sterile body sites.
ISHP	Integrated School Health Programme
KZN PTC	KwaZulu-Natal Pharmaceutical & Therapeutics Committee
LARC	Long-Acting Reversible Contraceptives
LBW	Low Birth Weight
LBW	Low Birthweight
LINC	Limpopo Initiative for Newborn Care
LIS	Laboratory Information System
LMIC	Low- and Middle-Income Country
MaMMAS	Maternal Morbidity and Mortality Audit System
MCC	Medicines Control Council (former regulatory authority)
MDR	Multidrug-Resistant
MEC	Member of the Executive Council – provincial health authority responsible for health services at provincial level.
MoH	Ministry of Health
MSF	Médecins Sans Frontières
NAGI	National Advisory Group on Immunisation – independent technical advisory body providing recommendations on vaccines to the NDoH.
NCCEMD	National Committee on Confidential Enquiries into Maternal Deaths
NCE	New Chemical Entity
NDMP	National Drug Master Plan
NDoH	National Department of Health
NEMLC	National Essential Medicines List Committee
NGO	Non-Governmental Organization
NHC	National Health Council
NHI	National Health Insurance
NHLS	National Health Laboratory Service
NICD	National Institute for Communicable Diseases
NPV	Net Present Value
NSP	National Strategic Plan
O2	Oxygen
OAT	Opioid Agonist Therapy
OPEX	Operational Expenditure
OST	Opioid Substitution Therapy

Acronym/ Abbreviation	Description
P1	Pillar 1 – Market Data and Evidence for Decision-Making
P2	Pillar 2 – Portfolio-Based Logic
P3	Pillar 3 – Whole-of-Government Coordination and Capacity
P4	Pillar 4 – Whole-of-Market Engagement
PATH	Program for Appropriate Technology in Health
PCV	Pneumococcal Conjugate Vaccine
PCV10	10-valent Pneumococcal Conjugate Vaccine
PCV13	13-valent Pneumococcal Conjugate Vaccine
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHC	Primary Healthcare
PLHIV	People Living with HIV
POCT	Point-of-Care Test
PPE	Personal Protective Equipment
PPH	Postpartum Haemorrhage
PPH	Post-Partum Haemorrhage
QA	Quality Assurance
QALY	Quality-Adjusted Life Year
QIV	Quadrivalent Influenza Vaccine
RDT	Rapid Diagnostic Test
RHSC	Reproductive Health Supplies Coalition
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SAHCS	Southern African HIV Clinicians Society
SAHPRA	South African Health Products Regulatory Authority
SANAC	South African National AIDS Council
SDG	Sustainable Development Goal
SOP	Standard Operating Procedure
SpO2	Peripheral Capillary Oxygen Saturation
SSC	Surviving Sepsis Campaign
STGs	Standard Treatment Guidelines
TAC	Treatment Action Campaign
TAF	Tenofovir Alafenamide
TB	Tuberculosis
TB-LAM	Tuberculosis Lipoarabinomannan Urine Test
TCO	Total Cost of Ownership
Tdap	Tetanus, Diphtheria, and Acellular Pertussis Vaccine
TDF	Tenofovir Disoproxil Fumarate
TIV	Trivalent Influenza Vaccine
TPT	Tuberculosis Preventive Therapy
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TXA	Tranexamic Acid
UHC	Universal Health Coverage
UNFPA	United Nations Population Fund
VL	Viral Load
WHO	World Health Organization
WoCP	Women of Childbearing Potential

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1. INTRODUCTION

South African Health System Context

South Africa's health system operates within a sustained quadruple burden of disease, encompassing maternal and child health, conditions, communicable diseases, non-communicable diseases, and violence and injury (Achoki 2022, Koch 2024, Mayosi 2009, Coovadia 2009). These health challenges coexist with long-standing structural inequities, differential access to services, and capacity constraints across levels of care (Gilson 2017, Ataguba 2018). The system is further shaped by fiscal consolidation, declining external donor funding, increasing input costs, and broader macroeconomics (South African National Treasury 2024). Concurrently, South Africa is navigating a major health system reform through the phased implementation of National Health Insurance (NHI), with the stated policy objective of achieving Universal Health Coverage (UHC) by 2030 (WHO 2023, Whyle 2023).

Health technologies, defined here as medicines, diagnostics, medical devices and equipment, are a core component of health system functioning and are embedded within the World Health Organization's (WHO) health system building blocks; particularly governance, financing, drug and equipment supply systems, human resources for health and health information systems (WHO 2010). In South Africa's public sector, personnel expenditure accounts for more than two-thirds of total health spending, while goods and services, including medicines, constitute the second-largest expenditure category at approximately 28% of the health budget (South African National Treasury 2024, Cleary 2014). This makes the effective introduction, prioritisation, and use of health technologies critical to service delivery, fiscal sustainability, and equity.

Systematic, transparent and well-governed processes for introducing health technologies are important for supporting effective and efficient use of limited public resources. Such processes can facilitate alignment between technology adoption and national health priorities, ensure the use of available clinical, economic, and programmatic evidence, and promote compliance with safety, quality, and regulatory standards (Drummond 2008, Chalkidou 2018). From an operational perspective, clearly articulated processes may reduce avoidable delays, limit duplication of assessment and review functions, and enable more predictable and coordinated implementation within routine service delivery (Lehoux 2012, O'Rourke 2020).

South Africa has an established regulatory and policy architecture for health technology introduction, with demonstrated capacity for large-scale rollout across priority health programmes. However, the way introduction decisions are made and operationalised in practice remains insufficiently documented (compared to other processes, like, for instance, policy making for delivery of priority health programs). Pathways from research, pilots, or demonstration projects into routine public sector delivery are shaped by multiple actors across institutional, regulatory, financing, and implementation environments (Erasmus 2008, Gilson 2017). Decision-making pathways and criteria are not consistently articulated; stakeholder roles, incentives, and perspectives remain insufficiently understood; and institutional facilitators and constraints, including coordination mechanisms, are not well described. Consequently, the baseline evidence needed to assess current practice or guide system reform remains limited.

This landscape assessment examines how health technologies are introduced into South Africa's public health sector, with a focus on medicines, vaccines, diagnostics, and medical devices. It maps decision-making pathways, identifies key actors and roles, and assesses the institutional, regulatory, financing, and implementation factors that shape whether innovations move from evidence, pilots, or policy approval into routine service delivery.

Undertaken as part of the Advancing Country-Led Innovation Introduction through Government Engagement and EvideNce (ALIGN) Consortium, the assessment provides a formative baseline of current practice. It identifies strengths in existing policy and governance processes, as well as areas where coordination, transparency, and implementation linkages could be strengthened.

The findings will inform the next steps of ALIGN-South Africa (SA), including implementation activities, stakeholder engagement, and programme learning. They will also provide a reference point for tracking progress over the course of the project. Although focused on South Africa, the governance challenges and opportunities identified are likely

to be relevant to other consortium countries and comparable health systems seeking to strengthen alignment across health technology assessment, regulation, purchasing, and implementation.

This evidence is particularly timely as South Africa advances health system reform under National Health Insurance. Stronger functional linkages across these decision arenas will be critical to reducing delays, improving uptake, supporting equitable access, and realising the efficiency gains needed for progress toward Universal Health Coverage (WHO 2014, Baltussen 2019).

Evidence from LMIC settings, including South Africa, indicates that weak coordination across these decision arenas can limit the operational impact of HTA recommendations, contributing to delayed adoption, uneven sub-national uptake, and poor translation into routine service delivery (Lehoux 2012, Gilson 2017). Strengthening functional linkages across health technology assessment, regulation, purchasing, and implementation will be important for realising the efficiency and equity gains envisioned under NHI.

The work provides a formative baseline of current practice, identifying both strengths in the policy process and areas that could be strengthened. It will inform the next steps of the ALIGN project, including implementation activities, stakeholder engagement, and programme learning. It will also serve as a reference point for tracking progress over the course of ALIGN. Although focused on South Africa, the governance challenges and opportunities identified are likely to be relevant across consortium countries and comparable health systems seeking to strengthen coordination between health technology assessment, regulation, purchasing, and implementation under UHC-oriented reform.

Health system structure

The South African public sector health system is organised into a three-tier structure for health service delivery and patient referral, found across the nine provinces. As shown in Figure 1.1, the primary care platform, consisting of primary healthcare clinics and district hospitals, serves as the first point of entry into the system. At this level, the majority of patients receive health promotion, health prevention and curative services. Secondary and regional hospitals provide specialised health services, while tertiary hospitals deliver highly specialised care to the most complex and critically ill patients. Some provincial tertiary and academic hospitals may offer services at a national level because of their advanced specialisation, like the Red Cross Children's Hospital in Cape Town, Western Province.

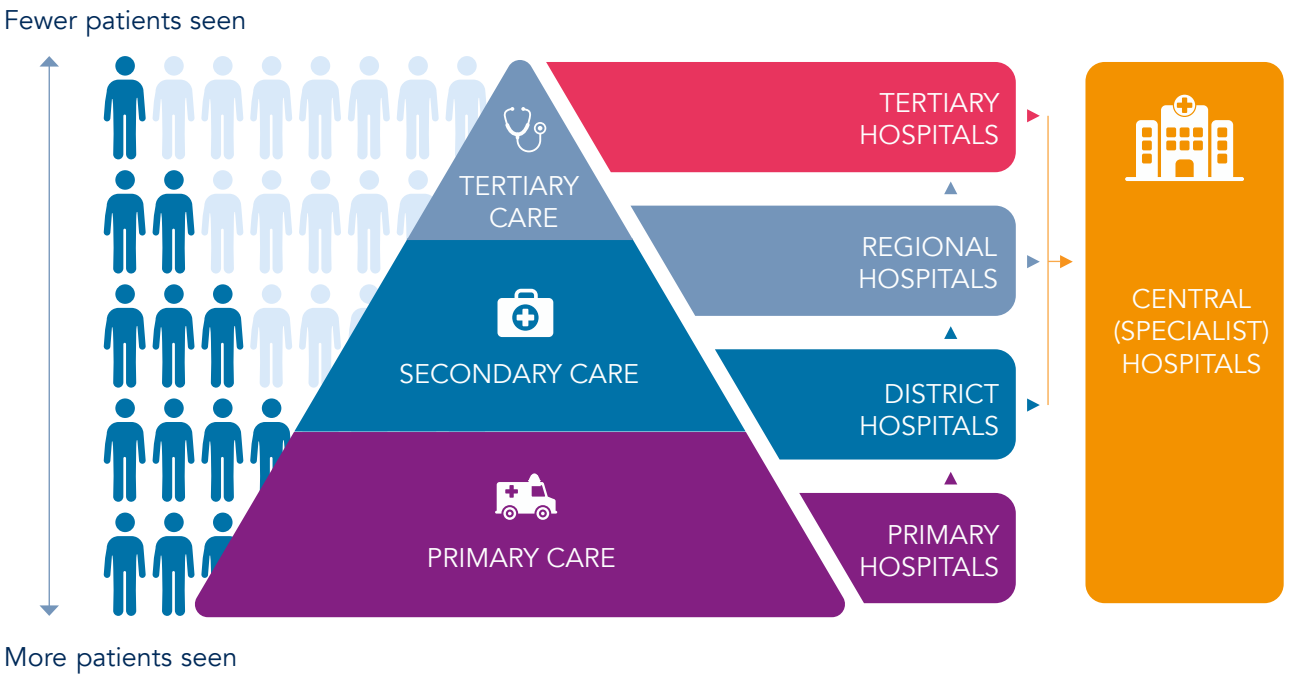


Figure 1.1 The 3-tier types of health facilities and referral systems in the South African public sector (Lubuzo 2024)

Governance and financing

Public-private structure

The South African health system is characterised by a two-tier public-private structure in terms of financing and delivery platforms. Publicly financed health services constitute the principal source of care for most of the population. Health services are usually free of charge at the PHC level, with minimal cost at the hospital level for the majority of the population without health insurance. A smaller, insured segment relies predominantly on private health providers for primary and hospital care, at higher costs. Private healthcare is funded mainly through medical schemes, typically linked to employer-subsidised insurance benefits and employee contributions, as well as out-of-pocket payments. Recent national household survey data indicate that medical scheme coverage has remained relatively stable over the past two decades, declining only marginally from 15.9% in 2002 to 15.7% in 2023 and 15.5% in 2024, with higher coverage in wealthier provinces such as the Western Cape and Gauteng (StatsSA 2024, 2025).

Health financing in South Africa comprises a mix of general taxation, medical schemes, and out-of-pocket payments, with private sources playing a disproportionate role (Ataguba 2012). Despite serving only 14.6% of the population, the private sector accounts for nearly half of total health expenditure (~43%), largely for high-cost services and medicines. In contrast, the publicly funded system, responsible for 85.4% of the population, remains chronically under-resourced (Barber 2018, CMS 2024). This imbalance continues to place pressure on health care access, quality, and efficiency - and this financial imbalance is the central challenge being addressed through NHI reform. In addition, the private sector's concentration of financial resources and health professionals has accelerated an internal brain-drain, further weakening public service delivery. Public sector facilities, particularly at the primary care level, face persistently high patient loads, long waiting times, supply-chain constraints including medicine stockouts, and uneven quality of care. Health system functioning and access to quality health care also vary substantially between provinces, with the economically stronger provinces having stronger health systems. While the private sector is highly resourced and able to deliver high-quality services, it has limited accessibility for the majority and faces risks of financial unsustainability due to continuing cost escalations (Mehdi 2025).

National and provincial decentralised governance

The South African government operates as a semi-federalised system of political and administrative governance in which the national authority provides strategic stewardship, legislation, financing frameworks and oversight for the whole country, while substantial implementation authority is decentralised to provinces (RSA 1996). Provincial governments are responsible for health system stewardship at the sub-national level, including strategic planning, budgeting, service delivery, and monitoring and evaluation. Accordingly, the National Department of Health (NDoH) sets national policy direction, norms and standards, and strategic frameworks, while provincial departments hold primary responsibility for financing, managing, and delivering health services (including hospitals and district health services) within their jurisdictions (RSA 2004).

At the operational level, provincial health departments govern the district health system, which is designed to anchor primary healthcare (PHC) delivery through geographically defined districts aligned with municipal boundaries. This arrangement is complemented by municipal health (local authority) services, which focus primarily on preventive and promotive health services, including maternal and child health interventions (such as immunisation), and communicable disease control (Hall 2006). Fiscal governance reinforces this decentralised model, primarily through financial mechanisms such as equitable share allocations and conditional grants. With a large share of national health funding allocations transferred to provinces, this balances provincial autonomy in implementation with nationally specified priorities, conditions, and accountability requirements (National Treasury 2025).

Governance of health technology selection and introduction in South Africa

Health technology introduction, including medicines, vaccines, medical devices, diagnostics, and digital and AI-enabled tools, in South Africa is governed by a multi-level framework in which regulatory approval, policy inclusion, procurement, and implementation are institutionally separated across national and provincial spheres.

At the national level, authorities determine the degree of procurement centralisation (for example, pooled purchasing or national tenders), establish the regulatory and reimbursement framework, and define pricing rules, contracting modalities, and the identity of dominant public purchasers within otherwise fragmented markets. These national instruments, such as regulation, technical guidance, and procurement frameworks, set policy intent, but their realisation depends on provincial implementation capacity, budget cycles, contracting arrangements and service delivery readiness. Consequently, understanding health technology introduction in South Africa requires analysing both national policy intent and provincial implementation practice. Differences in how provinces operationalise and sequence national instruments may shape when and whether technologies are ultimately adopted (Coovadia 2009).

In practice, technologies must pass through several distinct but interrelated decision points: regulatory authorisation, inclusion in clinical or benefit policies, procurement and pricing processes, and translation into provincial budgets, contracting capacity, and service readiness. Although all technologies are assessed against shared policy objectives, such as safety, effectiveness, efficiency, value for money, and equity, the regulatory and purchasing and implementation pathways may vary by technology type. Table 1 summarises the key governance instruments, lead institutions, and core decision points that shape public-sector selection and purchasing across technology categories, illustrating how these pathways diverge across medicines, diagnostics, medical devices, and digital and AI-enabled technologies.

For example, medical devices and in vitro diagnostics (IVDs) are regulated under distinct frameworks by the South African Health Products Regulatory Authority (SAHPRA), which has also issued guidance on Artificial Intelligence/ Machine Learning (AI/ML)-enabled medical devices (SAHPRA 2016). As a result, provinces face additional coordination and capacity requirements to align regulatory, procurement, and service delivery processes, even when national policy intent is clear. Framework legislation establishes shared national-provincial responsibility for health services, while sector-specific legislation governs medicines, diagnostics, devices, and digital technologies through distinct regulatory and purchasing arrangements. National authorities set norms, standards, and procurement architectures, whereas provinces are responsible for budgeting, contracting, and service delivery. Consequently, technology adoption depends not on a single decision, but on alignment across regulatory authorisation, inclusion in clinical or benefit policies, procurement mechanisms, and provincial implementation capacity.

This assessment draws on the ALIGN framework to examine how well these functions work together in practice. The framework identifies four interdependent building blocks for strengthening health technology introduction systems: market data for decision-making; portfolio-based logic; whole-of-government coordination and capacity; and whole-of-market engagement (Lanthorn et al., 2025). Together, these pillars describe the system functions that , when active and aligned, support more timely, transparent, and coherent introduction decisions (Figure 1.2).

Figure 1.2. The ALIGN framework based on four pillars (Lanthorn 2025)

As shown in Table 1, responsibilities for health technology regulation, selection, and purchasing are distributed across multiple legal instruments, institutions, and decision points that vary by technology type. This institutional fragmentation can result in uneven and delayed uptake, even where clinical value and national priorities are well established. This highlights the importance of integrated purchasing arrangements and strengthened health technology assessment (HTA) functions under current NHI reforms to support coherent benefit inclusion, reimbursement, and implementation across provinces.

Table 1. Key governance instruments for public-sector health technology selection

Technology	Primary legal / policy basis	Lead institution(s)	Core decision point
Medicines & vaccines	Medicines and Related Substances Act (1965)[1]; National Drug Policy[2]; STGs/EML	SAHPRA; NDoH	Regulatory approval; EML/STG inclusion; procurement eligibility
Diagnostics (IVDs)	National Health Laboratory Service Act (2000)[3]; Medicines and Related Substances Act	NHLS; SAHPRA	Test selection and validation; diagnostic algorithms
Medical devices	Medicines and Related Substances Act (device amendments); SAHPRA 2016 regulations[4]	SAHPRA; NDoH	Regulatory approval; procurement and service readiness
Digital & AI technologies	Medicines and Related Substances Act (software/AI as medical device); National Digital Health Strategy[5]	SAHPRA; NDoH	Regulatory classification; interoperability and data governance
Benefit inclusion & purchasing	National Health Insurance Act (2023)[6]; PFMA (1999)[7]	NHI; National Treasury	HTA-informed benefit inclusion; reimbursement and contracting

Abbreviations: AI=artificial intelligence, IVD=in vitro diagnostics, NDoH=National Department of Health, NHI=National Health Insurance Fund, NHLS=National Health Laboratory Service, PFMA=Public Finance Management Act, SAHPRA=South African Health Products Regulatory Authority, STGs/EML=Standard Treatment Guidelines and Essential Medicines List

Medicine pricing and health technology governance

Within South Africa's decentralised health system, health technology introduction provides a concise lens for examining policy coordination and implementation. Pharmaceutical pricing is a particularly informative tracer, reflecting the coexistence of private-sector price regulation through the Single Exit Price (SEP) framework and centrally coordinated public-sector procurement via competitive tendering (National Department of Health SEP and tender regulations) (Wouters 2019). These parallel arrangements generate distinct price-formation logics across sectors and fragmentation. Despite formal controls, transparency remains incomplete, particularly in relation to logistics fees and incentive-like practices within supply chains (Bangalee 2016). How these arrangements will be consolidated or reconfigured under NHI, through a single purchaser, a defined

1 *South African Health Products Regulatory Authority (SAHPRA). Medicines relating to medical devices and in vitro diagnostics, 9 December 2016. Available from: https://sahpra.org.za/wp-content/uploads/2019/09/20161209_Medical-Device-Regulations_Gov-Gazette-40480.pdf [Accessed 12 February 2026]*

2 *South African Department of Health. National Drugs Policy. Pretoria: Government of South Africa; 1996. Available from: https://www.gov.za/documents/other/national-drugs-policy-01-jan-1996 [Accessed 12 February 2026]*

3 *Republic of South Africa (RSA). Act No. 37 of 2000: National Health Laboratory Service Act, 2000. Available at: https://www.gov.za/sites/default/files/gcis_document/201409/a37-000.pdf [Accessed 17 February 2026]*

4 *South African Health Products Regulatory Authority (SAHPRA). Medicines relating to medical devices and in vitro diagnostics, 9 December 2016. Available from: https://sahpra.org.za/wp-content/uploads/2019/09/20161209_Medical-Device-Regulations_Gov-Gazette-40480.pdf [Accessed 12 February 2026]*

5 *National Department of Health (NDoH). National Digital Health Strategy for South Africa 2019–2024. Pretoria: National Department of Health; 2019. Available from: https://www.health.gov.za/wp-content/uploads/2020/11/national-digital-strategy-for-south-africa-2019-2024-b.pdf [Accessed 17 February 2026]*

6 *Republic of South Africa (RSA). National Health Insurance Act, 2023 (Act No. 20 of 2023). Government Gazette 50664, 16 May 2024. Pretoria: Government Printer; 2024. Available from: https://www.gov.za/sites/default/files/gcis_document/202405/50664nathealthinsuranceact202023.pdf [Accessed 17 February 2026]*

7 *Republic of South Africa (RSA). Public Finance Management Act, 1999 (Act No. 1 of 1999). Pretoria: Government Printer; 1999. Available from: https://www.gov.za/sites/default/files/gcis_document/201409/a1-99.pdf [Accessed 17 February 2026]*

benefit package, and strategic purchasing—remains uncertain, with implications for affordability and equity (Solanki 2025). These dynamics highlight the relevance of health technology introduction for understanding the institutional alignment challenges that HTA-informed benefit package reform under NHI seeks to address.

Alignment of HTA with NHI benefit design

The NHI Act establishes a policy framework with the potential to consolidate historically fragmented health technology selection pathways through HTA-informed benefit design and strategic purchasing by a single national fund (Thomas 2004, Whyle 2023). If implemented as intended, HTA could provide a systematic mechanism for linking evidence on safety, clinical effectiveness, cost-effectiveness, and budget impact to coverage and reimbursement decisions across technology classes, consistent with international experience in low- and middle-income countries (Baltussen 2019, Chalkidou 2014). However, the extent to which these potential gains are realised will depend on institutional alignment between HTA processes, regulatory approval, procurement arrangements, and provincial implementation systems.

Approach and Scope of this Report

This report presents a landscape assessment of health technology introduction in the South African public sector, undertaken as part of the ALIGN programme's evidence and analysis workstream. It provides a baseline understanding of how selected health technologies are prioritised, assessed, financed, introduced, and implemented across the public health system.

The assessment draws a structured review of national policies, legislation, clinical guidelines, procurement frameworks, and programme documents, complemented by consultations with key stakeholders from government, regulatory bodies, technical agencies, and implementation partners. The multi-case health policy analysis was conducted under a separately approved research protocol.

The report is organised around four core analytical chapters:

1. **Multi-case health policy analysis** — a cross-cutting assessment of selected medicines, vaccines, diagnostics, and devices to identify common decision-making pathways, enabling conditions, bottlenecks, and implementation constraints.
2. **Application of the ALIGN framework to the multi-case health policy analysis** — synthesis of findings using the ALIGN framework to identify system strengths, priority gaps, and practical opportunities to improve coordination, efficiency, transparency, and accountability.
3. **Individual case analyses** — detailed case studies of selected health technologies, documenting the specific policy, regulatory, financing, procurement, and implementation pathways that shaped their introduction.
4. **Stakeholder analysis** — a mapping of key actors, institutional roles, decision points, incentives, and coordination mechanisms across the health technology introduction pathway.

Together, these chapters provide a structured evidence base on how health technologies are introduced into the public health sector which will guide implementation activities, stakeholder engagement, and programme learning of ALIGN aimed at supporting government efforts to strengthen the efficiency, equity, and coordination of health technology introduction in South Africa.

2. MULTI-CASE HEALTH POLICY ANALYSIS

The multi-case health policy analysis comprised 21 purposively selected cases (20 retrospective, one prospective) across medicines, vaccines, diagnostics, and medical devices, selected to reflect variation in technology type, decision pathways, and outcomes (Leong, 2026a). Data collection was based primarily on structured document review, supplemented by targeted key informant interviews to validate timelines and clarify decision points.

Cases were analysed using a standardised health policy cycle framework, covering agenda-setting, appraisal, adoption, procurement, implementation, and monitoring (Walt 1994). An HTA-informed lens was applied broadly to explore how evidence on effectiveness, safety, affordability, feasibility, equity, and system readiness informed decisions across the full policy and implementation pathway (O'Rourke 2020).

Data were coded using a structured thematic categorisation matrix (Annexure B), combining inductive themes with four predefined domains: upstream system drivers, decision-system mechanisms, implementation mediators, and downstream outcomes. Cross-case and cross-category synthesis identified recurring patterns, differences across technology types, and linkages across domains, including how financing, governance, delivery platforms, and system capacity shaped implementation feasibility, uptake, sustainability, and learning.

This approach enabled systematic comparison across diverse cases while retaining sensitivity to context, sequencing, and feedback across the pathway from prioritisation to implementation.

The study was conducted under an approved doctoral protocol from the Stellenbosch University Health Research Ethics Committee (Ref: S25/03/046), with National Health Laboratory Services (NHLS) authorisation obtained where laboratory service data were accessed.

2.1. Methods

METHODS AT A GLANCE

Component	Description
Design	Case study design for health policy analysis
Conceptual approaches	Health policy analysis framework, Policy cycle framework, Health technology assessment framework
Cases	Purposive case selection to capture variation in pathways and outcomes. Twenty -one (21) cases across medicines, vaccines, diagnostics, and devices
Data collection methods	Document review (primary) and targeted key informant interviews (multi-case health policy analysis)
Multi-case health policy analysis	Standardised case templates for extracting data from documents for each case, using the health policy cycle framework for data extraction and synthesis; cross-case synthesis; cross-category synthesis

2.2. Findings

Key findings

- **System alignment drives uptake:** Across cases, introduction of new health technologies depended on alignment between evidence, regulation, financing, procurement, delivery capacity, and monitoring.
- **HTA is applied across the pathway:** Effectiveness, safety, affordability, feasibility, equity, and system readiness shaped decisions from agenda-setting through to implementation and monitoring.
- **Established platforms enable scale:** Technologies integrated into routine delivery systems achieved faster, more sustained uptake; fragmented governance, weak financing, or limited readiness slowed implementation.
- **Medicines:** Introduction was relatively formalised, with **SAHPRA approval** and **NEMLC appraisal** as key gateways. Timelines varied widely, shaped by regulatory readiness, affordability, procurement, and service capacity.
- **Vaccines**: Introduction was governed through **NAGI appraisal, NHC endorsement**, EPI planning, and Treasury-linked financing. Routine EPI integration supported scale, while campaign-based or seasonal models added complexity.
- **Diagnostics:** Introduction was shaped by **SAHPRA approval, NHLS technical evaluation**, procurement, and guideline codification. Laboratory-based tests scaled more readily through NHLS platforms; point-of-care tests required stronger facility-level governance, training, and quality assurance.
- **Medical devices:** Introduction was more variable and often shaped by procurement authority, budget delegation, infrastructure readiness, workforce capacity, lifecycle costs, and post-implementation review. Sub-national implementation sometimes preceded national policy consolidation.

The multi-case health policy analysis is presented by health technology category: medicines, vaccines, diagnostics and medical devices. Each synthesised technology category describes the following areas:

- typical pathways for introduction;
- timelines;
- roles of stakeholder engagement and advocacy;
- evidence and contextual information used;
- observed enablers and challenges; and
- a summary with suggested potential solutions.

2.2.1. Selected cases

This section synthesises findings from 21 purposefully selected cases across four technology categories: medicines (n=9), vaccines (n=3), diagnostics (n=5), and medical devices (n=4). Twenty cases were analysed retrospectively, and Umbiflow™ was included as a prospective case of a locally developed PHC antenatal Doppler innovation. Cases were selected to reflect variation in technology type, policy pathway, delivery platform, and implementation outcome. Individual case descriptions are provided in Table 2, below and in detail in Annexure A. Comprehensive individual case summaries are available in the data repository on SUNScholarData (Leong, 2026b).

Table 2. Purposefully selected health technology cases included in the multi-case analysis (n=21)

Technology category	Case area	Purposefully selected cases	Introduction focus
Medicines	HIV and TB	DTG; TAF; donated fluconazole; 3HP	Shaped by global guidance, established HIV/TB programmes, comparative effectiveness, safety, resistance patterns, price negotiations, catalytic financing, pharmacovigilance, and supplier dynamics.
	Emergency care	TXA; noradrenaline versus adrenaline	Decisions reflected contextualised review of international evidence and health system readiness. TXA was included for PHC-level postpartum haemorrhage following provincial appeal; noradrenaline was not adopted as first-line for adult septic shock.
	Family planning	Etonogestrel implant; DMPA-SC	Decisions balanced effectiveness with method choice, acceptability, equity, delivery feasibility, and cost. Implementation required provider training, supply adaptation, and additional operational requirements for self-administration.
	Substance use disorder	Methadone for opioid substitution therapy	Routine policy introduction was declined, with pilot evidence commissioned to assess local feasibility and effectiveness. Key constraints included fragmented governance, limited funding, weak programme ownership, and equity concerns.
Vaccines	Routine and targeted immunisation	HPV; PCV; QIV	Adoption and routinisation were shaped by disease burden, vaccine performance, immunisation governance, financing and procurement, delivery-platform readiness, and surveillance capacity.
Diagnostics	HIV, TB, cryptococcal disease, COVID-19, and ANC screening	HIV viral load testing; reflex CrAg screening; donated COVID-19 Ag-RDTs; dual HIV/syphilis POCT; TB-LAM urine test	Cases examined how diagnostic prioritisation, technical evaluation, regulatory approval, procurement, service platform, quality assurance, and programme monitoring shaped uptake and use.
Medical devices	Respiratory support, neonatal monitoring, and ANC screening	Apnoea monitors; CPAP; HHFNO; Umbiflow™	Three cases had progressed through adoption and implementation, while Umbiflow™ illustrated earlier-stage evidence generation and policy positioning for a locally developed PHC antenatal screening innovation.

Abbreviations: 3HP = 3-month once-weekly isoniazid and rifapentine regimen; Apnoea monitors = apnoea monitoring devices; COVID-19 Ag-RDTs = COVID-19 antigen rapid diagnostic tests; CPAP = continuous positive airway pressure; CrAg = cryptococcal antigen; DMPA-SC = subcutaneous depot medroxyprogesterone acetate; DTG = dolutegravir; dual HIV/syphilis POCT = dual HIV/syphilis point-of-care test; GeneXpert = molecular diagnostic platform for tuberculosis; HHFNO = heated humidified high-flow nasal oxygen; HPV = human papillomavirus vaccine; methadone OAT/OST– opioid agonist therapy/ opioid substitution therapy; PCV = pneumococcal conjugate vaccine; QIV = quadrivalent influenza vaccine; TAF = tenofovir alafenamide; urine TB-LAM = urine tuberculosis lipoarabinomannan test; TXA = tranexamic acid; Umbiflow™ = Doppler-based antenatal screening device; VL = viral load

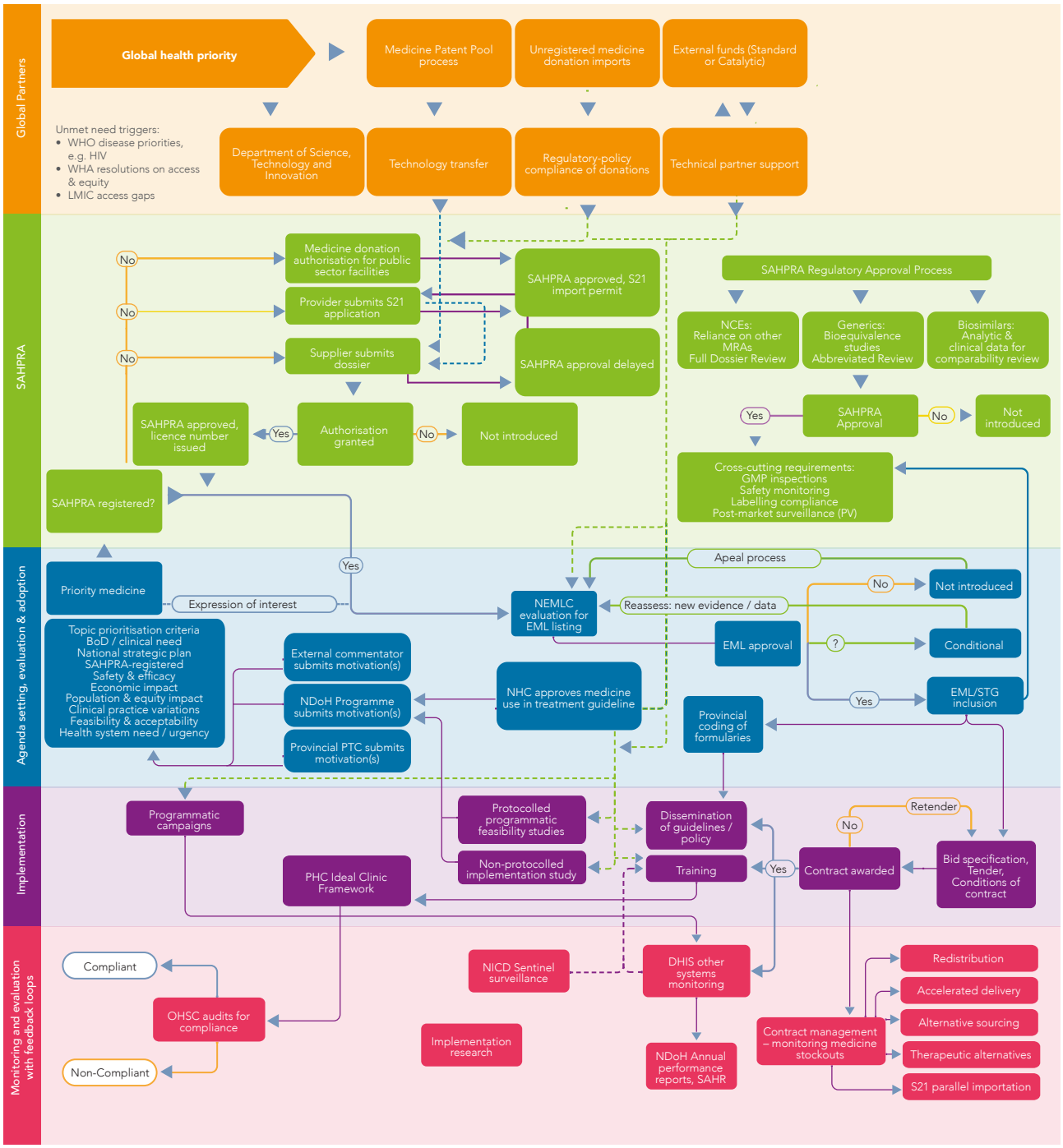
2.2.2. Typical introduction pathways across technology categories

Across medicines, vaccines, diagnostics, and medical devices, introduction followed a broadly similar policy pathway, but with category-specific governance arrangements, evidence requirements, and implementation constraints.

Common pathways

Figure 2.1. Common pathways for innovation introduction

Figure 2.2. Process map for the introduction of medicines in the South African public sector



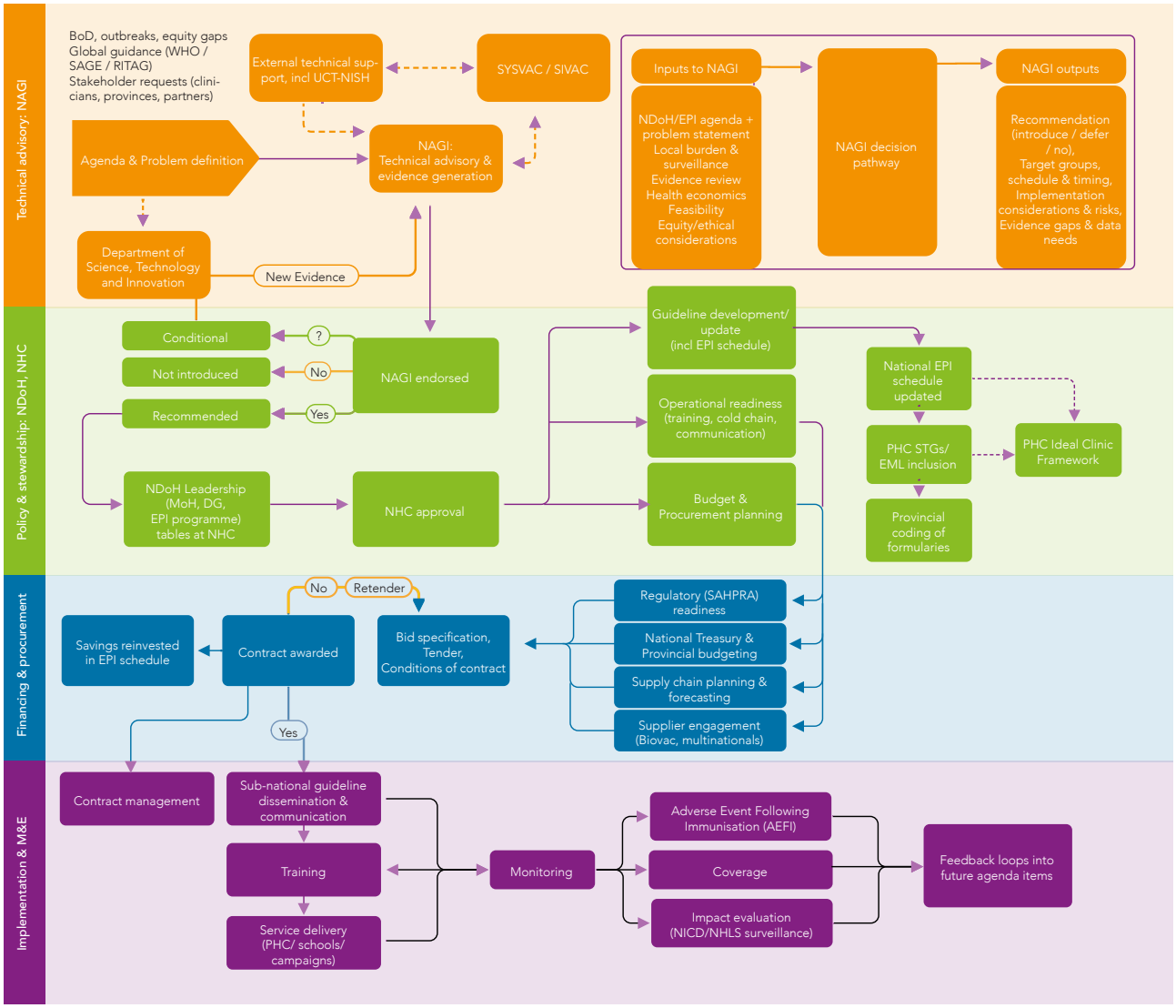
Abbreviations: *BoD=burden of disease; DHIS=District Health Information System; EML/STGs=Essential Medicine List and Standard Treatment Guidelines; NEMLC=National Essential Medicines List Committee; LMIC=Low- and Middle-Income Country; NCE=new chemical entity; NHC=National Health Council; NICD=National Institute for Communicable Diseases; OHSC=Office of Health Standards and Compliance; PHC=Primary Healthcare; PTC=Pharmacy and Therapeutics Committee; S21=Section 21 of the Medicines and Related Substances Act (Act 101 of 1965); SAHPRA=South African Health Products Regulatory Authority; SAHR=South African Health Review; WHA=World Health Assembly; WHO=World Health Organization*

Adapted from: *Leong TD, et al. From prioritization to access: decision pathways for essential health technologies in South Africa's public sector. medRxiv 2026.06.29.26356812. Available from: https://doi.org/10.64898/2026.06.29.26356812*

Category-specific pathways

- **For medicines,** introduction typically followed a formal, rule-based pathway: **SAHPRA approval, NEMLC evidence appraisal, STGs/EML codification, and National Treasury-governed procurement**. Appraisal considered effectiveness, safety, affordability, feasibility, equity, resistance patterns, and pharmacovigilance requirements. Rollout was faster and more structured, where medicines aligned with established **HIV, TB, PHC, or family planning delivery platforms**, supported by existing programme systems, procurement channels, and monitoring infrastructure. Refer to the process map in Figure 2.2.
- For **vaccines**, introduction typically proceeded through **NAGI technical appraisal**, **SAHPRA approval**, **EPI programme planning**, **NHC endorsement**, and **Treasury-linked financing and procurement**. Appraisal focused on disease burden, vaccine performance, safety, affordability, budget impact, delivery feasibility, and surveillance evidence. Rollout was strongest where vaccines were integrated into the **routine PHC EPI platform**, while school-based or seasonal delivery models required additional coordination, cold-chain planning, and adaptive monitoring. Refer to the process map in Figure 2.3.

Figure 2.3. Process map for the introduction of vaccines in the South African public sector



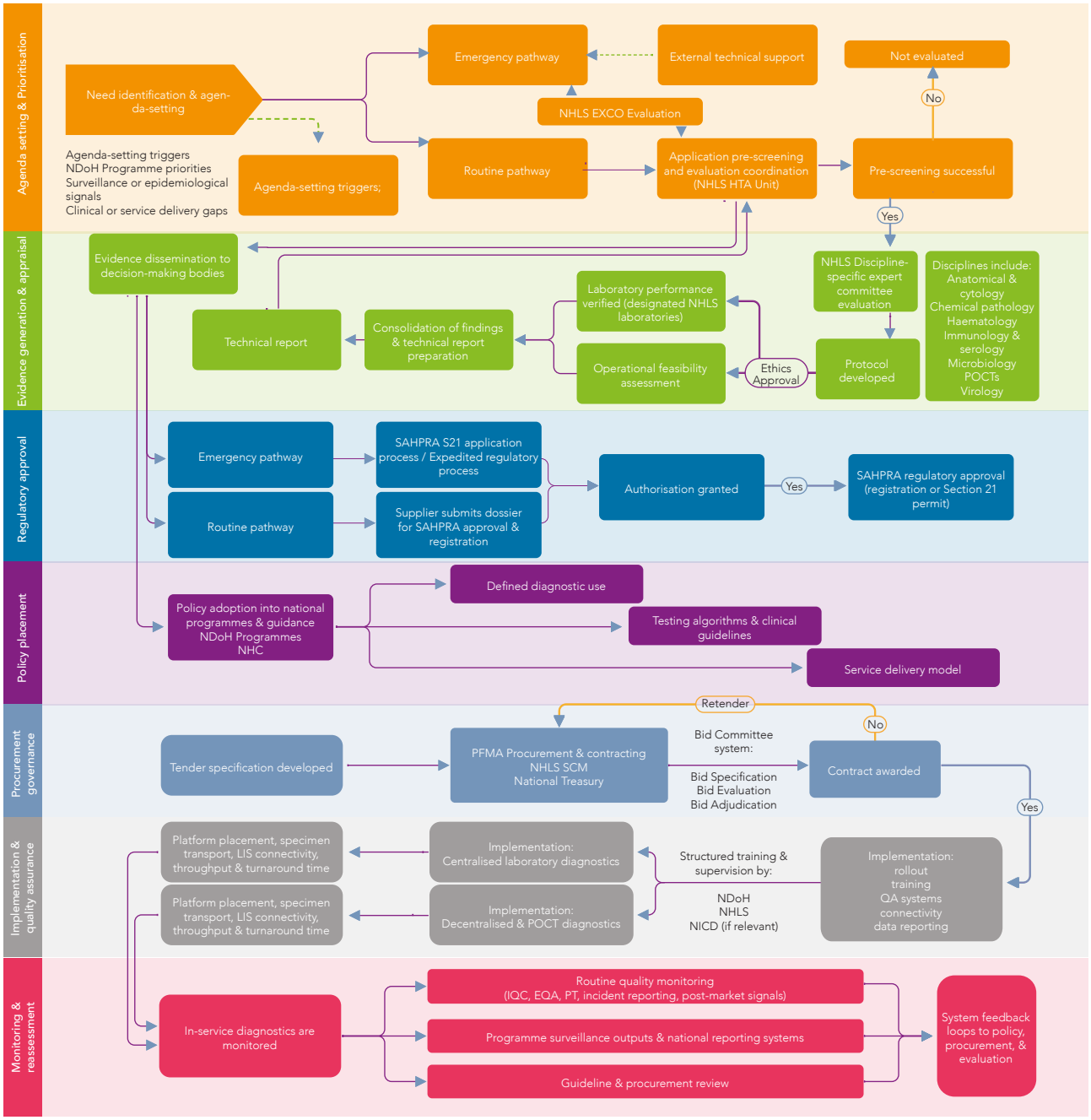
Abbreviations: *AEFI=Adverse Event Following Immunisation; BoD=burden of disease; DG=Director General; EPI=Expanded Programme on Immunisation; MoH=Minister of Health; NAGI= National Advisory Group on Immunisation; NHC=National Health Council; NHLS=National Laboratory Services; NICD=National Institute for Communicable Diseases; PHC=Primary Healthcare; RITAG=Regional Immunisation Technical Advisory Group, SAGE=Strategic Advisory Group of Experts on Immunization to the WHO; SAHPRA=South African Health Products Regulatory Authority; STGs/EML=*

Standard Treatment Guidelines and Essential Medicines List; SIVAC=Supporting Independent Immunization and Vaccine Advisory Committees Initiative; SYSVAC=Systematic Reviews of Vaccines (project by WHO, to support NITAGs including NAGI with technical evidence); UCT-NISH= University of Cape Town National Immunisation Safety Hub (AEFI monitoring, vaccine economics & policy training); WHO=World Health Organization

Adapted from: *Leong TD, et al. From prioritization to access: decision pathways for essential health technologies in South Africa's public sector. medRxiv 2026.06.29.26356812. Available from: https://doi.org/10.64898/2026.06.29.26356812.*

- **For diagnostics**, introduction generally followed a pathway of programme prioritisation, **NHLS-led technical evaluation, SAHPRA approval, NDoH guideline integration**, and **NHLS or Treasury-governed procurement**. Appraisal emphasised diagnostic performance, clinical utility, operational feasibility, quality assurance, and fit within diagnostic algorithms and service platforms. Laboratory-based diagnostics scaled more readily through the **NHLS laboratory network**, while **point-of-care tests required additional facility-level** training, supervision, supply-chain support, and quality assurance. Refer to the process map in Figure 2.4.
- **Medical device** introduction followed a **lifecycle-oriented pathway** from **service-need identification to regulatory compliance, technical and feasibility appraisal, procurement authorisation, deployment, utilisation monitoring, and lifecycle review**. Appraisal focused on clinical need, technical suitability, infrastructure and workforce readiness, maintenance, total cost of ownership, equity, and sustainability. Implementation was facilitated by alignment with service platforms, site readiness, biomedical support, and planned maintenance, and constrained by infrastructure gaps, lifecycle costs, and weak replacement planning. As shown in Figure 2.5, six decision domains structured this pathway, aligned with established HTA and health-system frameworks: prioritisation, appraisal, procurement, implementation, monitoring, and lifecycle review (Drummond 2015, Glassman 2017, INAHTA 2017, OECD 2017, WHO 2010, 2011, 2014)

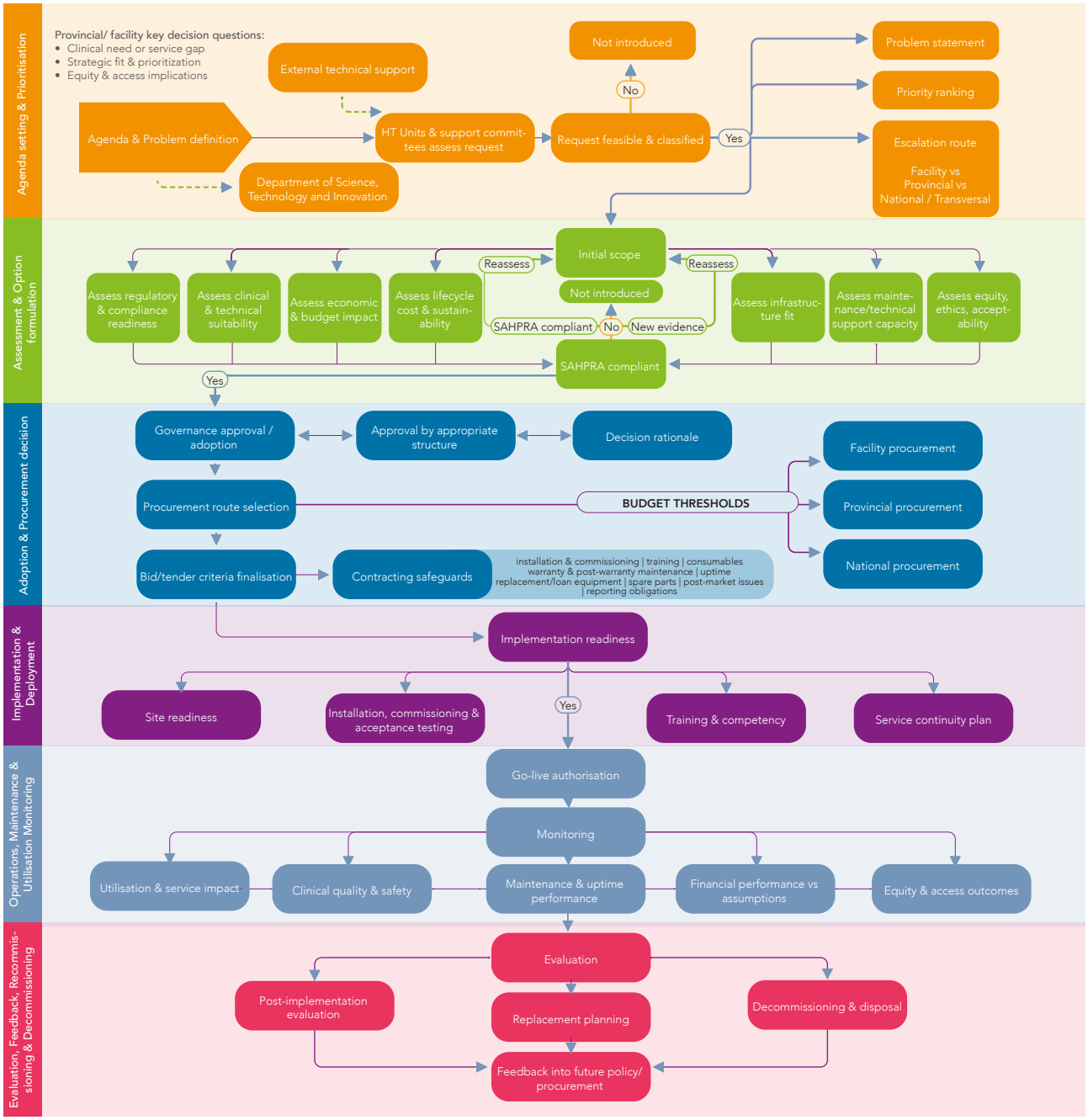
Figure 2.4. Process map for the introduction of diagnostics in the South African public sector



Abbreviations: *EQA=external quality assessment; EXCO=Executive Committee; IQC=internal quality control; LIS=laboratory information system; NdoH=National Department of Health; NHC=National Health Council; NHLS=National Health Laboratory Service; NICD= National Institute for Communicable Diseases; PFMA=Public Finance Management Act; POCT=point-of-care testing; PT=proficiency testing; QA=quality assurance; SAHPRA=South African Health Products Regulatory Authority; SCM=supply chain management*

Adapted from: *Leong TD, et al. From prioritization to access: decision pathways for essential health technologies in South Africa's public sector. medRxiv 2026.06.29.26356812. Available from: https://doi.org/10.64898/2026.06.29.26356812*

Figure 2.5. Process map for the introduction of medical devices in the South African public sector



Abbreviations: *SAHPRA=South African Health Products Regulatory Authority*

Adapted from: *Leong TD, et al. From prioritization to access: decision pathways for essential health technologies in South Africa's public sector. medRxiv 2026.06.29.26356812. Available from: https://doi.org/10.64898/2026.06.29.26356812*

Summary: introduction pathways

- Medicines and vaccines generally followed more formalised national advisory pathways.
- Diagnostics relied on NHLS-led technical evaluation and programme integration.
- Medical devices followed more decentralised and procurement-driven pathways, with greater emphasis on infrastructure, maintenance, and lifecycle management.
- Across all categories, successful introduction depended on evidence as well as effective alignment between regulation, financing, procurement, delivery readiness, implementation capacity and monitoring systems.

2.2.3. Timelines

Integrated synthesis of timelines across technology categories

Across technology categories, timelines from agenda-setting to routinised implementation ranged from **months in some cases to as much as a decade or more.** Variation was not explained by evidence strength alone. Rather, pace and predictability of adoption were shaped by the extent of alignment across **regulation, technical appraisal, affordability, financing, procurement, delivery readiness, and monitoring systems.** Technology introduction could therefore be understood as a **governance and implementation process**, rather than a once-off evidence-to-policy decision. Case-level timelines are provided in Annexures A and B.

Key timeline patterns

i. Emergency-accelerated adoption

Some technologies moved rapidly when political urgency, safety concerns, or public health emergencies created a policy window. In these cases, appraisal, procurement, and implementation were compressed or occurred in parallel.

Examples include DTG policy revision, TXA, HPV vaccination, COVID-19 Ag-RDTs, and COVID-19-related CPAP scale-up. These cases suggest that accelerated adoption is possible where urgency is matched by regulatory flexibility, financing, procurement capacity, and delivery-system mobilisation.

ii. Sequential but conditional adoption

Medicines and vaccines most often followed more formalised national pathways, but progression remained conditional on key gateways. Regulatory approval, price reductions, tender feasibility, fiscal space, and programme readiness frequently determined whether evidence translated into implementation.

Examples include 3HP, TAF, PCV optimisation, and QIV uptake. These cases illustrate that technical recommendation alone was insufficient where affordability, procurement timing, or service readiness were unresolved.

iii. Implementation-led diffusion

Diagnostics and medical devices commonly followed more decentralised or operationally driven pathways. For diagnostics, NHLS-led evaluation, laboratory capacity, workflow integration, and programme alignment were central. For devices, facility or provincial decisions often preceded national guideline consolidation.

Examples include HIV viral load monitoring, CrAg screening, TB-LAM, dual HIV/syphilis testing, neonatal respiratory monitoring, HHFNO, and Umbiflow™. These cases show that implementation evidence, infrastructure readiness, training, maintenance capacity, and procurement arrangements were often as important as formal appraisal.

iv. Protracted, incomplete, or non-adoption

Several technologies experienced long delays, partial uptake, or non-adoption despite (or because of) available evidence. These trajectories were associated with unresolved affordability, intersectoral complexity, regulatory uncertainty, limited delivery capacity, or weak fit with existing service platforms.

Examples include methadone for opioid substitution therapy, fluconazole access outside conventional sequencing, noradrenaline non-adoption, and some medical device pathways requiring prolonged periods to routinisation.

Cross-category implications

Across all categories, introduction broadly followed a common policy-cycle pathway; however, the relative weight of specific functions varied by technology type. Medicines and vaccines were shaped primarily by formal advisory, regulatory, and approval processes; diagnostics by technical validation, NHLS capacity, and programme integration; and medical devices by decentralised procurement, infrastructure readiness, maintenance capacity, and lifecycle management.

Across categories, implementation was frequently **non-linear.** Policy adoption, procurement, provider training, and operational readiness often evolved in parallel, and in some cases, implementation preceded formal policy consolidation. This was particularly evident for emergency diagnostics and devices.

Policy implications

For policymakers, the central finding is that evidence appraisal is necessary but not sufficient. Timely and sustainable introduction requires early coordination across **regulatory, fiscal, procurement, programme, infrastructure, and monitoring functions.** Delays are most likely where these functions are treated sequentially or

managed in isolation. Accelerated and equitable uptake is more likely where there is explicit and early links in the decision-making process, to evidence review of affordability assessment, procurement planning, delivery readiness, and post-introduction monitoring.

2.2.4. Roles of stakeholder engagement and advocacy

Stakeholder engagement influenced technology introduction across all categories by shaping **agenda-setting, evidence interpretation, feasibility assessment, financing, implementation planning, and scale-up**. Formal decision-making authorities generally remain within public-sector governance structures, but stakeholder influence varied by technology type and point in the policy cycle (see Annexure C for details).

Cross-category findings

Across cases, stakeholders played four recurring roles:

i. **Setting the policy agenda:** WHO guidance, national strategic goals, civil society advocacy, professional bodies, donors, and public health emergencies helped elevate technologies for consideration.
ii. **Interpreting evidence and feasibility:** Technical advisory groups, clinical experts, academic institutions, the NHLS, NICD, NAGI, and programme specialists supported contextual appraisal of effectiveness, safety, affordability, and implementability.
iii. **Enabling implementation:** NDoH programmes, provincial departments, facilities, procurement units, cold-chain systems, laboratory networks, biomedical engineering units, and service platforms translated decisions into delivery.
iv. **Mobilising resources and accountability:** Donors, development partners, civil society, professional associations, and advocacy groups supported financing, access, acceptability, and implementation oversight.

Category-specific stakeholder roles

- **Medicines:** Medicines were shaped mainly through global normative guidance, national strategic goals, expert advisory processes, civil society mobilisation, and donor alignment. WHO recommendations often informed agenda-setting. Clinical experts and professional bodies contributed to contextual evidence interpretation, while NEMLC and related statutory structures retained formal decision authority. Civil society advocacy was mostly absent, except in specific cases where key crises points emerged and access was constrained, including fluconazole, opioid substitution therapy, and DTG counselling and autonomy debates. Donors and global partners helped accelerate prioritisation and affordability in selected cases, although donor-supported access could raise sustainability concerns where domestic financing was not yet secured.
- **Vaccines:** Vaccine introduction occurred within a relatively institutionalised immunisation governance architecture. NAGI provided independent technical appraisal, drawing on surveillance, safety, regulatory, economic, and feasibility evidence. NDoH EPI and intergovernmental structures translated recommendations into programme decisions and provincial implementation. Procurement units, cold-chain systems, PHC, school health, and seasonal influenza platforms supported rollout and optimisation. Professional bodies and public health advocates contributed to policy visibility, communication, and acceptability. Overall, stakeholder engagement was embedded in routine governance structures, supporting continuity and legitimacy.
- **Diagnostics:** Diagnostics were governed through nationally coordinated but multi-actor arrangements, with a strong role for laboratory-system leadership. The NHLS supported technical evaluation, validation, quality assurance, procurement support, and implementation through laboratory and point-of-care platforms. NDoH programmes determined policy placement within clinical algorithms, guidelines, and disease-specific service platforms. SAHPRA provided regulatory oversight, including expedited access mechanisms during emergencies. Academic institutions, NICD-linked expertise, clinical advisory groups, programme experts, civil society, and development partners supported appraisal, prioritisation, and implementation, particularly for COVID-19 diagnostics and TB-LAM.
- **Medical devices:** Medical device introduction involved the most distributed and decentralised stakeholder configuration. National structures

provided standards, emergency guidance, and later codification through STGs/EML, clinical guidance, and training frameworks. However, provincial departments, facilities, clinicians, nursing managers, biomedical engineering units, and procurement structures often shaped early prioritisation and implementation. Academic institutions, research councils, technology partners, NGOs, professional bodies, and development partners contributed to innovation, evaluation, pilots, training, and advocacy. SAHPRA and SABS/SANS provided regulatory and standards oversight. Stakeholder influence was closely tied to infrastructure readiness, capital budgeting, maintenance capacity, lifecycle management, and service-platform fit.

Policy implications

The evidence suggests that multi-stakeholder and across-government engagement (mostly within sectors) was treated as a core component of the technology introduction pathway, rather than as an ad hoc consultation step. An effective introduction required early coordination between statutory decision-makers, technical experts, implementers, funders, civil society, and service-delivery platforms. There were no formal structures for engagement with civil society. Civil society engagement was absent in most cases, except in a few crisis-driven cases (e.g., fluconazole for advanced HIV care).

For policymakers, three implications follow:

- **Engage stakeholders early**, particularly when affordability, procurement, infrastructure, or delivery readiness may constrain uptake.
- **Clarify roles and decision rights**, especially in decentralised or implementation-led pathways such as diagnostics and devices.
- **Link advocacy and technical input to implementation planning**, so that policy decisions are accompanied by financing, procurement, training, monitoring, and sustainability arrangements.
- **Consider structured ways to promote engagement with civil society** to promote transparency and public trust in the introduction of new health technology.

2.2.5. Evidence and contextual information used

Across technology categories, decision-making drew on evidence domains broadly aligned with HTA: **effectiveness, safety, economic considerations, feasibility, equity, system readiness, and sustainability**. These inputs were not assessed in isolation. They interacted with regulatory, fiscal, procurement, operational, and governance considerations across the policy cycle.

Overall, global evidence often triggered review, but local adoption depended on whether the technology was **affordable, regulated, procurable, deliverable, monitorable, and sustainable** within the public health system.

Cross-cutting evidence domains

The table below, Table 3, list the various types of evidence and contextual information that was used in decision-making.

Table 3. Evidence and contextual inputs informing health technology introduction across categories

Evidence or contextual input	Role in decision-making
Global guidance and clinical evidence	Triggered agenda-setting, provided technical legitimacy, and created benchmarks for local review.
National strategic goal	National Development Plan and National department of health strategic goals triggered and supported agenda-setting.
Local burden and surveillance data	Established public health relevance, urgency, targeting, and equity considerations.
Safety and performance evidence	Informed adoption, restrictions, risk management, and iterative guideline updates.
Economic and procurement evidence	Shaped affordability thresholds, product choice, scale, timing, and sustainability.
Regulatory readiness	Determined whether technologies could progress to formal policy codification and routine use.
Service-readiness evidence	Assessed delivery-platform fit, workforce capacity, infrastructure, training, and workflow requirements.
Implementation and operational evidence	Informed phased rollout, pilots, adaptation, and scale-up decisions.
Monitoring and feedback data	Supported post-introduction review, optimisation, safety oversight, and adaptive management.
Advocacy and stakeholder evidence	Raised agenda visibility, highlighted unmet need, and influenced access, acceptability, and feasibility.

Category-specific emphasis

The primary evidence used for each technology category is described below:

- **Medicines:** Medicine decisions were strongly informed by **WHO guidance, national strategic goals, clinical trials, safety data, local burden, affordability, regulatory status, procurement feasibility, and service readiness**. Global guidance often initiated review, but adoption depended on local affordability, SAHPRA registration, tender feasibility, and fit with HIV, TB, maternal health, PHC, or family planning platforms. Safety surveillance and pharmacovigilance supported iterative policy revision, while advocacy influenced selected access-constrained cases.
- **Vaccines:** Vaccine decisions relied on **WHO guidance, national strategic goals, burden and surveillance data, vaccine efficacy and safety, affordability, procurement feasibility, delivery-platform requirements, and monitoring systems**. NICD/NHLS surveillance was particularly important for disease burden and impact assessment. Economic feasibility and fiscal space shaped scale, especially where higher unit costs or seasonal procurement cycles constrained uptake. Delivery-platform fit was central, particularly for school-based, routine EPI, and seasonal vaccine models.
- **Diagnostics:** Diagnostic decisions focused on **WHO guidance, national strategic goals programme need, diagnostic performance, laboratory validation, operational feasibility, regulatory standards, procurement conditions, and quality assurance**. Evidence was assessed not only for test accuracy, but also for whether the diagnostic could be delivered reliably through NHLS laboratory systems, point-of-care platforms, and disease-programme workflows. System readiness was especially important for decentralised POCTs.
- **Medical devices:** Device decisions drew most heavily on **audit signals, clinical suitability, infrastructure readiness, workforce capacity, regulatory and technical standards, procurement constraints, lifecycle costs, maintenance requirements, and routine utilisation data**. Evidence was often

generated iteratively through pilots, provincial implementation, and post-introduction monitoring. For devices, appraisal centred less on efficacy alone and more on safe, sustained use within real service environments.

Policy implications

Evidence use across categories was **multi-dimensional and context-dependent**. Clinical or technical evidence was necessary to justify consideration, but implementation decisions were shaped by affordability, regulation, procurement, delivery readiness, infrastructure, quality assurance, and monitoring capacity.

For policymakers, this points to the need for **pragmatic, HTA-informed appraisal tools** that integrate evidence on effectiveness, safety, cost, feasibility, equity, system readiness, and sustainability before technologies are adopted at scale.

2.2.6. Observed enablers

Across technology categories, progression from agenda-setting to implementation was enabled where **evidence, governance, financing, procurement, delivery platforms, and monitoring systems were aligned**. Enablers were therefore primarily system-level rather than product-specific. In general, the introduction was smoother when technologies addressed a recognised policy or service-delivery problem, were supported by credible evidence, had a clear institutional decision pathway, and could be absorbed into existing financing, procurement, and delivery systems.

Cross-category enablers

i. **Clear governance and decision authority:** Formal governance structures supported predictable decision-making and codification of adoption decisions. For medicines, this was reflected in NDoH, SAHPRA, and NEMLC processes; for vaccines, in the distinction between NAGI technical appraisal and NDoH/NHC policy authority; for diagnostics, in the interaction between NHLS technical leadership and NDoH programme decision-making; and for devices, in national standards combined with provincial and facility-level equipment governance.

ii. **Alignment with global guidance, national strategic priorities and local evidence:** WHO recommendations, local strategic priorities (e.g., comprehensive health services, prioritised health programmes), surveillance data, burden-of-disease evidence, clinical effectiveness data, safety evidence, and operational feasibility evidence helped legitimise adoption. Local data were particularly important where implementation risks were high or where technologies required adaptation to South African service platforms.

iii. **Early technical engagement and adaptive appraisal:** Pre-appraisal engagement with advisory, regulatory, laboratory, programme, or implementation stakeholders improved readiness for formal review. Conditional, interim, phased, or pilot-based pathways helped manage uncertainty around safety, affordability, evidence maturity, procurement feasibility, and operational readiness.

iv. **Financing and procurement readiness:** Protected or predictable financing enabled planning and scale-up. Existing procurement and supply-chain platforms reduced implementation friction, particularly for medicines, vaccines, and diagnostics. For devices, capital budgeting, procurement feasibility, maintenance planning, and replacement cycles were central to sustained use.

v. **Delivery-platform fit:** Technologies were introduced more effectively when integrated into established service platforms, including HIV, TB, family planning, antenatal care, immunisation, PHC, laboratory, outbreak-response, newborn-care, and ward-based oxygen-care platforms. Platform fit reduced the need for parallel systems and improved feasibility.

vi. **Quality assurance, monitoring, and feedback systems:** Routine information systems, surveillance platforms, pharmacovigilance, laboratory quality assurance, audit systems, and pilot monitoring enabled post-introduction oversight and iterative adjustment. These mechanisms supported both accountability and learning during scale-up.

vii. **Strategic stakeholder and partner engagement:** Civil society, professional bodies, donors, academic institutions, development partners, and manufacturers helped raise policy salience, support evidence generation, mobilise resources, improve acceptability, and address access constraints. Their contribution was most catalytic when aligned with domestic policy authority and sustainability planning.

Policy implications

The main enabling condition across categories was **system alignment**. Evidence appraisal was necessary, but adoption advanced most effectively when linked early to financing, procurement, delivery readiness, quality assurance, and monitoring.

For policymakers, this suggests three priorities:

- **Assess implementation readiness early,** alongside evidence and cost-effectiveness.
- **Use adaptive pathways where uncertainty remains,** including conditional approval (or non-adoption), phased rollout, pilots, and structured post-introduction review.
- **Plan for sustainability from the outset,** including domestic financing, procurement continuity, workforce training, infrastructure, maintenance, and monitoring.

2.2.7. Key barriers observed

Across technology categories, barriers were primarily **systemic rather than evidentiary**. Delays, uneven uptake, and sustainability risks generally reflected weak alignment between **policy adoption decisions and implementation systems**, including regulation, financing, procurement, service readiness, monitoring, and long-term planning.

Cross-cutting barriers

Table 4. Cross-cutting barriers to health technology introduction and their policy relevance

Barrier	Policy relevance
Policy–implementation misalignment	Adoption decisions often preceded consideration of procurement, training, infrastructure, workflow design, quality assurance, or monitoring readiness.
Financing and procurement constraints	Fiscal ceilings, affordability thresholds, tender delays, supplier dependence, weak forecasting, and stock instability limited scale and continuity.
Regulatory and sequencing delays	Delayed registration, label alignment, or guideline codification slowed routine implementation. Interim or donation-based access created sustainability and governance risks.
Fragmented governance	Unclear roles across institutions, programmes, and levels of government weakened coordination, especially for point-of-care diagnostics and devices.
Uneven service readiness	Provincial, facility, workforce, and infrastructure variation produced inequitable access and inconsistent implementation quality.
Weak monitoring and feedback	Routine systems often lacked sufficient granularity to track uptake, safety, supply continuity, clinical action, equity, and performance.
Sustainability risks	Donor support, donations, emergency procurement, and crisis financing accelerated access but were not always converted into routine financing, maintenance, or workforce plans.
Limited patient and end-user participation	Patient and end-user perspectives were not routinely embedded in formal decision-making, limiting insight into acceptability, access, and implementation barriers.

Category-specific barriers

- **Medicines:** Barriers centred on **regulatory sequencing, affordability, procurement stability, service readiness, and monitoring**. Delays in registration or guideline codification slowed routine uptake, while fiscal constraints, supply instability, and uneven provincial readiness affected scale and equity. Formal civil society participation was limited, although civil society advocacy influenced selected access-constrained cases.
- **Vaccines:** Barriers reflected **governance sequencing, fiscal space, procurement timing, delivery-platform complexity, and data limitations**. Political acceleration sometimes outpaced technical sequencing. School-based and seasonal delivery models created access and operational challenges, while fragmented information systems constrained performance management. Formal civil society participation was limited.
- **Diagnostics:** Barriers were concentrated in **point-of-care governance, procurement vulnerability, quality assurance, and laboratory–clinical feedback loops**. Policy adoption sometimes preceded procurement, training, and clinical decision-support. Supplier concentration, tender delays, and weak follow-up of diagnostic results limited effective implementation. Formal civil society participation was limited.
- **Medical devices:** Barriers reflected **variable appraisal standards, infrastructure dependence, fragmented lifecycle management, and uneven sub-national capacity**. Safe and sustained use depended on oxygen systems, engineering support, consumables, maintenance, training, replacement planning, and routine budgets. Where these were weak, devices risked under-use or unsustained scale-up. Formal civil society participation was limited.

Policy implications

For policymakers, the main lesson is that adoption decisions should be linked explicitly to implementation readiness. This requires early assessment of **affordability, procurement feasibility, workforce and infrastructure capacity, quality assurance, monitoring, end-user needs, and sustainability**.

A more integrated introduction pathway would reduce delays, improve equity, and increase the likelihood that technologies adopted in policy are implemented effectively and sustained in routine service delivery.

2.2.8. Prospective case: Umbiflow™ as a PHC antenatal Doppler innovation

Key findings

- **Umbiflow™ addresses a persistent PHC diagnostic gap** in detecting placental insufficiency and stillbirth risk.
- **Evidence suggests technical validity, PHC feasibility, provider acceptability, and improved detection of abnormal placental blood flow.**
- **The device remains pre-policy:** routine adoption depends on SAHPRA registration, costing, implementation readiness, referral capacity, maintenance, and monitoring.

Umbiflow™ is a locally developed portable Doppler device designed for PHC antenatal services. It measures the umbilical artery resistance index as a proxy for fetoplacental blood flow, enabling earlier identification and referral of pregnancies at risk of placental insufficiency. Unlike handheld fetal Dopplers, which assess fetal heart rate only, Umbiflow™ supports detection of impaired placental circulation in low-resource settings.

Evidence generation has progressed from technical validation to PHC implementation research. Studies indicate agreement with conventional Doppler ultrasound, the feasibility of midwife-led screening, improved detection of abnormal Doppler findings, and early signals of improved perinatal outcomes. Larger implementation studies have generated evidence on workflow integration, training, referral processes, remote quality assurance, and system performance.

Umbiflow™ has recently been registered for routine use by SAHPRA, but has not been adopted into national policy. Future policy consideration will require regulatory approval, economic evaluation, procurement planning, provider training, referral protocols, maintenance arrangements, and integration into routine ANC monitoring systems.

Umbiflow™ evidence-generation pathway

The Umbiflow™ evidence pathway progressed from technical validation to PHC-based implementation research and early district-scale rollout, generating evidence on clinical effectiveness, feasibility, referral integration, and scalability. As summarised in Annexure D, these studies preceded SAHPRA registration and formal policy adoption, serving as preparatory evidence to inform future policy appraisal.

Policy implications

Umbiflow™ illustrates a locally developed diagnostic innovation moving from validation toward potential policy appraisal. Any future scale-up should be conditional on regulatory approval, affordability, PHC readiness, referral capacity, quality assurance, maintenance, and routine monitoring. Umbiflow™ may strengthen PHC detection of placental insufficiency, but remains a pre-policy innovation.

2.2.9. Synthesis Across Categories

Across medicines, vaccines, diagnostics, and medical devices, introduction followed a broadly common policy-cycle pathway: **prioritisation, appraisal, regulatory approval, policy adoption, financing, procurement, implementation, monitoring, and review**. However, the relative importance of specific functions differed by category.

Adoption was shaped not by evidence alone, but by alignment across **regulation, affordability, financing, procurement, service readiness, infrastructure, monitoring, and stakeholder coordination**. HTA-related considerations were evident across the pathway, but were applied variably and often pragmatically rather than through a standardised lifecycle process.

Key findings

- **Evidence was necessary but insufficient:** Clinical effectiveness, safety, diagnostic performance, or technical benefit triggered consideration, but implementation depended on affordability, procurement feasibility, delivery readiness, and sustainability.
- **Pathways were non-linear:** Policy endorsement, procurement, training, implementation, and monitoring often progressed in parallel. In some diagnostic and device cases, piloting or implementation preceded formal national codification.
- **System alignment determined pace and sustainability:** Introduction was smoother where advisory processes, financing, procurement, delivery platforms, and monitoring systems were coordinated.
- **Category-specific requirements mattered:** Medicines and vaccines were more strongly shaped by formal advisory, regulatory, and guideline processes. Diagnostics depended on NHLS technical evaluation, quality assurance, and programme integration. Devices depended on infrastructure readiness, capital budgeting, maintenance, engineering capacity, and lifecycle management.
- **HTA was unevenly institutionalised:** HTA functions were strongest at the adoption stage and less consistently applied to implementation monitoring, reassessment, impact, and sustainability.

Across categories, introduction followed a common policy-cycle pathway, but the dominant governance mechanisms and implementation requirements differed by technology type. Table 5 summarises these category-specific differences.

Table 5. Category-specific pathways and implementation dependencies for health technology introduction

Category	Main pathway features	Main implementation dependencies
Medicines	SAHPRA approval, NEMLC appraisal, STG/EML codification, procurement linkage	Affordability, regulatory readiness, supply continuity, service-platform fit, pharmacovigilance
Vaccines	NAGI appraisal, NDoH/NHC endorsement, EPI planning, Treasury-linked financing	Fiscal space, procurement timing, cold chain, delivery platform, surveillance
Diagnostics	NHLS technical evaluation, SAHPRA oversight, guideline integration, programme adoption	Laboratory or POCT readiness, QA, procurement, training, clinical workflow integration
Medical devices	More decentralised, procurement- and implementation-led lifecycle pathway	Infrastructure, engineering support, maintenance, training, utilisation monitoring, replacement planning

2.3. Discussion

The multi-case health policy analysis shows that the South African public sector has a structured, evidence-informed architecture for health technology introduction, but one that remains insufficiently integrated across the full policy-to-implementation cycle. Access is shaped by evidence, as well as the alignment of regulatory approval, policy endorsement, financing, procurement, delivery readiness and post-introduction monitoring. Formal decision pathways are most developed for medicines and vaccines; diagnostics and medical devices rely primarily on laboratory, programme, provincial, facility and procurement systems.

A key finding is that decision-making remains weighted towards upstream adoption, with comparatively less emphasis on implementation feasibility, sustainability, adaptation, substitution or disinvestment. Where health system components were aligned, technologies moved more effectively from evidence to access. Where there was fragmented sequencing, constrained fiscal space, weak procurement readiness and service-delivery capacity, variable provincial capacity, or limited monitoring with limited post-introduction loops, implementation was delayed, uneven or unsustained. Global guidance and donor support often accelerated prioritisation, but also created sustainability risks when domestic financing, procurement continuity and delivery capacity were not secured.

These findings are consistent with the literature showing that HTA is most effective when institutionalised within real decision points, linked to resource allocation, and applied across the technology lifecycle rather than as a stand-alone technical exercise (O'Rourke 2020, Drummond 2008, Bertram 2021). They also align with priority-setting and MCDA literature, which emphasises that decisions in resource-constrained settings require explicit consideration of clinical value, affordability, equity, feasibility, acceptability and implementation consequences (Baltussen and Niessen 2006; Thokala 2016). Vaccine-decision literature similarly highlights the importance of transparent criteria, programme feasibility, financial sustainability and stakeholder engagement in national introduction decisions (Donadel 2021). The South African cases reinforce these global findings while highlighting that operational readiness and procurement feasibility can be binding constraints even where clinical evidence is strong.

Strengths and limitations

The multi-case health policy analysis's strength is its cross-technology, system-level design. It allows comparison across products, programmes and policy pathways, and identifies recurrent bottlenecks that would be less visible in single-case analyses. The use of a standardised policy-cycle framework supports synthesis across heterogeneous technologies.

Limitations include reliance on documentary evidence, a mainly national-level lens, limited stakeholder interviews in the current phase, and incomplete capture of provincial, facility, patient, industry and civil-society perspectives. These limitations are most material for diagnostics and devices, where pathways are less formalised, and implementation is more decentralised.

Policy implications

Findings from the multi-case health policy analysis suggest that technology adoption should be managed as a **coordinated lifecycle policy process**, rather than a once-off approval decision. Strengthening alignment between **evidence appraisal, regulation, financing, procurement, implementation readiness, monitoring, and sustainability planning** would support more timely, equitable, and durable access across all technology categories.

This requires institutionalising **pragmatic HTA-informed appraisal that explicitly considers affordability, equity, feasibility, delivery readiness and sustainability**. Appraisal should be linked early to budget, procurement, workforce, infrastructure, quality assurance, maintenance, supply-continuity and monitoring requirements, particularly for diagnostics, POCTs, devices and decentralised innovations.

Post-introduction monitoring should track uptake, equity, safety, utilisation, costs and service outcomes, with findings routinely feeding into policy revision, reassessment, substitution and disinvestment decisions. **Structured engagement** with patients, providers, civil society, procurement actors and end-users would strengthen legitimacy, feasibility and responsiveness across the technology lifecycle.

Further research should assess how national adoption decisions translate into provincial and facility-level implementation, and how financing and procurement shape equitable access. Prospective studies should examine whether earlier market intelligence, portfolio planning and whole-of-government coordination improve timely and sustainable introduction.

2.4. Conclusion

The multi-case HPA shows that South Africa has a strong foundation for evidence-informed health technology introduction, but access depends on how well decisions are translated into financed, procured and implementable services. The central policy challenge is therefore not only selecting the right technologies, but governing their full lifecycle—from appraisal and adoption to implementation, monitoring, adaptation and disinvestment. Strengthening this alignment would support more timely, equitable and sustainable access to health technologies across the public health system.

3. ADDITIONAL INDIVIDUAL CASE STUDIES

The multi-case health policy analysis draws on twenty retrospective cases across medicines, vaccines, diagnostics, and devices to identify system-level patterns in health technology introduction. Four in-depth case studies complement this analysis by tracing specific introduction pathways in greater detail, focusing on TB and HIV innovations where South Africa's experience offers particularly instructive lessons for the ALIGN programme.

Two retrospective cases examine completed introduction processes. The BPaL case study traces how South Africa combined early access programmes, a formal evidence-to-decision process through the National Essential Medicines List Committee (NEMLC), and phased national rollout to achieve rapid, high-coverage adoption of a major therapeutic innovation for drug-resistant TB (Annexure H). The GeneXpert MTB/RIF case study examines the rollout of molecular TB diagnostics from 2011 — one of the earliest national adoptions of rapid molecular diagnostics globally — and draws out lessons about the relationship between speed, system readiness, and governance transparency that remain relevant for future innovations.

Two prospective cases examine introductions that are either underway or in preparation. The TB vaccine preparedness case examines how South Africa is positioning itself for the future introduction of adult TB vaccines ahead of licensure, focusing on coordination, evidence generation, and regulatory readiness rather than implementation. The lenacapavir case traces the prospective introduction of a long-acting injectable for HIV prevention, examining what happens when regulatory, financing, and procurement pathways align under time pressure, and what the transition from donor-supported access to domestic financing means for sustainability.

These four cases provide the detailed evidence that the cross-case synthesis draws on to assess how the four ALIGN pillars function across different technology types, introduction stages, and system conditions. Summaries of these case study reports are described below.

3.1. Retrospective Cases

3.1.1. BPaL regimen for drug-resistant TB

The BPaL-L regimen (bedaquiline, pretomanid and linezolid, with levofloxacin) is an all-oral, six-month treatment for rifampicin-resistant TB that replaced regimens lasting up to two years and relying on injectables. South Africa's adoption is instructive because it shows a major therapeutic innovation moving from global recommendation to near-universal national use in roughly a year, built on existing programme strength rather than new institutions.

Policy

The decisive policy moment came in December 2022, when the WHO issued consolidated guidance recommending six-month all-oral regimens for most people with rifampicin-resistant TB. South Africa did not adopt this wholesale. The National Essential Medicines List Committee (NEMLC) ran a formal adolopment review, adapting the global recommendation to local conditions against explicit evidence-to-decision criteria — clinical benefit and harm, feasibility, acceptability, equity, resistance patterns and cost. That review selected levofloxacin as the preferred fluoroquinolone, giving the country its own variant, BPaL-L. Leadership within the National TB Programme, including officials with direct experience of earlier drug-resistant TB access programmes, kept the regimen on the agenda and moved it from endorsement to a revised national rifampicin-resistant TB Clinical Reference Guide without the stalling that often follows appraisal.

Regulatory

Regulatory approval was not the rate-limiting step. Bedaquiline was registered as early as 2014 under the former Medicines Control Council, and pretomanid followed FDA approval in 2019 with SAHPRA registration in 2021. By the time the policy review began, the components were already available in country, which meant the national decision turned on how to use the regimen rather than whether it could be supplied.

Financing

The source documents the regimen's economic logic — a shorter, all-oral course lowers hospitalisation, monitoring and adherence-support costs relative to the regimens it replaced — but they do not describe a discrete financing or budget decision. This is a genuine gap in the available record rather than an omission in the summary.

Procurement

The case study treats procurement as running through existing national TB medicine supply arrangements rather than as a separate pathway, and does not detail tender or pricing steps. No detail has been inferred here that the source does not support.

Implementation

National rollout began on 1 September 2023 and was deliberately phased, with provinces moving off longer regimens as readiness allowed. The National Department of Health supported the transition through structured training, virtual mentorship and clinical advisory mechanisms at national and provincial level, and adapted existing TB surveillance and pharmacovigilance platforms to track uptake, safety and early outcomes. Uptake was rapid: by late 2024 roughly 90% of eligible adults were on BPaL-L, with more than 7 400 patients initiated by early 2025. The pace reflected accumulated programme experience and the confidence built through earlier clinical access work, which let implementation proceed as managed learning rather than a standing start.

Timeline of milestones

Date	Milestone	Level
2014	Bedaquiline registered (Medicines Control Council)	National
2019	Pretomanid receives FDA approval	Global
2020	WHO statement: BPaL permissible under operational research	Global
2021	Pretomanid registered with SAHPRA	National
Dec 2022	WHO consolidated guidelines recommend six-month BPaL/BPaLM	Global
Aug 2023	National BPaL-L introduction webinar	National
Sep 2023	NEMLC endorsement; revised RR-TB Clinical Reference Guide	National
1 Sep 2023	Phased national rollout begins	National
Late 2024	~90% of eligible adults on BPaL-L; 7 400+ initiated by early 2025	National

Lessons for the ALIGN programme

BPaL-L shows what becomes possible when global guidance meets a national appraisal structure that can adapt it credibly, and when programme leadership carries a decision through to implementation. The transferable points are the value of early clinical access work in reducing decision uncertainty, the need to invest in safety monitoring and training ahead of rollout — linezolid toxicity being the live concern here — and the gain from treating introduction as an adaptive, learning-oriented process. The case also points to less well developed areas: pharmacovigilance capacity at scale, the transparency of deliberative processes, and the thin documentation of financing and procurement.

3.1.2. GeneXpert MTB/RIF

GeneXpert MTB/RIF is a rapid molecular test that detects M. tuberculosis and rifampicin resistance in about two hours, replacing smear microscopy as the initial diagnostic for presumptive TB. South Africa's rollout from 2011 was one of the earliest and most ambitious national adoptions of the technology anywhere, and it remains instructive precisely because it shows both the reach of decisive central action and the limits of moving faster than the system underneath can absorb.

Policy

The policy decision was deliberate and, in one respect, bolder than the global guidance it followed. After the WHO issued a conditional recommendation in December 2010, South Africa chose to use GeneXpert as the universal initial test for everyone with presumptive TB, rather than restricting it to people living with HIV as the WHO initially advised. That choice was grounded in local epidemiology — a high burden of smear-negative TB, extensive HIV–TB co-infection, and the need to detect drug resistance earlier — and South African research sites had themselves contributed to the global evidence base. The decision was taken through executive authority, with the Minister of Health issuing a direct instruction to proceed rather than working through a formal committee, and the national diagnostic algorithms became the de facto record of the policy.

Regulatory

At the time of rollout, South Africa had no formal regulatory pathway for in vitro diagnostics. The Medicines Control Council regulated medicines, but diagnostics like GeneXpert were not subject to local review, so adoption relied on WHO guidance, international regulatory assessments, and the NHLS's own technical verification and quality assurance. This reliance-based approach enabled speed. The environment has since matured — SAHPRA now holds a mandate for in vitro diagnostics — but those processes remain relatively young, and local review still leans heavily on WHO prequalification and stringent foreign regulators rather than de novo assessment. For the ALIGN programme, this is a standing feature of the diagnostics pathway rather than a transitional gap.

Financing

No formal health technology assessment preceded adoption; the economic case was practical rather than analytical, resting partly on the expectation that GeneXpert would reduce smear-microscopy workloads. Early expansion was carried by donor financing, particularly Gates-funded trial sites and PEPFAR, which lowered the cost and logistical barriers during the period before domestic systems took over. National Treasury support followed once procurement cycles were established, and financing has since settled into routine forecasting, donor coordination, and national costing updates that inform procurement and scale decisions. The sequence — donor catalysis first, domestic financing consolidating later — is a recurring pattern worth flagging for cases where that handover is less smooth.

Procurement

Procurement was centralised through the NHLS, which used the existing national laboratory network to place instruments and manage supply at scale, with national and local forecasting cycles in effect by 2013. The main vulnerability was concentration: dependence on a single platform and supplier (Cepheid) exposed the programme to pricing pressure, cartridge stockouts, and limited competitive leverage, and the strain became visible when GeneXpert platforms were diverted to SARS-CoV-2 testing during the pandemic. South Africa has since begun diversifying — introducing Roche Cobas systems at higher-volume sites and BD MAX platforms at lower-volume laboratories — which points toward greater resilience but came after, rather than ahead of, the risk materialising.

Implementation

Implementation was centralised and fast. Phase 1 placement began on World TB Day 2011 with instruments in 25 sites across nine high-burden districts, routine testing started in October 2011, and by 2013 GeneXpert had effectively replaced smear microscopy in most high-burden districts. From the outset, instruments were interfaced with NHLS laboratory information systems and the Central Data Warehouse, giving early national visibility of testing volumes, turnaround times and resistance patterns — a genuine strength of the rollout. At the same time, instrument placement often ran

ahead of training, which left uneven adherence to the testing algorithm, variable submission of confirmatory specimens, and difficulty interpreting rifampicin-resistant results. Multiple evaluations documented substantial losses along the diagnostic and treatment cascade despite the better test, with delays in treatment initiation and incomplete follow-up of negative or indeterminate results. These were system limitations — staffing, specimen transport, IT literacy, weak laboratory–clinical integration — that a diagnostic alone could not fix. System strengthening through quality assurance, remote connectivity, dashboards and expanded training gradually stabilised performance, and the smoother transition to Xpert Ultra in 2017–2018 showed the value of that more mature platform.

Timeline of milestones

Date	Milestone	Level
Dec 2010	WHO conditional recommendation for Xpert MTB/RIF	Global
Early 2011	Ministerial decision: universal GeneXpert testing replaces smear microscopy	National
24 Mar 2011	Phase 1 placement — 25 sites across nine high-burden districts	National
Oct 2011	Routine testing begins; ~129 technologists trained	National
2011–2013	Phased national rollout; LIS/CDW integration; procurement cycles established	National
2013	GeneXpert effectively replaces smear microscopy in most high-burden districts	National
2017–2018	Transition to Xpert MTB/RIF Ultra	National
2020	COVID-19: ~22% drop in TB testing; platforms diverted to SARS-CoV-2	National
2021–2023	Recovery and optimisation; ~173 laboratories by April 2023; diversification begins	National

Lessons for the ALIGN programme

GeneXpert shows what strong central leadership and early alignment with global guidance can achieve — unprecedented speed and national scale through an existing laboratory network. It also shows the cost of letting deployment outrun readiness. The transferable points are to treat training, workflow redesign, quality assurance and data integration as core parts of introduction rather than downstream fixes; to engage mid-level implementers and frontline staff in planning rather than only endorsing decisions from the top; to build platform and supplier diversification into procurement from the start rather than after a shock; and to treat introduction as an adaptive process with a proper post-introduction evaluation framework, which was the clearest gap in the early years.

3.2. Prospective Cases

3.2.1. Adult TB vaccine preparedness

South Africa is preparing for the future introduction of adult TB vaccines ahead of licensure, rather than introducing a product that already exists. The case matters because it shows how a country can position its systems for a major innovation well before a regulatory decision is possible, and because South Africa's role as a leading trial site — including the M72/AS01E Phase 3 study — gives it both the imperative and the practical experience to plan in earnest.

Policy

TB vaccines have been a stated national priority for some years, anchored in South Africa's persistent adult TB burden, high TB–HIV co-infection, and the limits of current prevention, and reflected in the National TB Strategic Plan 2023–2028. The catalyst that turned long-standing intent into structured

planning was the WHO's TB Vaccine Readiness Framework in May 2024, which gave the country a shared reference for aligning work across policy, regulation, delivery, financing, modelling and community engagement while leaving prioritisation in national hands. Decision-making has run through established structures — the National Department of Health and National TB Programme, with technical advice from NAGI's TB Vaccine Working Group — and has been incremental and consensus-driven rather than a single adoption decision, which suits a pre-licensure stage.

Regulatory

SAHPRA holds the mandate for vaccine authorisation, lot release and post-licensure safety monitoring, and its requirements are documented. What does not yet exist is a product to assess or a defined approval and pharmacovigilance timeline for a specific candidate, so regulatory work at this stage is about readiness — clarifying review pathways in advance — rather than a completed step.

Financing

Financing is one of the least settled areas. There is no dedicated funding stream for adult vaccine procurement, and budgets are constrained. National documents acknowledge the need for early resource mobilisation but cannot yet provide procurement budgets, because the vaccine is unlicensed. South Africa has instead positioned itself in the global financing conversation, co-leading the Finance and Access Working Group of the TB Vaccine Accelerator Council with the WHO and Gavi, and using its G20 Presidency to co-host a November 2025 meeting on equitable pricing and sustainable financing. A country-specific health technology assessment and investment case still need to be completed.

Procurement

Procurement systems are not yet optimised for a high-cost adult vaccine, and planning centres on the likelihood of constrained early supply — how to allocate and prioritise scarce initial doses. South Africa's engagement in global market-shaping is, in effect, early procurement strategy, but no national procurement framework is in place.

Implementation

Operational readiness is the largest gap. South Africa has limited routine adult vaccination platforms compared with its well-established childhood immunisation programme, fragmented adult immunisation data systems, and constrained workforce capacity, and cold-chain, delivery-model and data-integration work all still need strengthening. The intent is a phased introduction built around priority populations and delivered through existing TB, HIV and primary health care platforms. Coordination has been formalised through the TB Vaccine Preparedness Steering Committee, established in April 2025, and a national multi-stakeholder preparedness workshop in July 2025, while trial-site capacity at Wits RHI and AHRI offers operational experience that can carry into rollout.

Timeline of milestones

Date	Milestone	Level
2023–2028	TB vaccine preparedness embedded in National TB Strategic Plan	National
2023–2024	South African Novel TB Vaccines Preparedness Consortium formed	National
Early 2024	TB Vaccine Working Group established under NAGI	National
Mar 2024	M72/AS01E Phase 3 dosing begins at first SA site (Wits RHI)	National
6 May 2024	WHO publishes TB Vaccine Readiness Framework	Global
Apr 2025	TB Vaccine Preparedness Steering Committee established	National
Jul 2025	National TB Vaccine Preparedness Workshop	National
6 Nov 2025	G20 side-meeting on financing and access, co-hosted by SA and WHO	Global

Lessons for the ALIGN programme

The TB vaccine case shows that preparedness for a major innovation can be advanced well ahead of licensure through deliberate coordination, evidence generation and trial leadership, with a global framework serving as the organising reference and high-level political engagement lending credibility. It also exposes what readiness on paper does not yet cover: adult vaccination infrastructure is less well developed than the childhood platform, adult immunisation data are fragmented, there is no dedicated financing or procurement pathway for a high-cost vaccine, the country-specific HTA is incomplete, and coordination across TB, HIV, primary care and immunisation remains partial. Community engagement and trust-building, in particular, have not yet been drawn into a phased national communication strategy — a gap worth closing early given the post-COVID confidence environment.

3.2.2. Lenacapavir for HIV prevention

Lenacapavir is a first-in-class, long-acting injectable HIV capsid inhibitor used as pre-exposure prophylaxis, given as a six-monthly subcutaneous injection after an oral lead-in. It addresses the adherence problem that limits daily oral PrEP, and trial efficacy was exceptionally high. The case is instructive because it shows how quickly the South African system can move when regulatory, financing, policy and procurement pathways align under time pressure — and because the central question it raises is sustainability, as donor-funded initial access gives way to domestic financing.

Policy

Policy moved fast and in step with global endorsement. The WHO recommended injectable lenacapavir on 14 July 2025, and the day after, the Minister of Health accepted a Global Fund offer to procure it through an existing grant — an early signal of political prioritisation. The National Essential Medicines List Committee recommended EML inclusion on 4 September 2025, conditional on price and SAHPRA registration and informed by economic analysis from HE²RO, with a call for comment on standard treatment guidelines in early November and NEMLC/NDoH approval for EML inclusion on 18 November 2025. A national roundtable convened by SANAC and the NDoH in mid-October 2025 anchored the planning.

Regulatory

Gilead filed with SAHPRA in March 2025 under expedited arrangements linked to the EU-M4all pathway, and SAHPRA registered the product on 27 October 2025 — making South Africa the first African country to approve twice-yearly lenacapavir for prevention. The speed came from leaning on global assessment: WHO prequalification on 6 October 2025 and the EMA's accelerated review fed a formal abridged national route. This is the same reliance on stringent foreign regulators seen in the GeneXpert case, but channelled this time through an established SAHPRA expedited pathway rather than the absence of one.

Financing

Initial access rests on donor financing. South Africa secured an early allocation through a Global Fund grant — a US$29 million investment providing roughly 456 000 initiations over two years — within a broader Global Fund–Gilead agreement to supply up to two million people across low- and middle-income countries over three years. The supply is explicitly limited and to be managed strategically. The NDoH has signalled its intent to integrate lenacapavir into domestic financing and the EML, and generic agreements brokered through Unitaid, CHAI, Wits RHI and Dr Reddy's point to a price near US$40 per person per year from 2027. How smoothly the country moves from donor-supported procurement to sustained domestic financing is the defining issue for this introduction.

Procurement

Early procurement runs through the Global Fund, with first shipments expected in early 2026 and public-sector purchase of generics anticipated from 2027 as voluntary licensing widens supply and lowers price. The early period therefore depends on a single originator product, with diversification built into the medium-term plan rather than available at the outset.

Implementation

Rollout is prospective. A phased public-sector introduction is planned for April 2026, targeting roughly 300 to 360 high-performing clinics across high-incidence districts, with the NDoH indicating six provinces and 23 districts. Implementation resources — clinical guidelines, monitoring and evaluation tools, training curricula and supply-chain planning — are being finalised between January and March 2026, followed by provider training, site-readiness assessments and piloting of nurse-initiated delivery models. The plan builds directly on South Africa's oral PrEP experience and differentiated service delivery, targeting populations at highest risk, including adolescent girls and young women, men who have sex with men, sex workers and people who inject drugs, through clinic, pharmacy and community-based channels.

Timeline of milestones

Date	Milestone	Level
Jun–Nov 2024	PURPOSE-1 and PURPOSE-2 trials report high efficacy	Global
18 Jun 2025	US FDA approves lenacapavir for PrEP	Global
9 Jul 2025	Global Fund–Gilead access agreement	Global
14 Jul 2025	WHO recommends injectable lenacapavir	Global
15 Jul 2025	NDoH accepts Global Fund offer to procure	National
4 Sep 2025	NEMLC recommends EML inclusion (conditional)	National
6 Oct 2025	WHO prequalification of first products	Global
27 Oct 2025	SAHPRA registers lenacapavir — first in Africa	National
18 Nov 2025	NEMLC/NDoH approve EML inclusion	National
Apr 2026 (planned)	Phase-one public-sector rollout (~300–360 clinics)	National
2027 (expected)	Generic procurement for public-sector purchase	National

Lessons for the ALIGN programme

Lenacapavir shows the system at its fastest: an expedited regulatory route built on global assessment, catalytic donor financing, prompt WHO and NEMLC policy action, and an introduction designed on top of an existing oral PrEP platform together compressed the path from trial results to registration into little more than a year. The hard part is what follows. Sustaining access as donor support tapers depends on EML inclusion translating into domestic budget and on generic pricing materialising from 2027, and the constrained initial supply has to be rationed through credible prioritisation. The case also reinforces a point common to the others — that registration and even strong acceptability do not guarantee uptake, which will turn on differentiated, stigma-sensitive delivery for the populations most at risk.

4. CROSS-CASE SYNTHESIS USING THE ALIGN FRAMEWORK

We analysed 22 retrospective health technology introduction cases, comprising 166 mapped decision points, using the ALIGN framework. The 22 cases analysed in this chapter include the 20 retrospective cases from the multi-case health policy analysis, the two retrospective deep-dive case studies (BPaL-L and GeneXpert), and exclude the prospective Umbiflow™ case, which is addressed separately in Section 2.2.8 and Annexure D.

Key Findings

- **P1 (Market data and evidence for decision-making)** was present in most decision points, particularly in HIV, TB, maternal health and immunisation platforms. However, evidence appraisal is not always synchronised with financing and procurement cycles.
- **P2 (Portfolio logic)** was applied selectively and unevenly. Bundled/pooled or comparative planning took place primarily in ART pathway integration, advanced HIV disease packages, maternal emergency bundling, contraceptive method mix decisions, diagnostic cascade alignment, and HPV delivery through the Integrated School Health Programme (ISHP) platform.
- **P3 (Whole-of-government coordination)** was the most consistently activated pillar, reflecting strong formal governance structures. Regulatory, guideline, and procurement systems are well established. Delays arise primarily from sequencing misalignment rather than the absence of governance. Direct monitoring and evaluation of the effectiveness of policy implementation and its health impacts are not fully institutionalised as part of the policy improvement cycle.
- **P4 (Whole-of-market engagement)** was most visible in HIV treatment (defiance campaign during a health crisis), updated drug-resistant TB regimen, harm-reduction for OST, donor-supported pilots, and emergency-response contexts (COVID), but remains less institutionalised outside these domains. There is a gap in institutionalised structures for engagement with health advocates in decision-making.

The most robust and predictable technology introduction pathways were observed when at least three ALIGN pillars were concurrently active within a coherent decision sequence.

Where the System Performs Best

Innovation introduction appears most predictable when surveillance and programme data are embedded in decision-making, portfolio bundling trade-offs are explicit, procurement cycles are aligned, and at least three ALIGN pillars operate concurrently within a coherent sequence. These conditions were most clearly observed in:

- ART platform optimisation and pathway integration
- Vaccine substitution and reinvestment within EPI
- Laboratory-based diagnostic scale-up (e.g., VL, reflex CrAg)

Where Fragmentation Occurs

Fragmentation most commonly occurs where tender cycles are misaligned with policy and guideline decisions; devices and capital goods lack an explicit portfolio framing; market engagement remains ad hoc outside crisis periods; and reinvestment logic is not systematically institutionalised within planning and budgeting processes.

Strategic Implications

Strengthening innovation introduction is less a question of creating new institutions than of reinforcing core system functions. Potential priorities include institutionalising focused portfolio review cycles; aligning appraisal and guideline decisions with procurement timelines; formalising cross-technology reinvestment logic; and embedding structured, whole-of-market engagement beyond periods of crisis.

Reinforcing these pillars in combination may strengthen policy, financing, and advocacy enablers - supporting more deliberate, data-informed, and system-aligned decisions on innovation introduction and scale-up.

Note: Refer to page abbreviations list for an explanation of the abbreviations and acronyms.

4.1. Analytic framing

This assessment analysed 22 health technology cases across medicines, vaccines, devices, and diagnostics. Across these cases, 166 discrete decision points were identified, time-ordered, and mapped against the four ALIGN pillars as defined by Lanthorn et al (2025) and operationalised in Annexure A/B.

Definitions Applied in This Analysis

Pillar 1 (P1): Market Data and Evidence for Decision-Making: Systems that integrate timely, trusted, and forward-looking data on demand (burden, utilisation, preferences), supply (pipeline, product availability), and system capacity (workforce, supply chain, infrastructure), enabling comparative assessment and trade-off decisions.

Pillar 2 (P2): Portfolio-Based Logic: Processes that coordinate, bundle, pool, substitute, or sequence related innovations across a programme area to optimise impact, coherence, and efficiency. Portfolio logic leverages shared characteristics such as type of innovation, population served, delivery platform, financing envelope, or point of care to reduce duplication and align investments.

- P2 **was coded only** when a decision was explicitly:

1. **Bundled** two or more related innovations into a coordinated package of care within a defined programme platform (e.g., CrAg screening integrated with pre-emptive fluconazole therapy and ART within the advanced HIV disease package); or
2. **Substituted, sequenced, or reallocated resources** across innovations within the same programme portfolio (e.g., substitution of PCV13 with PCV10 with reinvestment to support Tdap procurement within EPI); or
3. **Positioned a new product within an existing shared delivery platform or clinical cascade** in a way that improved coherence and reduced duplication (e.g., DTG integration across adult, maternal, and PMTCT ART pathways).

- P2 was **not applied to** routine programme scale-up, general optimisation discussions, comparative clinical trade-offs without cross-product bundling, or single-product implementation without portfolio reconfiguration.

Pillar 3 (P3): Whole-of-Government Coordination and Capacity: Deliberate alignment across ministries, departments, regulatory authorities, procurement entities, and levels of government to ensure sequencing of approvals, budgeting, guideline updates, and implementation planning.

Pillar 4 (P4): Whole-of-Market Engagement: Structured engagement between government and actors beyond government, including civil society, professional bodies, private providers, industry, donors, and funders, to inform prioritisation, surface constraints, improve accountability, and strengthen rollout feasibility.

4.2. Findings

4.2.1. Observations Across the Four ALIGN Pillars

Across 22 cases and 166 documented decision points, the ALIGN framework reveals a patterned but uneven distribution of governance activity across the four pillars. All pillars are visible; however, their intensity, function, and mode of activation differ. The cases demonstrate a system that is comparatively strong in generating and using data for prioritisation (P1) and in coordinating across government structures (P3); more selectively engaged in deliberate portfolio optimisation (P2); and variably structured in engagement with actors beyond government (P4).

Rather than operating sequentially, the pillars function as overlapping governance logistical domains. In many cases, two or more pillars are applied simultaneously, for example, when new epidemiological evidence (P1) triggers interdepartmental coordination (P3), or when donor/ civil society engagement (P4) intersects with programme reconfiguration (P2).

• Pillar 1 (P1): Market Data and Evidence for Decision-Making

P1 is the most consistently observed pillar across the dataset. Decision points frequently draw on integrated assessments of disease burden and surveillance trends, utilisation and programme performance, product pipeline and regulatory developments, safety signals, affordability and budget impact, and infrastructure and workforce readiness.

Across cases, P1 commonly included:

- surveillance and audit data (e.g., GERMS-SA/ NICD, HIV indicators, neonatal and maternal audits)
- trial evidence and global normative guidance

- regulatory status and product availability
- cost and budget impact analysis
- system-readiness assessments
- and less so, civil society demand

P1 often operated as a risk-management function. In high-burden contexts (e.g., advanced HIV disease, postpartum haemorrhage, cervical cancer prevention), data shaped urgency and implementation sequencing. In other cases, emerging safety signals or uncertainty (e.g., DTG in pregnancy, TAF in specific subpopulations) required repeated reassessment of benefit–risk trade-offs.

The strength of P1 suggests an established culture of evidence-informed deliberation, particularly in HIV, TB, maternal health, and immunisation platforms. However, forward-looking market intelligence (e.g., anticipating pipeline entrants, pricing trajectories, tender readiness) remains less consistently embedded.

• Pillar 2 (P2): Portfolio-Based Logic

P2 appears more selectively and only where explicit portfolio reconfiguration occurred. Because coding required deliberate bundling, substitution, sequencing, or integration within a shared programme platform, routine scale-up did not qualify as part of the portfolio-based approach.

Where present, P2 reflects deliberate efforts to optimise coherence and efficiency within defined programme envelopes. Examples include:

- **Integrated disease and care portfolios**: Portfolio logic was applied by bundling and sequencing related interventions across prevention, treatment, and diagnostic pathways (especially in HIV/TB and maternal care).
- **Platform-based integration:** New technologies were commonly introduced through existing service-delivery platforms (rather than standalone programmes) to improve coherence and reduce duplication.
- **Resource optimisation and reinvestment:** Portfolio decisions also occasionally supported substitution, prioritisation, and reinvestment within constrained budgets (e.g., PCV13 substituted with PCV10 with savings reinvested in expanding the EPI programme with Tdap procurement).

P2 decisions were typically fiscally and operationally strategic, leveraging shared delivery platforms (ANC, EPI, ART, school health, NHLS workflows), financing envelopes, or target populations to reduce fragmentation.

However, P2 remains comparatively infrequent relative to P1 and P3. Many innovations were introduced as discrete additions rather than through portfolio rebalancing. This suggests that while programme-specific optimisation occurs, portfolio governance is not yet systematically institutionalised across all domains.

Operationalising portfolio logic within existing committee processes

Although P2 appears selectively in the mapped decision points, case evidence shows that portfolio thinking is often built into routine technical appraisal processes, rather than treated as a separate function. Committees such as the National Essential Medicines List Committee (NEMLC) and the National Advisory Group on Immunisation (NAGI) typically review multiple treatment or product options within a programme area, weighing factors such as effectiveness, safety, cost, and feasibility.

In practice, this leads to implicit portfolio optimisation within programme-level decisions. For example, ART policies are set across different regimen options (e.g., TDF- vs TAF-based backbones aligned with DTG), contraceptive technologies are introduced as part of a broader method mix, and vaccine decisions are made within the EPI platform, including choices about substitution and reinvestment. Overall, this suggests that portfolio logic is already in use, but not formally recognised or applied as a cross-cutting planning function, and is instead embedded within programme-specific governance and decision-making processes.

• Pillar 3 (P3): Whole-of-Government Coordination and Capacity

P3 is the most commonly represented pillar across the cases. Introducing or modifying innovations routinely required alignment across multiple state actors, including:

- National technical advisory committees
- Regulatory authorities
- Treasury and budgeting structures
- Procurement entities
- National and provincial departments of health
- Laboratory and surveillance institutions
- Implementation platforms and professional governance structures

P3 was particularly evident where sequencing across decision stages was critical. This included regulatory approval preceding STGs/EML inclusion, guideline revision preceding procurement, and tender timing shaping the feasibility of national rollout. In decentralised contexts, national–provincial coordination was essential to ensure consistency and avoid inequitable implementation. In emergency contexts (e.g., COVID-19 diagnostics and respiratory support), P3 activity was intensified, with compressed timelines and rapid coordination across disaster management, regulatory, clinical governance, and supply chain systems.

Overall, P3 reflects a well-established governance architecture capable of aligning approvals, financing, and implementation across levels of government. Its consistent presence suggests that intergovernmental coordination is a core system strength.

Structure of intra-governmental coordination

The consistent activation of P3 reflects the presence of well-established, formal coordination structures across the policy cycle, operating at technical, policy, and implementation levels. Decision-making typically followed a sequenced, multi-tiered process, rather than a single coordinating platform. At the national level, technical appraisal was undertaken through expert committees (e.g., NEMLC, NAGI); policy endorsement and intergovernmental alignment occurred through structures such as the National Health Council, which links national and provincial decision-making on financing, procurement, and implementation.

Coordination is further distributed across:

- **Programme and advisory structures** (e.g., HIV, TB, maternal health technical working groups and think tanks), supporting guideline development and contextualisation.
- **Regulatory and procurement systems** (e.g., SAHPRA, National Treasury, transversal tender processes), enabling market authorisation and market entry.
- **Provincial and facility-level governance mechanisms**, including pharmaceutical and therapeutics committees and capital equipment/bid committees, which align procurement and service delivery decisions.

This indicates that coordination is highly institutionalised but functionally distributed, with different structures responsible for sequential stages of decision-making and implementation.

- ## Pillar 4 (P4): Whole-of-Market Engagement

P4 captures structured engagement with actors beyond government, including civil society, donors, industry, professional bodies, private providers, and funders. Its presence varied by sector.

P4 was most prominent in:

- HIV/TB and advanced HIV access pathways
- Harm reduction and OST service development
- Donation-based and market-shaping pathways
- Emergency responses
- Cases where professional or external technical networks generated feasibility evidence

Engagement served multiple functions:

- Mobilising political and civil society momentum
- Strengthening accountability and legitimacy
- Generating real-world feasibility data
- Surfacing implementation constraints
- Negotiating access, pricing or donation agreements
- Enabling coordinated rollout and phased expansion across national and provincial levels

However, P4 was not uniformly structured across all innovations. In many device and routine procurement cases, engagement remained largely internal to the government. This suggests that whole-of-market engagement is most pronounced where external actors are organised, financially influential, or politically catalytic, but is less systematically embedded in routine technology introduction pathways.

Platforms for whole-of-market engagement

P4 operates through a combination of formal consultation platforms and context-specific mechanisms, rather than a single institutional structure. Structured engagement is most evident in:

- **National strategic planning processes** (e.g., NSP development), which convene government, civil society, donors, and technical partners around shared priorities
- **Global and national multi-stakeholder platforms** (e.g., FP2030), shaping policy direction and implementation approaches in areas such as family planning

- **Programme-specific advisory and technical collaborations**, including partnerships with professional bodies, research institutions, and implementing partners

In addition, less formalised pathways, such as civil society advocacy, donor-supported pilots, and emergency coordination platforms (e.g., COVID-19 response), play an important role in shaping access, feasibility, and scale-up.

Overall, these findings indicate that while whole-of-market engagement is influential in agenda-setting, access negotiation, and implementation, it remains unevenly institutionalised and often episodic, particularly outside high-priority or crisis contexts.

4.2.2. ALIGN Pillar Application Across Cases

A summary of the application of the ALIGN pillars across the cases is presented in Table 6, and is described in detail in Annexure B.

Table 6. Frequency and Strength of ALIGN Pillars Across 22 Cases (n = 166 decision points)

ALIGN Pillar	Decision points (n)	Overall Application	Most active application	Where least applied	Interpretation
P1 – Market data or evidence for decision-making	94	High	HIV/TB platforms (ART optimisation, VL, CrAg, BpAL, GenExpert); Vaccine substitution (PCV); Safety signal responses (DTG)	Devices; early emergency authorisations	Technical appraisal capacity is well established, particularly in communicable disease platforms, though less consistently embedded in capital equipment domains.
P2 – Portfolio logic	19	Targeted, selective	ART backbone optimisation; PCV substitution and Tdap reinvestment; Advanced HIV cascade; Contraceptive method mix	Devices; standalone introductions	Portfolio optimisation is applied strategically in mature programme platforms, but is not yet institutionalised system-wide
P3 – Whole-of-government coordination	123	Very high	STGs/EML decisions; SAHPRA sequencing; Treasury transversal tenders; Guideline integration	Tender timing misalignment; operational lag post-adoption	Governance decision-making architecture is robust and consistently activated, serving as the structural backbone of technology introduction
P4 – Whole-of-market engagement	20	Episodic	HIV, TB and harm-reduction cases; Donor-supported pilots; COVID-19 emergency response	Routine guideline updates; device procurement	Engagement with civil society, donors, and private actors is influential when activated but not uniformly institutionalised

Table 6 demonstrates that whole-of-government coordination (P3) is the most consistently activated pillar across the 123 decision points, followed by market data/evidence (P1), with 94 decision points. Whole-of-market engagement (P4) was less frequently present (20 decision points) and concentrated in specific domains (notably HIV, harm reduction, donor-supported pilots, and emergency contexts). Portfolio logic (P2) (19 decision points) was also less frequently observed and remained selective rather than routine. These patterns suggest that while the system is procedurally robust and evidence-informed, greater institutionalisation of portfolio optimisation and structured market engagement could enhance coherence and predictability.

While Table 6 describes the frequency of each ALIGN pillar individually, Table 7 assesses how the pillars combine within single decision points. This configuration analysis provides insight into the dominant governance patterns through which innovations move, highlighting whether decisions are primarily evidence-driven, coordination-led, portfolio-optimised, market-engaged, or some combination thereof. Table 7, therefore, shifts the focus from pillar presence to governance decision-making architecture in practice.

Table 7. Cross-Pillar Combination Patterns (n = 166 decision points)

ALIGN Pillar Combination	Decision points (n)	Relative frequency	Typical case example(s)	System performance pattern
P1 + P3	46	Most common	TAF early reviews; Noradrenaline; Vaccine updates; TXA reassessments	Evidence-informed decisions progressing through formal governance channels
P1 + P2 + P3	8	Selective	DTG pathway integration; TAF targeted optimisation; PCV substitution/reinvestment; TXA bundling in E-MOTIVE; TB-LAM integration	Evidence-informed portfolio optimisation executed through formal governance pathways; among the most coherent and predictable introduction sequences
P2 + P3	8	Targeted	HPV; reflex CrAg integration; contraceptive method-mix; apnoea monitor equipment-package bundling	Deliberate portfolio integration/bundling within established governance processes
P3 + P4	11	Episodic	Fluconazole access pathway; COVID Ag-RDT rollout; methadone OST implementation and agenda-setting	Government coordination shaped by donor, civil society, private-sector, or partner engagement
P1 + P4	3	Rare	3HP donor-supported pilots/ demonstration projects; HHFNO Western Cape feasibility pilots	Agenda-setting and evidence generation are influenced by external actors before full intergovernmental activation
P2 + P3 + P4	2	Very rare	COVID Ag-RDT donation integration within the national testing cascade	Coordinated portfolio optimisation with structured stakeholder engagement

P1=Market data or evidence for decision-making
P2=Portfolio logic
P3=Whole-of-government coordination
P4=Whole-of-market engagement

Dominant decision-making configuration: Evidence + government coordination (P1 + P3)

Table 7 shows that the dominant configuration is P1 + P3 (Market data or evidence for decision-making + Whole-of-government coordination; n=46 decision points). This indicates that most innovations are evidence-informed and progress through established coordination mechanisms, without necessarily incorporating portfolio reconfiguration or structured market engagement. This represents the system's prevailing decision-making architecture in this data set.

Selective use of portfolio logic (P2-inclusive configurations)

Portfolio-inclusive configurations are more selective. The combination of P1 + P2 + P3 (Market data or evidence for decision-making + Portfolio logic + Whole-of-government coordination; n=8 decision points) reflects the most structurally aligned pathway, integrating market data and evidence, portfolio optimisation, and coordinated execution. P2 + P3 (Portfolio logic + Whole-of-government coordination; n=8 decision points) similarly demonstrates that portfolio logic was typically applied within established governance processes, rather than a standalone function, and often alongside evidence.

Targeted but non-systematic role of market engagement (P4)

Configurations that included whole-of-market engagement (P4) were less frequent but played an important role in specific domains, particularly HIV and emergency response contexts, suggesting that structured stakeholder engagement is influential but not systematically embedded. P3 + P4 (Whole-of-government coordination + Whole-of-market engagement; n=11 decision points) reflects situations where government coordination is shaped or accelerated by civil society, donors, or private-sector actors. Less common combinations, P1 + P4 (Market data or evidence for decision-making + Whole-of-market engagement; n=3 decision points) and P2 + P3 + P4 (Portfolio logic + Whole-of-government coordination + Whole-of-market engagement; n=2 decision points), indicate that engagement can support early evidence generation or more integrated portfolio approaches, but is not systematically embedded across decision pathways.

Overall pattern: Limited but strategic integration across pillars

Overall, the dataset is dominated by one- and two-pillar configurations, with three-pillar alignment being selective and concentrated in cases where there is clearer portfolio integration and system-wide coordination. This suggests that while more integrated configurations exist, they are not the default mode of decision-making and tend to emerge in more complex or strategically prioritised interventions.

4.3. Discussion

The cross-case synthesis suggests that South Africa has a comparatively mature policy architecture for health technology introduction, but that system performance depends less on the presence of individual governance functions than on their timely and coordinated activation. Across the 22 cases and 166 decision points, evidence use and whole-of-government coordination emerged as the dominant decision-making pattern. This indicates a system with substantial technical appraisal capacity and established procedural mechanisms for regulatory review, guideline development, budgeting, procurement, and implementation planning.

However, the findings also suggest that evidence-informed and procedurally robust decisions do not necessarily produce coherent or timely implementation. The prevailing P1 (evidence) + P3 (whole-of-government coordination) configuration appears to support technical legitimacy and administrative execution but may be insufficient where innovations require explicit trade-offs across products, delivery platforms, or financing envelopes. In these situations, weakly institutionalised portfolio logic can result in fragmented sequencing, delayed procurement readiness, or missed opportunities for substitution, bundling, and reinvestment.

Portfolio logic (P2) was most evident in mature programme platforms, including ART optimisation, immunisation, laboratory diagnostics, and selected maternal health interventions. These platforms appear better able to use routine data, defined delivery channels, and established review cycles to compare options, sequence adoption, and integrate new technologies into existing service models. By contrast, devices and capital equipment were less consistently embedded in portfolio-based planning, particularly where workforce, infrastructure,

maintenance, and lifecycle costs were not fully integrated into adoption decisions. This suggests that portfolio governance is present but remains unevenly formalised across technology categories.

Whole-of-market engagement (P4) also appears influential but episodic. In HIV, TB, donor-supported pilots, and emergency-response contexts, external actors helped shape agenda-setting, generate feasibility evidence, negotiate access, and strengthen accountability. However, outside these domains, engagement with civil society, professional bodies, funders, implementation partners, private providers, and industry was less systematically embedded. This pattern suggests that market engagement is often activated when political urgency, donor investment, or organised advocacy is present, rather than functioning as a routine component of the innovation pathway.

A key implication is that South Africa's principal challenge is not the absence of institutionalisation, but sequencing and integration. Delays and fragmentation appear to arise when regulatory approval, guideline revision, financing decisions, procurement cycles, and implementation readiness are not aligned. This is particularly important in a constrained fiscal environment, where technology introduction must increasingly be justified not only by clinical value, but also by affordability, opportunity cost, delivery feasibility, and system-wide coherence.

Strengthening the innovation pathway, therefore, requires targeted refinement of existing governance functions. First, portfolio review cycles should be more explicitly linked to medium-term expenditure planning, procurement calendars, and pipeline monitoring. Second, appraisal and guideline processes should include earlier procurement-readiness and implementation-readiness checks. Third, reinvestment rules should be formalised so that savings from substitution, price reductions, or procurement efficiencies can be redirected transparently to programme strengthening. Fourth, structured whole-of-market engagement should be institutionalised beyond crisis settings, with clearer mechanisms for incorporating civil society, technical partners, funders, professional groups, and implementation actors into priority-setting and rollout planning.

Overall, the findings indicate that the ALIGN pillars are most powerful when applied as an integrated governance sequence rather than as discrete functions. Evidence confers technical legitimacy; portfolio logic improves allocative and delivery coherence; government coordination enables policy execution; and market engagement strengthens feasibility, accountability, and uptake. More consistent activation of these functions in combination could improve the predictability, efficiency, and equity of health technology introduction.

Policy implications

- **Planning.** Forward-looking portfolio planning appears most developed within ART, EPI, and selected NHLS-led diagnostic platforms, where routine review cycles and surveillance data support anticipatory decision-making. However, device and capital investment planning appears less consistently integrated with workforce capacity, maintenance systems, and infrastructure readiness. Horizon scanning for pipeline innovations remains uneven across programme areas, reducing the predictability of downstream evidence review, financing, procurement, and implementation planning. Institutionalising portfolio review cycles aligned with medium-term fiscal and Treasury planning horizons could improve predictability, resource sequencing, and readiness for innovation introduction.
- **Coordination.** The governance architecture for health technology introduction appears established and functional. However, sequencing misalignment, particularly between regulatory approval, STGs/EML updates, financing decisions, and tender cycles, may generate avoidable delays between policy adoption and implementation. Formalised interdepartmental sequencing protocols, including procurement and tender-readiness checkpoints, could reduce time-to-implementation and strengthen alignment across approval, budgeting, procurement, and rollout processes.
- **Financing predictability.** Pooled procurement and transversal mechanisms are well established in ART, EPI, and selected diagnostic platforms, supporting scale, price stability, and purchasing efficiency. However, tender-cycle timing variability, non-awards, and delayed market readiness can introduce financing uncertainty and slow implementation. Portfolio reinvestment logic, such as using vaccine savings to support broader schedule strengthening, is visible but remains episodic

rather than institutionalised. Multi-year, portfolio-based budgeting and reinvestment frameworks could strengthen portfolio planning, improve financing coherence, and increase predictability across innovation cycles.

Overall, the findings indicate that the ALIGN pillars are most powerful when applied as an integrated governance sequence rather than as discrete functions. Evidence confers technical legitimacy; portfolio logic improves allocative and delivery coherence; government coordination enables policy execution; and market engagement strengthens feasibility, accountability, and uptake. More consistent activation of these functions in combination could improve the predictability, efficiency, and equity of health technology introduction.

4.4. Conclusion

This analysis shows that South Africa has an established institutional foundation for introducing health technologies. Established technical advisory committees, regulatory processes, guideline systems, procurement mechanisms, and intergovernmental coordination provide a relatively mature framework for evidence-informed decision-making. This is particularly evident in programme areas with routine data systems, established review cycles, and mature delivery platforms, including ART, immunisation, and certain diagnostic pathways.

However, the findings also suggest that institutional capacity alone is insufficient for timely, effective, and implementation-ready technology introductions. The most predictable pathways were those in which multiple ALIGN pillars were activated together and sequenced effectively in a coordinated manner. This includes evidence-informed prioritisation, aligning regulatory and procurement steps, whole-of-government coordination and engaging with the market to strengthen feasibility and access.

The key policy message is therefore that South Africa does not necessarily require new parallel structures for introducing new innovations. Instead, the priority is to strengthen the sequencing, coordination, and institutional integration of existing functions across the full innovation pathway. This implies a shift from decision-making that is technically sound but often fragmented to a more deliberate and portfolio-based approach to governance that is ready for implementation. In practical terms, this requires systematic horizon scanning and regular portfolio reviews, closer coordination between appraisal and procurement cycles, clear checkpoints for procurement and implementation readiness, established mechanisms for reinvestment, and more structured engagement with market and implementation stakeholders.

Integrating these functions within existing policy, financing, and procurement processes could improve the predictability of introducing new technologies, improve value for money, and promote more equitable access to effective health technologies. The ALIGN framework outlines a clear reform agenda: rather than establishing additional institutional layers, it emphasises the disciplined integration of evidence, portfolio planning, financing, procurement, implementation readiness, and stakeholder engagement throughout the innovation lifecycle.

5. STAKEHOLDER FINDINGS: ROLES, GAPS, AND INFLUENCE DYNAMICS

5.1 Overview of the Stakeholder Ecosystem

The introduction of new health technologies in South Africa occurs within a complex ecosystem comprising government institutions, regulatory authorities, research organisations, development partners, industry actors, civil society organisations, and implementation structures operating across national, provincial, district, and facility levels (Leonard et al., 2018). This stakeholder analysis demonstrates that innovation adoption is not determined by a single decision-making body but rather by the interaction of multiple actors whose mandates span evidence generation, regulation, financing, procurement, implementation, monitoring, and community engagement(Lehoux et al., 2017; Silva et al., 2018).

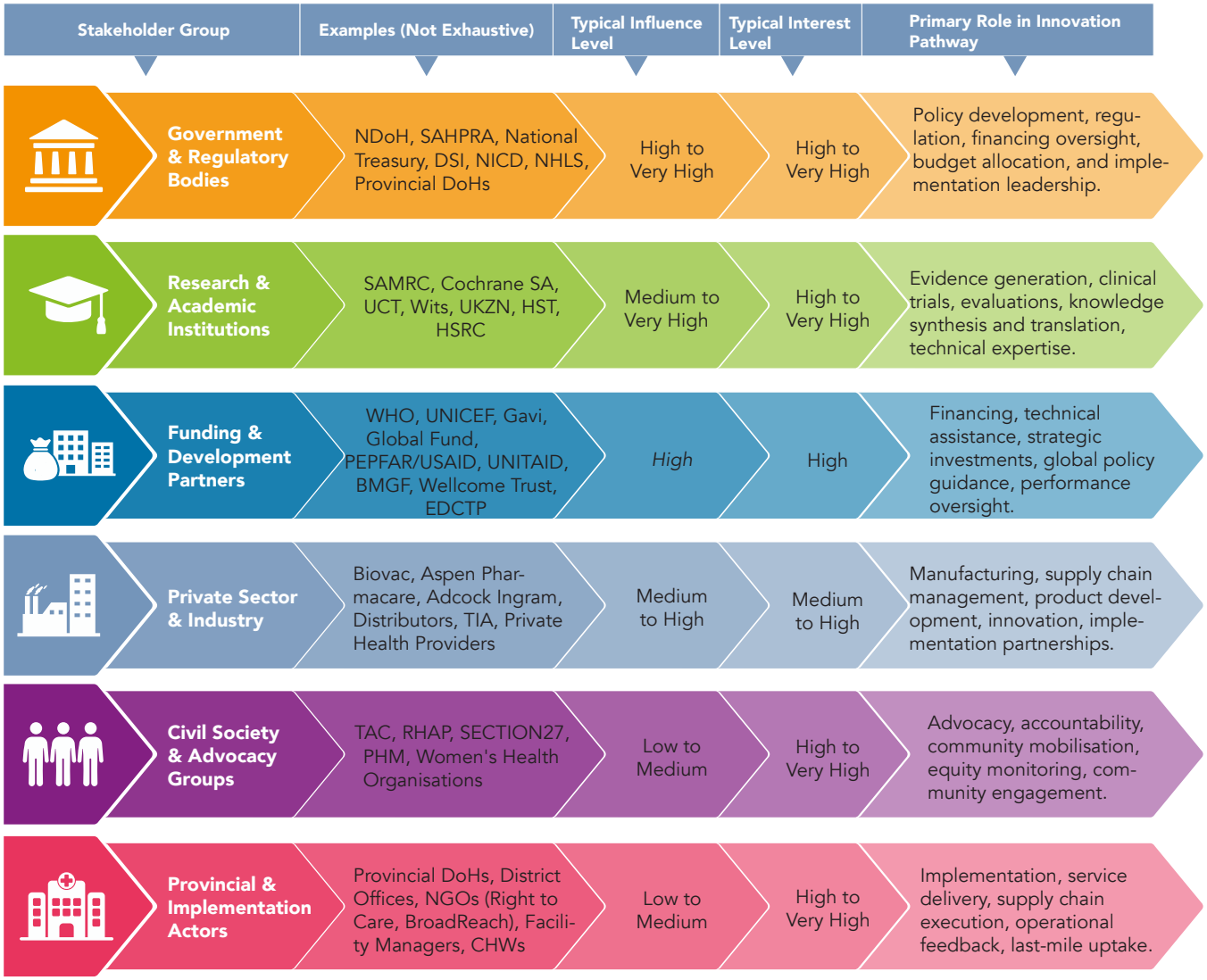
Consistent with findings from the broader landscape assessment, health technology introduction follows a non-linear pathway characterised by multiple decision points and interdependencies. While South Africa possesses a relatively mature governance architecture for health technologies, successful innovation uptake depends on alignment across regulatory approval processes, policy adoption mechanisms, financing arrangements, procurement systems, and implementation capacity. **The stakeholder mapping exercise revealed that many delays observed during technology introduction are not attributable to a lack of evidence or policy support, but rather to gaps in coordination between institutions operating at different stages of the innovation lifecycle**.

Stakeholders were grouped into six broad categories reflecting their primary functions within the health innovation ecosystem (Figure 5.1): Government and Regulatory Bodies; Research and Academic Institutions; Funding and Development Partners; Private Sector and Industry; Civil Society and Advocacy Organisations; and Provincial and Implementation Actors. Although each group contributes unique expertise and authority, their effectiveness ultimately depends on the quality of interactions and coordination mechanisms between them.

Figure 5.1: Stakeholder Ecosystem Map

Figure 5.2 maps the six stakeholder categories according to their typical level of influence and interest within the South African public health innovation ecosystem, reflecting how authority, engagement, and primary function vary across the system. The findings indicate that stakeholder influence is unevenly distributed across the system. Some institutions exercise significant authority over strategic decisions, financing, and regulatory approval, while others exert influence through implementation experience, technical expertise, advocacy, or community engagement. Understanding these dynamics is critical for strengthening innovation governance.

Figure 5.2: Summary Stakeholder Categorisation and influence



Note: Influence and interest vary by context , disease area and stage of the innovation life cycle. Ratings reflect relative influence and interest within the South African public health innovation ecosystem.

5.2 Stakeholder Roles Across the Health Technology Introduction Pathway

The analysis demonstrated that stakeholder influence varies substantially across the stages of health technology introduction. At the earliest stages of innovation development, research institutions, universities, product developers, and funding partners play central roles in generating evidence, conducting clinical trials, and identifying promising technologies for future adoption (Blanco et al., 2023). Institutions such as the South African Medical Research Council (SAMRC), Cochrane South Africa, universities, and development partners contribute critical evidence that informs subsequent policy and regulatory decisions (Edwards et al., 2019; Stewart et al., 2019).

As technologies progress towards regulatory review, the role of the South African Health Products Regulatory Authority (SAHPRA) becomes increasingly prominent (Keyter et al., 2018, 2020). SAHPRA functions as a key gatekeeper within the innovation pathway, determining whether products meet the required standards for safety, quality, and efficacy. Regulatory approval represents a critical milestone; however, the stakeholder analysis demonstrates that approval alone does not guarantee adoption within the public health system (Lehoux et al., 2017).

Following regulatory approval, the focus of influence shifts from product safety compliance to systemic integration, with national policy and programme stakeholders becoming the primary drivers of adoption. The National Department of Health, comprising its Innovation and Research Directorate, HIV/AIDS and TB Directorate, and Maternal, Newborn and Child Health Directorate, serves as the strategic gatekeeper in this transition. These stakeholders are pivotal, as they determine whether an innovation is formally incorporated into national strategies, treatment guidelines, and service delivery programmes, transforming regulatory approval from a theoretical milestone into a tangible component of the public health system. These decisions are often informed by evidence reviews, programme priorities, health technology assessments, budget considerations, and implementation feasibility assessments.

Financing and procurement stakeholders emerge as particularly influential during the transition from policy adoption to implementation. National Treasury, donor agencies, development partners, and procurement entities shape the affordability and sustainability of innovation introduction. The landscape assessment consistently identified financing and procurement arrangements as the primary determinants of implementation timelines, often outweighing scientific evidence in significance. This reflects deeper structural fragmentation, wherein misaligned institutional mandates and the absence of a unified budgetary framework frequently create bottlenecks that impede adoption regardless of an innovation's demonstrated efficacy (Walwyn & Nkolele, 2018).

While the National Department of Health establishes the strategic framework for innovation adoption, implementation authority remains decentralised, largely concentrated within provincial health systems.

Provincial Departments of Health, district health offices, facility managers, and frontline healthcare workers ultimately determine whether nationally approved innovations are translated into routine service delivery. This finding highlights the importance of provincial engagement in innovation planning and explains why national approval does not necessarily result in rapid implementation across all provinces.

Civil society organisations, advocacy groups, and community representatives influence innovation introduction through mechanisms that differ from formal decision-making authority. These actors contribute to public accountability, demand creation, community acceptability, and equity considerations. Their involvement is particularly important for ensuring that technology introduction processes remain responsive to patient needs and community priorities.

Figure 5.3: Innovation Lifecycle and Stakeholder Roles

5.3 Influence Dynamics and Decision-Making Authority

The stakeholder analysis identified a relatively small group of institutions that possess both high decision-making authority and strong interest in innovation introduction. These stakeholders occupy critical positions within the governance ecosystem and directly influence whether innovations advance through the adoption pathway.

The National Department of Health emerged as the most influential stakeholder across all technology categories. Through its policy leadership role, the Department determines strategic priorities, oversees programme implementation, establishes national guidelines, and ultimately decides whether innovations are integrated into routine health services. Within the Department, programme-specific directorates serve as important entry points for innovation adoption and frequently act as champions for technologies aligned with national priorities.

SAHPRA, while primarily focused on regulatory functions, also exerts considerable influence on innovation timelines. Regulatory review processes often represent the first formal gateway within the introduction pathway, and delays at this stage may have downstream implications for policy adoption and procurement planning.

The South African Medical Research Council occupies a unique position within the ecosystem. Beyond its role in evidence generation, SAMRC functions as a trusted intermediary between research, policy, and implementation stakeholders. This position enables

the organisation to facilitate evidence-informed decision-making and support coordination across traditionally fragmented institutional boundaries.

Development partners such as WHO, UNICEF, Gavi, Global Fund, and PEPFAR also emerged as influential actors. Their influence extends beyond financing and includes technical guidance, implementation support, evidence generation, and participation in policy dialogue. In several case studies reviewed during the landscape assessment, donor-supported innovations progressed more rapidly because financing, technical assistance, and implementation support were available simultaneously.

At the opposite end of the spectrum, civil society organisations, district-level structures, and community representatives generally possess limited formal decision-making authority but demonstrate consistently high interest in innovation introduction. Although these stakeholders rarely determine adoption decisions directly, they significantly influence implementation success, community uptake, and accountability processes.

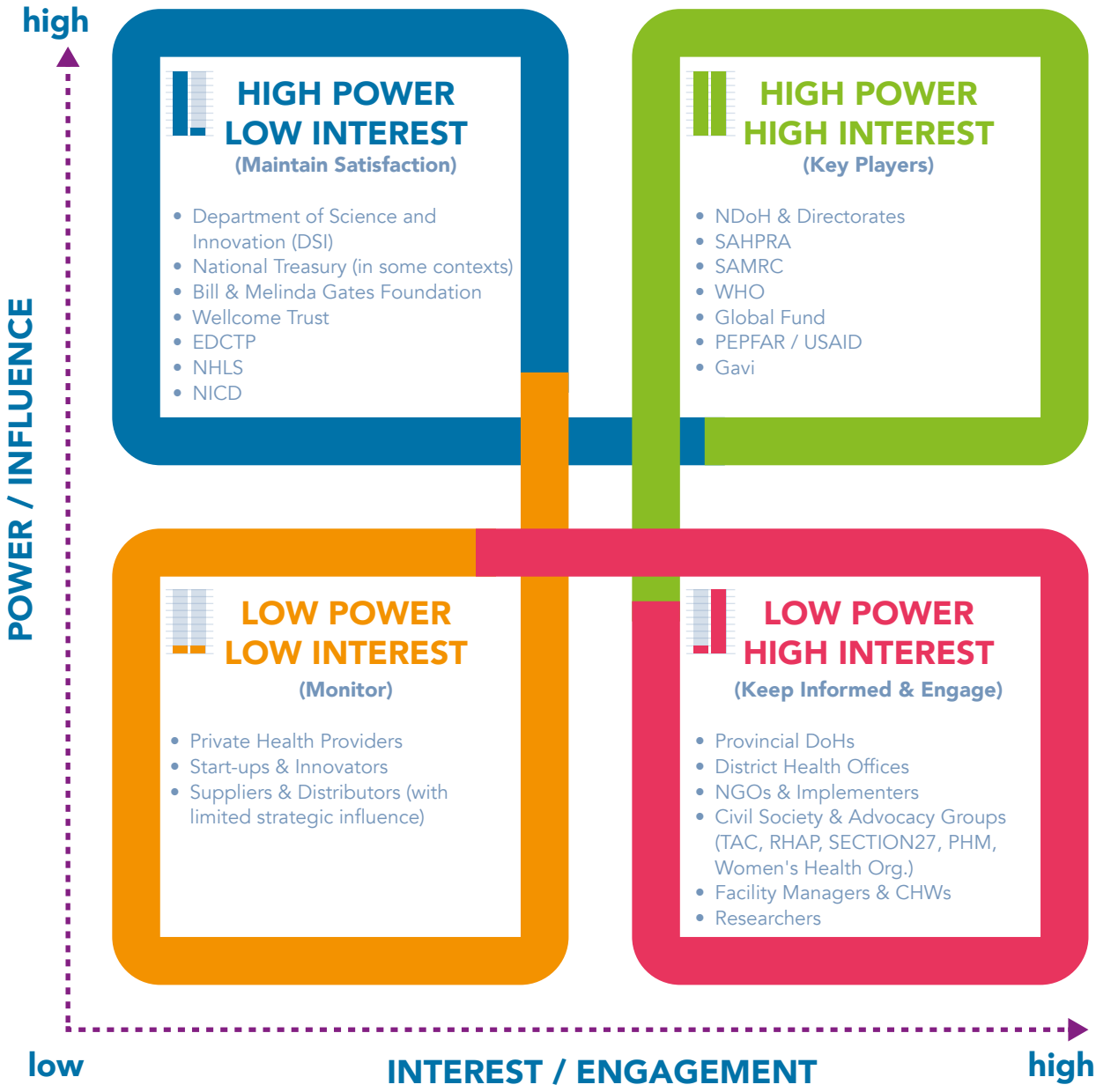


Figure 5.4: Power–Interest Matrix

5.4 Coordination Gaps and System Bottlenecks

A core finding emerging from the stakeholder analysis is that the health innovation ecosystem remains deeply fragmented, persisting despite the presence of formal governance structures (Desveaux et al., 2019). Stakeholders frequently operate within organisational silos, a structural condition that fundamentally hinders systemic efficiency. This misalignment manifests in persistent duplication of effort, protracted decision-making cycles, and a systemic inability to leverage collaborative opportunities, ultimately stalling the translation of innovation into routine service delivery. Specifically, the lack of alignment between health departments and industry-focused entities often results in policy incoherence, as each body pursues divergent mandates without a unified budgetary framework (Walwyn & Nkolele, 2018). Moreover, the absence of functional synergy between development partners and local governance systems creates significant service delivery gaps, particularly in regions where donor support is inconsistently distributed according to disease prevalence.

The most profound coordination gap exists between national decision-making authorities and provincial implementation systems. While national stakeholders are responsible for policy development, guideline updates, regulatory oversight, and financing negotiations, provincial departments retain substantial responsibility for implementation planning, budgeting, workforce deployment, and service delivery. This functional bifurcation often creates significant implementation bottlenecks; the lack of early, systematic engagement with provincial actors, who possess granular knowledge of facility-level constraints, frequently results in national policies that are misaligned with local operational realities, thereby delaying the translation of innovations into routine service delivery. Furthermore, the integration of these innovations necessitates a more holistic HTA approach that actively bridges the gap between high-level policy formulation and the practical, context-specific constraints encountered at the district level (Hollingworth et al., 2021).

A further recurring challenge is the siloed nature of innovation planning, specifically the inadequate integration of financing and procurement stakeholders. Stakeholder interviews and document reviews consistently indicate that critical requirements, such as affordability, budget impact, procurement feasibility, and supply chain readiness, are often relegated to post-policy phases rather than being embedded within initial discussions. Consequently, while technologies may secure strategic policy support, they frequently encounter significant implementation delays due to unresolved financial or procurement impediments.

To mitigate these risks, it is imperative that financing and operational oversight be integrated earlier in the innovation lifecycle to ensure that policy aspirations remain tethered to fiscal and logistical realities. This necessitates the establishment of formalised coordination bodies capable of aligning HTA outcomes with national health agendas and procurement mandates (Fontrier et al., 2021). Such institutionalization could mirror strategies currently being explored in other contexts, where forming advisory committees serves to bridge the divide between evidence generation and actual budget allocation (Jugathpal et al., 2023). Furthermore, establishing cross-institutional communication channels is essential for bolstering a country's capacity for HTA research, ensuring that localized evidence effectively informs national-level decision-making (Aryankhesal et al., 2024).

The analysis also identified limited engagement between public sector decision-makers and market actors. Manufacturers, distributors, and private sector innovators are frequently consulted only after key decisions have been made. Earlier engagement could improve forecasting, facilitate local manufacturing opportunities, strengthen supply chain planning, and support more realistic implementation timelines.

Civil society participation represents another area requiring improvement. While many stakeholders acknowledged the value of community engagement and patient perspectives, consultation mechanisms remain inconsistent and largely dependent on individual programmes. This limits opportunities to identify implementation barriers, address equity concerns, and strengthen accountability throughout the innovation lifecycle.

Figure 5.5: Coordination Gaps Across the Innovation Pathway

5.5 Stakeholder Network Dynamics

The stakeholder ecosystem functions as a complex adaptive network characterised by multiple formal and informal relationships. Strong linkages currently exist between regulatory agencies, national policy structures, development partners, and research institutions. These relationships support evidence generation, policy development, and regulatory review processes and contribute to South Africa's ability to introduce new technologies at scale.

However, the analysis identified several relationships that remain weak or underdeveloped. Interactions between Treasury and implementation stakeholders are often indirect, reducing opportunities to align budgeting decisions with operational realities. Similarly, communication between market actors and government stakeholders is frequently episodic rather than systematic. Relationships between national planning structures and provincial implementers also require strengthening to reduce implementation delays and improve operational readiness.

These findings suggest that stakeholder relationships should be viewed as a strategic asset within the innovation ecosystem. Strengthening connections between stakeholder groups may yield greater improvements in innovation uptake than focusing solely on individual institutional performance.

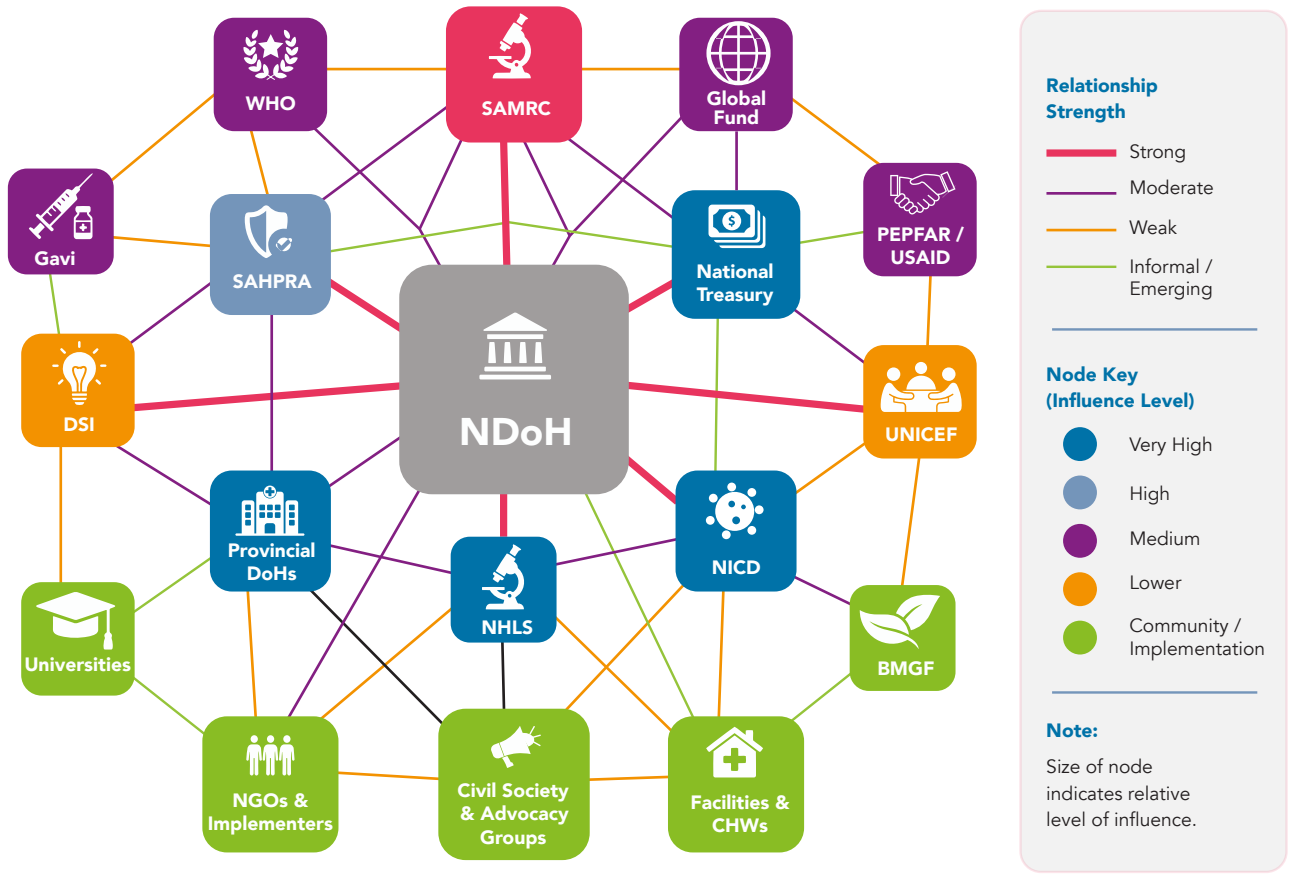


Figure 5.6: Stakeholder influence mapping

5.6 Implications for ALIGN

The stakeholder findings offer a robust justification for the establishment of the ALIGN framework and its associated coordination mechanisms. The analysis underscores that the most critical barriers to innovation are not inherent to any single institution but are systemic, stemming from entrenched organisational silos, fragmented decision-making, and critical disconnects between national planning and provincial implementation. By addressing these

structural coordination failures, the ALIGN model provides the necessary strategic framework to bridge institutional boundaries, harmonise stakeholder interests, and foster a more integrated, responsive health innovation ecosystem.

This transition toward a cohesive governance architecture necessitates a shift from hierarchical oversight to adaptive collaborative mechanisms that leverage the diverse expertise of both public and private actors (Hlongwane & Grobbelaar, 2022; Sibuyi et al., 2020). Furthermore, this transition must actively address the prevailing gaps in broad-based participation to ensure that innovation policies are filtered effectively across all levels of the system, thereby reducing misunderstandings regarding institutional roles and responsibilities (Mbuyazi et al., 2025). Such an iterative approach to governance acknowledges the dynamic nature of these stakeholder ecosystems and ensures that policy design remains adaptable to evolving social and economic conditions.

Moreover, institutionalising these participatory frameworks requires ongoing, evidence-based stakeholder mapping to ensure that power structures remain aligned and that divergent interests are consistently harmonised throughout the policy implementation lifecycle (Meymand et al., 2025). Such bridging factors are essential for institutionalizing these domain-spanning linkages, ensuring that the necessary relational and formal structures are in place to translate high-level strategies into operational success across both the outer and inner contexts (Crable et al., 2022).

The proposed ALIGN project is well positioned to serve as a central convening mechanism capable of connecting evidence producers, regulators, policymakers, funders, implementers, and community representatives. By facilitating these cross-sector interactions, the ALIGN project acts as a critical "bridging factor" (Crable et al., 2022) that mitigates the systemic fragmentation currently characterising the innovation ecosystem (Mbuyazi et al., 2025). This function is essential for transforming siloed, episodic relationships into adaptive collaborative governance, ensuring that diverse expertise is synthesised to align policy, budgeting, and procurement with operational realities (Hlongwane & Grobbelaar, 2022; Meymand et al., 2025). By creating structured platforms for engagement, ALIGN can improve information sharing, strengthen alignment between decision-making processes, and reduce fragmentation across the innovation pathway.

The findings further suggest that stakeholder engagement must be strategically differentiated according to influence, function, and the capacity for collaborative value creation (Hlongwane & Grobbelaar, 2022). Aligning high-power stakeholders with formal governance mechanisms ensures necessary strategic oversight and directional alignment. Simultaneously, the inclusion of implementation stakeholders, civil society organisations, and private sector actors via thematic working groups and the Stakeholder Forum addresses existing gaps in broad-based participation (Mbuyazi et al., 2025).

This structured, multi-tiered approach effectively harmonises divergent interests (Meymand et al., 2025) and ensures that innovation policies are filtered across the entire system, shifting from episodic engagement toward a more integrated and adaptive collaborative governance model. By fostering such multisectoral engagement, the ALIGN project acts as a learning incubator that promotes the development of co-creation skills across the innovation landscape (Sobral et al., 2024). Ultimately, this transition requires moving beyond top-down mandates to embrace distributed leadership models, where experimenters are empowered to facilitate dialogue and navigate the complexities inherent in scaling healthcare solutions (Côté-Boileau et al., 2019). This shift towards co-creation and equal partnerships is vital, as it enables the development of culturally pertinent, socially robust solutions that are better suited for diverse local contexts (Erismann et al., 2021). By adopting this intermediary role, the ALIGN project helps prevent risks associated with power asymmetries and conflicting incentives, ultimately acting as a catalyst for trust-based cooperation between traditionally disconnected sectors (Cresswell et al., 2020; Nonet et al., 2022).

Ultimately, strengthening stakeholder coordination represents one of the most important opportunities for improving health technology introduction in South Africa. Through enhanced collaboration, improved transparency, and more inclusive decision-making, ALIGN can contribute to a more responsive and efficient innovation ecosystem capable of accelerating equitable access to priority health technologies.

6. WHAT THIS MEANS FOR ALIGN IN SOUTH AFRICA

The picture that emerges across this assessment is of a health system that is technically capable but not consistently connected. South Africa has the advisory committees, regulatory processes, guideline systems and procurement mechanisms needed to introduce new health technologies, and it uses evidence well. What it lacks is the connective tissue that would carry an innovation from evidence through financing, procurement and provincial implementation without avoidable delay. This is the space ALIGN is designed to occupy, and its value lies less in building new institutions than in making the existing ones work together more deliberately.

Two gaps matter most for ALIGN to address. The first is the disconnect between national decision-making and provincial implementation, which is where nationally approved innovations most often stall. The second is the late entry of financing and procurement, which tend to be treated as downstream questions rather than weighed at the point of prioritisation. ALIGN can add the most value by working at these seams, bringing provincial implementers and the financing and procurement functions into prioritisation early so that decisions are made with delivery realities and fiscal space already in view.

The four ALIGN pillars map directly onto what the assessment found. The system is already strong on market data and evidence and on whole-of-government coordination, so ALIGN's contribution there is to sharpen forward-looking market intelligence and tighten the sequencing between appraisal, guideline and procurement cycles, rather than to duplicate appraisal capacity that already exists. The larger opportunity lies in the two pillars the system applies only selectively. Portfolio logic is used well within mature platforms such as the ART programme and the EPI, but it is not yet a routine discipline. It is weakest in the device and diagnostic domains, where no formalised prioritisation pathway exists, and this is where extending it has the most to offer. Establishing portfolio logic where the system has no standing mechanism, rather than where one already operates, is the clearest test of whether the approach can be embedded in government practice.

Whole-of-market engagement is activated mainly in crises or where donors are present and ALIGN can give it a standing structure that is matched to the different roles stakeholders play. High-power actors can be aligned with formal governance mechanisms to provide strategic oversight and direction, while implementers, civil society organisations and private sector actors are brought in through thematic working groups and the Stakeholder Forum. This differentiated approach widens participation where it is currently thinnest, giving funders, industry, implementers and civil society a predictable route into priority-setting and rollout planning rather than consulting them after decisions are taken. .

This positions ALIGN as a convening and bridging mechanism rather than another decision-making body. Its comparative advantage is the ability to connect evidence producers, regulators, the National Department of Health, the National Treasury, provinces, funders and communities around a shared view of the introduction pathway. The prospective cases make the opportunity concrete. The lenacapavir rollout and the preparation for adult TB vaccines are live tests of whether the country can align regulation, financing, procurement and delivery ahead of need rather than in sequence. These sit within pathways the system already runs for medicines and vaccines. The device domain offers the complementary test: applying the same portfolio logic where the coordinating pathway has yet to be built. Taken together, they show ALIGN working at both ends of the spectrum, strengthening coordination where mechanisms exist and helping to establish it where they do not. These are precisely the situations in which earlier, better-coordinated engagement, the work ALIGN is set up to do, can shorten the path from a licensed product to equitable access.

7. OVERALL CONCLUSIONS AND RECOMMENDATIONS

This assessment set out to map how new medicines, vaccines, diagnostics and medical devices move into South Africa's public health system, and to identify what helps and what hinders. The central conclusion is consistent across all four components of the work. South Africa has a mature, rule-based architecture for health technology introduction, anchored in established regulatory, advisory, financing and procurement institutions, and it makes good use of evidence. A sound architecture has not, however, translated into consistently timely or equitable introduction. The binding constraint is not a shortage of institutions or evidence, but the way they are sequenced and connected across the pathway from prioritisation to routine use.

The multi-case analysis and the ALIGN framework synthesis point the same way. Decisions are most often evidence-informed and routed through formal government coordination, a combination that confers technical legitimacy and orderly execution but is less effective where introduction depends on explicit trade-offs across products, platforms or budgets. Portfolio logic and structured engagement with actors beyond government are applied selectively rather than as routine functions, and the most predictable introductions were the rare cases where evidence, portfolio thinking, coordination and market engagement were activated together and in sequence. Delays, by contrast, clustered where regulatory approval, guideline revision, financing and procurement cycles fell out of step, and where devices and diagnostics lacked the portfolio framing that medicines and vaccines more often receive.

The stakeholder and case evidence sharpens the point. The deepest coordination gap lies between national decision-making and provincial implementation, where national approval most often fails to become service delivery, and financing and procurement are too often engaged only after policy is set. The four in-depth cases show both sides of this. BPaL-L and GeneXpert demonstrate how far decisive leadership and an existing platform can carry an innovation, while also exposing how readily implementation readiness, supplier concentration and post-introduction monitoring are left behind. The lenacapavir and adult TB vaccine cases show the system at its most anticipatory, and they bring the sustainability question to the fore: aligning regulation, financing and procurement ahead of need, and carrying access from donor support into domestic financing.

The practical implication is encouraging. Because the foundations are in place, strengthening introduction is largely a matter of disciplined integration rather than new structures. The recommendations below follow from the findings and are directed at the National Department of Health and its partners.

Recommendations

1. **Align appraisal, guideline and procurement cycles.** Build procurement- and implementation-readiness checks into appraisal and guideline processes, so that affordability, supply-chain feasibility and delivery capacity are weighed when a technology is prioritised rather than after it is adopted.
2. **Institutionalise portfolio review.** Establish regular, forward-looking portfolio review cycles linked to the medium-term expenditure framework and Treasury planning, extending the portfolio discipline already used in the ART programme and the EPI to the device and diagnostic domains where it is weakest.
3. **Close the national–provincial gap.** Bring provincial implementers into prioritisation and planning early, so that national decisions reflect facility-level constraints and provincial budgeting and workforce planning can begin before, not after, national adoption.
4. **Engage financing and procurement from the outset.** Treat financing and procurement as design inputs at the point of prioritisation, including demand forecasting, tender readiness and contingency for supplier or platform concentration.
5. **Make whole-of-market engagement routine.** Give civil society, implementers, funders and industry a standing role in priority-setting and rollout planning, rather than activating engagement only during crises or donor-supported pilots.
6. **Formalise reinvestment and post-introduction monitoring.** Set transparent rules for redirecting savings from substitution or price reductions to programme strengthening, and embed monitoring of uptake and health impact as a standard part of the introduction cycle.

7. **Plan for the donor-to-domestic transition.** For donor-catalysed introductions such as lenacapavir, plan the shift to domestic financing and procurement from the start, using Essential Medicines List inclusion and generic-pricing pathways to sustain access.

Taken together, these steps would move health technology introduction in South Africa from a process that is technically sound but often fragmented to one that is deliberate, coordinated and ready for implementation, strengthening the country's ability to translate innovation into equitable and sustainable access

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ANNEXURES

The following annexures are attached to this report:

Annexure A: Compendium of illustrative case studies

Annexure B: Detailed case timelines, mapped to ALIGN pillars

Annexure C: Stakeholder categories across all technology groups

Annexure D: Case study - Umbiflow™

Annexure E: Concept for ALIGN mapping tool

Annexure F: Relationship between ALIGN outputs and doctoral research

Annexure A: Compendium of illustrative case studies

This document is provided as background information to inform the cross-case synthesis. The Landscape Assessment reports synthesis only; this document is not an academic publication and is not intended for citation.

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Acknowledgements: We sincerely thank all key informants who participated in this study. Ethical approval was granted by the Stellenbosch University Health Research Ethics Committee (Ref: S25/03/046), and we received institutional permission to access relevant laboratory service information from the National Health Laboratory Service (Ref: PR2562944). Participation was entirely voluntary, and all contributors provided informed consent. We are grateful for the time, expertise, and thoughtful reflections shared by informants, as well as for their responsiveness to follow-up queries. Their contributions were essential to understanding the policy and health-system processes described in this work.

We also extend our sincere appreciation to Retsedisitsoe Prudence Mazibuko for her technical support. In addition, sincere thanks for the guidance, oversight, and scholarly mentorship provided by academic PhD supervisors, Prof Tamara Kredo, Prof Andrew G Parrish, and Prof Lumbwe Chola, whose critical insights and sustained support strengthened this work throughout its development.

A. Illustrative Descriptive Case Summaries – Medicines

1. 3HP (Rifapentine + Isoniazid) for TB Preventive Therapy (TPT)

Purpose of this Summary: This summary provides an overview of the policy and system pathway through which a short-course (3-month) tuberculosis preventive therapy regimen was considered and introduced within the South African public health system.

Innovation

- **Type:** Medicine (oral formulation)
- **Intended use:** Tuberculosis preventive therapy, particularly among people living with HIV

Policy and Health System Context

- TB prevention has been a longstanding national policy priority within HIV and TB programmes.
- Shorter preventive regimens were referenced in national strategic planning documents over time.

Time Period Covered: Approximately 2017 to 2025

Descriptive Pathway Overview

- 2017–2019: Short-course preventive therapy was referenced in national policy discussions and strategic plans, including a conditional target for scale-up of 3HP by 2022.
- **2018:** WHO recommended 3HP for TPT.
- **2019–2021:** Research trials, donor-supported pilot and demonstration projects in selected settings generated supportive evidence.
- **2019 & 2022:** NEMLC deferred inclusion of 3HP on the EML due to the absence of a registered fixed-dose combination (FDC) and budgetary constraints.
- **2019-2024:** Ongoing advocacy for 3HP uptake was undertaken by international & local donor and civil society organisations.
- **2022:** South African Health Products Regulatory Authority (SAHPRA) approved a FDC of 3HP.
- **2024:** 3HP was included in the national Standard Treatment Guidelines and Essential Medicines List (STGs/EML).
- **2025:** Nationally, public-sector procurement was initiated.

Current Status[8] (as of 2025)

- Regulatory status: Registered medicine
- Guideline status: Included in national programmatic guidelines and STGs/EML Implementation status: Phased scale-up underway

8 *Status reflects the most recent verified information available to the Landscape Assessment at the time of drafting and is reported for contextual reference only.*

2. Dolutegravir (DTG) as ART, among women of childbearing potential and pregnancy

Purpose of this Summary: This summary provides an overview of the policy pathway through which dolutegravir use in ART for HIV positive women of childbearing potential and pregnancy was considered within the South African public health system.

Innovation

- **Type:** Medicine (oral formulation)
- **Intended use:** Antiretroviral therapy, including for HIV positive women of childbearing age (WoCP) and use during pregnancy

Policy and Health System Context

- HIV treatment optimisation has been a national priority.
- ART guidance has evolved in response to emerging global and local evidence.

Time Period Covered: Approximately 2018 to 2024/5

Descriptive Pathway Overview

- **2018:** The Tsepamo study identified a safety signal indicating an increased prevalence of congenital neural tube defects associated with DTG exposure at conception.
- **2018–2019:** Initial WHO interim guidance that reflected caution regarding DTG use in WoCP and during pregnancy.
- **July 2019:** Expanded Tsepamo data showed attenuated risk leading to revision of WHO guidelines, recommending DTG for all populations, including WoCP and pregnant women.
- **2019:** South Africa incorporated DTG into national ART guidelines (initially cautioning WoCP using DTG to use reliable contraception).
- **2018–2020:** Ongoing review by NEMLC and advisory structures, initially retaining caution for WoCP and during pregnancy.
- **June 2021:** NEMLC removed restrictions and recommends DTG for all populations, including pregnant women.
- **2023:** Updated programmatic guideline recommendations were issued reflecting revised recommendations (including in pregnant/ breastfeeding women) with strengthened counselling and family planning integration.
- **2024:** Primary healthcare (PHC) STGs/EML were updated; Consolidation and system integration of DTG across maternal and adult care pathways.

Current Status (as of 2024/5)

- Regulatory status: Registered medicine
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Routine use within ART programme

3. Tenofovir alafenamide (TAF) for HIV treatment

Purpose of this Summary: This summary provides an overview of the pathway through which tenofovir alafenamide (TAF) was considered for use in public-sector HIV treatment for patients who cannot tolerate standard tenofovir disoproxil fumarate (TDF)–containing ART regimens.

Innovation

- **Type:** Medicine (oral formulation)
- **Intended use:** Antiretroviral considered as a subgroup alternative where TDF is contraindicated / intolerance risk

Policy and Health System Context

- Optimising ART regimens for HIV patients has been an ongoing policy objective, including those who are intolerant to standard 1st line ART.
- Consideration of newer formulations of ART, such as TAF, occurred alongside cost and procurement processes.

Time Period Covered: Approximately 2019 to 2024/5

Descriptive Pathway Overview

- **2015-2017:** Global regulatory approvals were granted, and TAF-based regimens were shown to be non-inferior to existing ART regimens, with improved renal and bone safety profiles.
- **2019:** First NEMLC review declined inclusion of TAF in national STGs/EML, citing the adequacy of TDF-based regimens; limited pregnancy data; and the absence of SAHPRA approval.
- **2019–2024:** Evidence systematically reviewed across treatment-naïve, treatment-switch, pregnancy, and renal/bone subpopulations; emerging considerations included rifampicin compatibility during TB co-treatment and signals of weight gain.
- **March 2022:** SAHPRA approved a TAF-containing FDC (Biktarvy®).
- **2022:** NEMLC again did not recommend TAF, due to uncertainty regarding safety in pregnancy and cost considerations.

- **2024:** NEMLC reviewed new evidence and recommended a conditional and restricted STG/EML inclusion for patients with contraindications to TDF, including HIV-associated renal impairment (eGFR 30–50 mL/min), reduced bone mineral density, and hepatitis B co-infection, with an additional renal-impairment pathway for non-HIV hepatitis B.
- **2024-early 2025:** Implementation remained delayed and limited; early access occurred primarily through tertiary-level services, clinical trials, or Section 21 mechanisms[9] (when registered TAF was not available on the South African market). Procurement contracts were awarded for December 2025–November 2028, with non-awards of certain TAF products as no tender bids were received.

Current Status (as of 2024/5)

- Regulatory status: Registered medicine
- Guideline status: Included for defined indications in national programmatic guidelines and STGs/EML
- Implementation status: Limited or phased use

4. Donated fluconazole for cryptococcal meningitis in advanced HIV care

Purpose of this Summary: This summary provides an overview of the role of fluconazole in cryptococcal meningitis (CM) management within the public health system.

Innovation

- **Type:** Medicine (oral formulation)
- **Intended use:** Treatment and prevention of CM, an opportunistic AIDS infection

Policy and Health System Context

- CM was a leading cause of mortality and morbidity among people with advanced HIV in South Africa.
- Lack of access to generic fluconazole in South Africa made accessible, critical preventive care for HIV unaffordable for the NdoH.
- Treatment protocols have evolved with the availability of fixed-dose antiretroviral combination regimens.

Time Period Covered: Approximately 2000 to 2022

Descriptive Pathway Overview

- **Pre-2000:** Patented Diflucan® was unaffordable; legal generic supply/importation was constrained by patent and regulatory barriers (TRIPS flexibilities debate as context).
- **2000:** Treatment Action Campaign (TAC), supported by Médecins Sans Frontières (MSF), launched the "Christopher Moraka Defiance Campaign"; activists also pursued Section 21/exceptional access and high-profile generic importation to highlight barriers.
- **December 2000:** Pfizer rejected voluntary licensing/pricing demands; offered Diflucan® donation programme.
- **2001–2002:** Agreement was formalised (2001) and extended; MCC approval enabled donation for CM and oesophageal candidiasis; the Diflucan Partnership Program (DPP) was established with NdoH, with training/distribution partners.
- **2001–2004:** Rollout was initiated in tertiary hospitals; scale-up to ~300 facilities within ~3 years; monitoring noted large volume dispensed and extensive health worker training.
- **2004:** Patent expiry reduced reliance on the donation route over time as generics/ART expansion evolved.
- **2007–2011** (global consolidation): WHO EML inclusion (2007/2009) and Rapid Advice was issued in 2011 for cryptococcal disease.
- **2018–2022:** WHO guidance emphasised CrAg screening and pre-emptive therapy in advanced HIV disease.

Current Status (as of 2022)

- Regulatory status: Registered medicine
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Routine use

5. Tranexamic Acid (TXA) for Post-Partum Haemorrhage at Primary Healthcare level

Purpose of this Summary: This summary provides an overview of the pathway through which intravenous (IV) tranexamic acid (TXA) was introduced for the management of post-partum haemorrhage (PPH).

9 *Under Section 21 of the Medicines and Related Substances Act in South Africa, the SAHPRA can authorise the sale of unregistered medicines, medical devices, or in vitro diagnostics to a specified person or institution for a specified period. This pathway is used when registered alternatives are unavailable, typically for emergency or specific patient needs, and requires an application and compliance with regulatory guidelines.*

Innovation

- **Type:** Medicine (injectable)
- **Intended use:** Management of PPH

Policy and Health System Context

- Reducing maternal mortality, particularly deaths due to obstetric haemorrhage, has been a national priority.
- Postpartum emergency obstetric care was largely hospital-based, necessitating strengthened PHC–level protocols to address maternal mortality.

Time Period Covered: Approximately 2018 to 2024

Descriptive Pathway Overview

- **2017–2018:** WHO recommended TXA for the treatment of PPH, based on emerging evidence, noting a time-dependent benefit when administered within three hours.
- **2017–2019:** NEMLC recommends TXA as a second-line intervention restricted to hospital settings; use at PHC was not recommended.
- **2022–2023:** A subsequent NEMLC review reaffirmed the hospital-only restriction for TXA use.
- **Early 2023:** The KwaZulu-Natal Pharmaceutical and Therapeutics Committee submitted a formal appeal, prompting an expedited reassessment.
- **March 2023:** An accelerated NEMLC review process was reopened.
- **June/July 2023:** NEMLC endorsed TXA IV (1 g) as part of the WHO-aligned E-MOTIVE first-response bundle across all levels of care, including PHC, subject to prior medical practitioner approval.
- **2024:** TXA was integrated into PHC STGs/EML; procurement contracts were awarded (2024–2027), with monitoring planned through Maternal Morbidity and Mortality Audit System (MaMMAS) and future Saving Mothers reports.

Current Status (as of 2024)

- Regulatory status: Registered medicine
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Available within emergency obstetric services

6. Noradrenaline compared to adrenaline for the management of septic shock in adults

Purpose of this Summary: This summary provides an overview of the review and declined use of noradrenaline versus adrenaline as first-line therapy within public-sector critical and emergency care for managing septic shock in adults.

Innovation

- **Type:** Medicine (injectable)
- **Intended use:** Emergency management of adult septic shock; requires IV infusion, intensive monitoring, specialised staff, and is costlier than adrenaline.

Policy and Health System Context

- Vasopressors (noradrenaline or adrenaline) are used to treat refractory hypotension in adult septic shock. Although noradrenaline is preferred internationally as a first-line vasopressor, adrenaline remains first-line in some LMIC settings due to feasibility and equivalent outcomes.
- In South Africa's NEMLC has historically recommended adrenaline (epinephrine), reflecting local considerations of cost, availability, and health system capacity

Time Period Covered: 2021-ongoing

Descriptive Pathway Overview

- **Pre-2020:** Adrenaline was established as the first-line vasopressor in South African public-sector guidance.
- **2021:** International guidance (Surviving Sepsis Campaign Guidelines update) strongly recommended noradrenaline as first-line therapy.
- **October 2023:** NEMLC determined not to adopt noradrenaline as first-line, citing no clinically important outcome advantage and significant feasibility, cost, and equity concerns.
- **March 2024:** Adult Hospital STGs/EML were ratified, reaffirming adrenaline as first-line therapy for septic shock unresponsive to fluid resuscitation.
- **Ongoing:** Use continues to be monitored, with future review dependent on stronger, context-specific evidence and improved health-system readiness.

Current Status (as of 2025)

- Regulatory status: Registered medicine
- Guideline status: Not approved as first-line

vasopressor in the STGs and EML for adult septic shock
- Implementation status: Not in routine use for management of adult septic shock in the public sector

7. Etonogestrel implant for family planning

Purpose of this Summary: This summary provides an overview of the policy pathway for introducing new generation long-acting reversible contraceptive (LARC) technology, the etonogestrel contraceptive implant.

Innovation

- **Type:** Medicine (device-mediated, sub-dermal implant delivery)
- **Intended use:** Long-acting reversible contraception

Policy and Health System Context

- Expansion of contraceptive choice has been a national priority, including LARCs that can offer a broader range of options, rather than displacing existing options.
- Family planning services are mostly nurse-led and delivered primarily at the PHC level.

Time Period Covered: Approximately 2012 to 2023/4

Descriptive Pathway Overview

- **2012:** National guidelines mandated the integration of LARCs, including implants, as part of an expanded contraceptive method mix.
- **2013:** Although WHO-prequalified and SAHPRA-registered, NEMLC deferred adoption due to bleeding and efavirenz (EFV) interaction concerns.
- **February-June 2014:** The Minister of Health announced a national launch, and public-sector rollout began by June, supported by interim clinical guidance and initial UNFPA donations.
- **2014–2016:** Rapid initial uptake was followed by a marked decline as gaps in counselling, removal services, and overall service readiness emerged.
- **2015:** A national dialogue was convened to address misinformation and strengthen system readiness, including training, counselling, and removal capacity.
- **2018:** Included in the PHC STGs/EML, formalising existing standards for nurse scope, insertion and removal, and counselling.
- **2019–2021:** Policies were iteratively adapted to improve service quality, with a focus on training, counselling, removal services, and EFV interaction counselling.
- **2022–2023/24:** Routine monitoring demonstrated sustained uptake of implant use, despite persistent variation across provinces.

Current Status (as of 2023/4)

- Regulatory status: Registered medicine
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Routine but variable uptake

8. Depo-medroxyprogesterone acetate, subcutaneous injection (DMPA-SC) for family planning

Purpose of this Summary: This summary outlines the pathway for introducing self-administered subcutaneous DMPA into South Africa's public-sector contraceptive services.

Innovation

- **Type:** Medicine (injectable)
- **Intended use:** Injectable self-administered long -acting contraception

Policy and Health System Context

- Expanding contraceptive choice, including self-administered options, has been a national priority.
- DMPA-SC introduces a trained self-injection injectable option into a traditionally provider-administered injectable programme, supporting greater choice and differentiated service delivery.

Time Period Covered: Approximately 2019 to 2025

Descriptive Pathway Overview

- **2019:** National contraception clinical guidance incorporated DMPA-SC for provider-administered use.
- **2020:** The NEMLC conditionally endorsed DMPA-SC, subject to regulatory approval, an affordable access price, and stronger evidence on the feasibility and acceptability of self-administration.

- **2022:** WHO self-care guidance recommended self-administration of injectable contraception.
- **2024:** SAHPRA updated professional information to permit self-injection following appropriate training.
- **2024-2025:** Procurement governance and tender-cycle timing affected procurement readiness, and operationalisation had not yet commenced at the time of analysis.
- **2025:** Updated NEMLC appraisal reinforced training, counselling, and pharmacovigilance requirements during scale-up. DMPA-SC was added to the PHC STGs/EML, with donors and partners supporting national training and planning.

Current Status (as of 2025)

- Regulatory status: Registered medicine
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Phased implementation

9. Methadone opioid substitution therapy (OST) for clinical management of opioid dependence

Purpose of this Summary: This summary provides a descriptive overview of the policy and system pathway through which methadone for opioid substitution therapy (OST) has been considered, including ongoing deliberations regarding the introduction of OST into the South African public health system.

Innovation

- **Type:** Medicine (oral formulation)
- **Intended use:** Methadone opioid substitution (agonist) therapy (OST/OAT) is an oral opioid substitution treatment used to replace illicit opioid use with supervised methadone dosing. It can reduce opioid dependence, overdose risk, and HIV/HCV transmission as part of a harm-reduction approach to managing opioid use disorder.

Policy and Health System Context

- Opioid dependence and related harms have increasingly been recognised as a public health concern in South Africa.
- Harm reduction approaches, including OST, have featured in national policy discussions and civil society initiatives.
- Service delivery for opioid dependence has historically been fragmented, with limited integration into routine public-sector health services.

Time Period Covered: Approximately 2013 to 2024

Descriptive Pathway Overview

- **2013- 2017:** OST (methadone and buprenorphine) entered the national policy agenda under the National Drug Master Plan (NDMP) 2013–2017 and reinforced in the HIV/ TB/STI National Strategic Plan (2023-2028), as rising heroin/ nyaope[10]-related harms and links to HIV and TB elevated policy attention.
- **Pre-2016:** Methadone access was largely confined to private and donor-supported services, with public-sector use limited to detoxification and acute withdrawal management.
- **2016-2018 onwards:** Municipal and donor-funded programmes (e.g. COSUP) demonstrated feasibility, acceptability, and retention, but remained project-based and unevenly distributed.
- **August 2021:** NEMLC review called for multidisciplinary, supervised models—including psychosocial support, dosing and monitoring protocols, and diversion mitigation—and recommended implementation-research pilots; maintenance therapy was not included in the STGs/EML, with methadone retained for acute detoxification only.
- **2022:** Methadone was included in the national STGs/EML for opioid detoxification in hospital settings, subject to defined conditions, but not for maintenance therapy.
- **2024:** NdoH advanced implementation-research pilots to generate evidence for future STGs/EML deliberations on maintenance opioid substitution therapy.

Current Status (as of 2024)

- Regulatory status: Registered medicine
- Guideline status: Included in national STGs/EML for acute opioid withdrawal (detoxification); not included for harm-reduction maintenance therapy (OST/OAT).

10 *In South African, nyaope/ wonga is a mix of heroin, cannabis, and other substances such as methamphetamine (tik), methaqualone (Mandrax), and tobacco that is smoked and is used among adolescents and has been increasing, contributing to an increase in hospital admissions.*

- Implementation status: Public-sector use remains largely limited to detoxification; maintenance OST is being piloted in selected sites with restricted, supervised delivery models.

B. Illustrative Descriptive Case Summaries – Vaccines

10. Human Papillomavirus (HPV) Vaccine for preventing cervical cancer

Purpose of this Summary: This summary provides an overview of the policy and system pathway through which the HPV vaccine was introduced and subsequently adapted within the South African public health system.

Innovation

- **Type:** Vaccine
- **Intended use:** Prevention of cervical cancer through immunisation of adolescent girls

Policy and Health System Context

- Cervical cancer prevention has been a national public health priority, with HPV vaccination serving as a key public health preventive strategy.
- School health services have provided an established platform for adolescent health interventions, including school-based HPV vaccination.

Time Period Covered: 2014 to 2024

Descriptive Pathway Overview

- **Pre-2014:** South Africa's high cervical cancer burden, particularly among women living with HIV, established a strong policy rationale for HPV vaccination.
- **2014:** A national decision to introduce a school-based HPV vaccination programme as part of Suth Africa's Integrated School Health Programme, was formalised through ministerial resolutions and endorsement by the National Health Council. The Integrated School Health Programme is South Africa's school health platform for learner screening, health education, on-site services (including immunisation/deworming), and referral/follow-up.
- **2014:** Regulatory approval and ring-fenced conditional grant financing enabled the launch of a public-school–based HPV vaccination programme targeting Grade 4 girls.
- **2015–2019:** Annual campaign-based delivery was implemented in public primary schools, supported by coordinated action between the health and education sectors; inclusion of private schools remained under consideration.
- **2017:** Global guidance reaffirmed HPV vaccination as a cost-effective cervical cancer prevention strategy.
- **2020:** Programme delivery was severely disrupted by COVID-19, resulting in a sharp decline in coverage.
- **2023:** National guidelines were adapted following global policy shifts, with NAGI supporting a transition to a single-dose schedule in line with updated WHO guidance.
- **2024:** Selected provinces implemented single-dose HPV vaccination, while regulatory registration remained aligned to a two-dose schedule pending revision; private-school delivery remained operationally complex and limited.

Current Status (as of 2024)

- Regulatory status: Registered vaccine, single-dose administration pending SAHPRA approval
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Ongoing school-based delivery with programme adaptations

11. Quadrivalent Influenza Vaccine (QIV) for preventing seasonal influenza

Purpose of this Summary: This summary provides an overview of the incremental introduction of QIV alongside trivalent influenza vaccines (TIV) within South Africa's seasonal influenza vaccination programme.

Innovation

- **Type:** Vaccine
- **Intended use:** Seasonal prevention of influenza

Policy and Health System Context

- Seasonal influenza vaccination is delivered through targeted public-sector programmes rather than the routine immunisation schedule.
- Annual vaccine composition is informed by global surveillance and recommendations, though local surveillance systems monitor circulating influenza strains annually.

Time Period Covered: 2005 to 2025

Descriptive Pathway Overview

- **2005–2014:** National surveillance documented prolonged co-circulation of both influenza B lineages (B/Victoria and B/Yamagata), raising concerns about strain mismatch with TIV, which protects against two influenza A subtypes (A/H1N1 and A/H3N2), and a single influenza B lineage.
- **Pre-2020:** Public-sector influenza programmes relied primarily on TIV; modelling and economic analyses indicated that QIV could deliver incremental health gains and was likely to be cost-effective under sustained influenza B circulation.
- **2020:** QIV became available in the private sector, increasing policy salience through clinician and manufacturer advocacy.
- **2021–2023:** Public-sector policy adopted a flexible, non-committal position, allowing limited QIV procurement alongside TIV, constrained primarily by affordability and budget impact.
- **2024:** National programmatic guidelines and STGs/EML formally permitted use of either TIV or QIV, contingent on cost, availability, and seasonal considerations.
- **2024–2025:** Ongoing surveillance, annual guideline updates, and changing global influenza lineage ecology continued to inform seasonal vaccine policy and procurement decisions.
- **2025:** Updated WHO guidance, following the apparent global disappearance of the B/Yamagata lineage, repositioned TIV as the preferred influenza vaccine option.

Current Status (as of 2025)

- Regulatory status: Registered vaccine
- Guideline status: Included as an option in national programmatic guidelines and STGs/EML
- Implementation status: Seasonal use within constrained public-sector programmes

12. Pneumococcal Conjugate Vaccine (PCV) for preventing invasive pneumococcal disease

Purpose of this Summary: This summary provides an overview of the introduction and subsequent optimisation of pneumococcal conjugate vaccines (PCV) within South Africa's Expanded Programme on Immunisation (EPI).

Innovation

- **Type:** Vaccine
- **Intended use:** Prevention of invasive pneumococcal disease (IPD) in infants and young children

Policy and Health System Context

- Childhood pneumonia prevention via PCV has been a long-standing national child survival priority.
- Routine infant immunisation is delivered through the routine EPI schedule.

Time Period Covered: 2009 to 2025

Descriptive Pathway Overview

- Pre-2009: Surveillance documented a high invasive pneumococcal disease (IPD) burden, particularly among young children and people living with HIV.
- **2009:** PCV7 (7-valent PCV) was introduced into the national EPI as part of child-survival and under-five mortality reduction priorities.
- **2010s:** Routine administrative reporting and laboratory surveillance (GERMS-SA/NICD) documented substantial declines in vaccine-type IPD and monitored programme performance.
- **2011:** PCV13 (13-valent PCV) was registered for paediatric use, enabling consideration of broader serotype coverage.
- **2014:** PCV13 replaced PCV7 in the routine immunisation schedule following NAGI advice and NHC approval, informed by surveillance evidence of residual disease due to non-PCV7 serotypes.
- **2016-2021:** Rising EPI costs within a fully domestically funded programme prompted policy discussions on optimisation and long-term sustainability.
- **2023-2024:** NAGI review supported substitution of PCV13 with PCV10 on technical (overlapping serotype coverage, comparable immunogenicity and safety, and sustained declines in vaccine-type IPD) and cost grounds, followed by phased implementation through national tenders with no EPI schedule changes.
- **2024–2025:** Product substitution from PCV13 to PCV10 was implemented through national tender processes and phased stock transition, with no change to dosing schedule or target population; cost savings supported cross-programme reinvestment, including procurement of Tdap within the EPI, to enhance overall immunisation impact.

Current Status (as of 2025)

- Regulatory status: Registered vaccine
- Guideline status: Included in the EPI schedule, national programmatic guidelines and STGs/EML
- Implementation status: Routine national delivery through PHC services

C. Illustrative Descriptive Case Summaries – Devices

13. Apnoea monitors for neonatal respiratory and heart-rate monitoring

Purpose of this Summary: This summary outlines the policy and health-system pathway through which apnoea monitors were introduced and integrated into routine neonatal care within South Africa's public health system.

Innovation

- **Type:** Medical device
- **Intended use:** A non-invasive neonatal monitoring device that detects pauses in breathing and heart-rate abnormalities, alerting clinicians to respiratory instability. In public-sector newborn-care settings, apnoea monitors represent a low-complexity, high-impact technology supporting early detection of respiratory compromise.

Policy and Health System Context

- Persistently high early neonatal mortality due to prematurity and respiratory causes was documented through national perinatal audit systems and Saving Babies reports.
- National norms, standards, and clinical guidelines progressively defined minimum equipment requirements for neonatal services, including basic monitoring technologies.

Time Period Covered: 2000/2003–2024

Descriptive Pathway Overview

- **Early 1990s–early 2000s:** National perinatal audits and Saving Babies reports documented high neonatal mortality and identified inadequate monitoring equipment, including the absence of apnoea monitors.
- **2003–2005:** Savings Babies reports explicitly recommended apnoea monitors as essential equipment for neonatal and resuscitation care.
- **2006:** Apnoea monitoring was incorporated into the national Paediatric Hospital STGs, embedding its use within routine neonatal clinical pathways.
- **Mid 2000's–early 2010s:** Evidence and professional consensus strengthened around the feasibility, equity, and clinical value of scaling up neonatal monitoring, supported by provincial initiatives, notably the Limpopo Initiative for Newborn Care (LINC), and academic partners.
- **2010s:** Adoption expanded across district-level hospital neonatal services, supported by facility-based equipment committees and provincial programmes (including LINC), using established capital equipment governance structures rather than formal Health Technology Assessment (HTA) frameworks.
- **2013:** Apnoea monitors were formally designated as essential equipment in the Norms and Standards for Essential Newborn Care and operationalised through the Essential Newborn Care Quality Improvement Toolkit, including standard procurement specifications; implementation challenges persisted, including staff turnover, limited supplier training, and technical issues such as false alarms and sensor misplacement.
- **Mid 2010s- early 2020s:** Financial viability and procurement improved through bundling apnoea monitors within essential neonatal equipment packages and national toolkits, although fiscal constraints and inter-provincial variation remained.
- **2023:** Updated neonatal clinical guidelines reaffirmed apnoea monitoring as standard neonatal care, while audits continued to identify persistent equipment gaps linked to procurement and maintenance challenges.
- **2024:** System integration was strengthened through the inclusion of apnoea monitors in National Treasury transversal medical equipment procurement mechanisms, supporting greater standardisation of supply, pricing, and scale-up.

Current Status (as of 2024)

- Regulatory status: Regulated medical device authorised for market use in South Africa under SAHPRA medical device regulations.[11]

11 *Medical devices in South Africa are regulated by SAHPRA and must comply with applicable safety and performance standards; unlike medicines, they are not approved through a central medicines register.*

- Guideline status: Specified within national neonatal norms, programmatic guidelines and STGs/EML
- Implementation status: Routine use in designated neonatal units, subject to facility readiness and maintenance capacity

14. Continuous Positive Airway Pressure (CPAP) for non-invasive respiratory support in acute hypoxaemic respiratory failure

Purpose of this Summary: This summary provides an overview of the emergency introduction, scale-up, and subsequent institutionalisation of CPAP within South Africa's public health system.

Innovation

- **Type:** Medical device and service delivery modality
- **Intended use**: Non-invasive respiratory support for patients with acute hypoxaemic respiratory failure[12]. Unlike invasive mechanical ventilation, CPAP can be safely delivered outside intensive care units (ICUs) in general ward settings, provided that a reliable medical oxygen supply, appropriate infection-prevention measures, and adequately trained staff are in place.

Policy and Health System Context

- Prior to 2020, advanced respiratory support in the public sector was largely confined to ICU settings.
- The COVID-19 pandemic placed acute pressure on ICU capacity and oxygen supply, prompting the adoption of CPAP as a decentralised respiratory support strategy within hospital wards.

Time Period Covered: 2020–2025

Descriptive Pathway Overview

- **March–June 2020:** Rapid escalation of COVID-19 cases and ICU saturation elevated CPAP as a feasible ward-based respiratory support option to preserve critical-care capacity.
- **May 2020:** Emergency national COVID-19 clinical guidance positioned CPAP as an escalation modality for selected patients failing conventional oxygen therapy.
- **November 2020:** National and provincial audits assessed facility readiness, oxygen supply reliability, infection-prevention risks, and workforce capacity, indicating that CPAP could be safely used outside ICUs under defined conditions.
- **2020–2022:** National and provincial procurement of CPAP devices occurred alongside major investments in medical oxygen infrastructure, including bulk supply, concentrators, and reticulation[13] upgrades.
- **September 2021:** CPAP was formally incorporated into national COVID-19 clinical management guidelines, consolidating its use within national clinical governance frameworks.
- **2021-2022:** Scaled implementation continued, with CPAP deployment closely linked to oxygen-system strengthening, infection-prevention protocols, and staff training.
- **2023–2024:** Inclusion of CPAP within STGs, essential equipment frameworks, and training materials supported transition beyond emergency use toward routine service delivery.
- **2024–2025:** CPAP-related indicators were increasingly incorporated into routine quality-assurance processes and health-information systems, signalling early stages of institutionalisation within routine health-system processes.

Current Status (as of 2025)

- Regulatory status: Regulated medical device authorised for market use in South Africa under SAHPRA medical device regulations
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Available in selected public-sector hospitals, contingent on oxygen infrastructure and workforce capacity

15. Heated Humidified High-Flow Nasal Oxygen (HHFNO) for low-and extremely low-birthweight neonates

Purpose of this Summary: This summary provides an overview of the phased introduction and institutionalisation of HHFNO for neonatal respiratory support within South Africa's public health system.

12 *Acute hypoxaemic respiratory failure: Inadequate arterial oxygenation due to impaired gas exchange (e.g. pneumonia or ARDS), often requiring escalation beyond conventional oxygen therapy (Fan 2018, WHO 2022)*

13 *Improvements to piped oxygen distribution systems*

Innovation

- **Type:** Medical device and service delivery modality
- **Intended use:** Non-invasive respiratory support for low-birthweight (LBW) and extremely low-birthweight neonates (ELBW). HHFNO delivers heated, humidified high-flow oxygen-air blends via hospital gas distribution piping system; positioned as an intermediate or step-down modality alongside CPAP where access to invasive ventilation is limited.

Policy and Health System Context

- Persistent neonatal mortality from prematurity-related respiratory distress was documented through national and provincial perinatal audit systems.
- Access to non-invasive respiratory support was inconsistent, with CPAP and mechanical ventilation concentrated in tertiary facilities.
- Provincial medical-device governance structures oversee appraisal, procurement, and standardisation of neonatal respiratory technologies.

Time Period Covered: 2015–2025

Descriptive Pathway Overview

- **2015–2019:** Provincial and national perinatal audits identified persistently high mortality from respiratory distress among LBW and ELBW neonates, highlighting gaps in access to non-invasive respiratory support.
- **2018–2021:** Pilot implementation in Western Cape district, regional, and tertiary hospitals demonstrated the operational feasibility of HHFNO using existing oxygen infrastructure and standardised clinical protocols.
- **2019-2020:** Global evidence supports CPAP as first line, and HHFNO as step-down treatment for selected preterm babies.
- **2020–2021:** COVID-19–related pressure on oxygen systems accelerated strengthening of oxygen governance, monitoring, and coordination, indirectly enabling HHFNO scale-up.
- **June 2021:** HHFNO was formally adopted in the Western Cape through inclusion in the Periviable Preterm Care Framework as a step-down or intermediate respiratory modality.
- **2023:** Inclusion of HHFNO in the Paediatric Hospital-Level STGs/EML signalled national policy alignment.
- **April 2024:** HHFNO was incorporated into national neonatal clinical training materials.
- **2021–2025:** Western Cape provincial procurement[14] and phased distribution progressively expanded access to HHFNO across neonatal services, subject to facility readiness and oxygen-infrastructure capacity.

Current Status (as of 2025)

- Regulatory status: Regulated medical device authorised for market use in South Africa under SAHPRA medical device regulations.
- Guideline status: Included in provincial and national programmatic guidelines and STGs/EML
- Implementation status: Phased routine use of HHFNO in neonatal services, contingent on oxygen infrastructure, staffing, and maintenance capacity

D. Illustrative Descriptive Case Summaries – Diagnostics

16. Viral Load (VL) testing for HIV treatment monitoring

Purpose of this Summary: This summary provides an overview of the introduction and scale-up of HIV viral load (VL) testing as a routine laboratory service within the South African public health system.

Innovation

- **Type:** Laboratory-based molecular diagnostic
- **Intended use:** Monitoring antiretroviral therapy (ART) effectiveness and population-level viral suppression

Policy and Health System Context

- Rapid expansion of antiretroviral therapy (ART) created demand for reliable, standardised treatment monitoring. National laboratory services are delivered through the National Health Laboratory Service (NHLS), enabling centralised scale-up and quality assurance.

Time Period Covered: 2013–2024

14 *Unlike apnoea monitors and CPAP, which are included in National Treasury transversal medical equipment tenders, HHFNO has been procured primarily through provincial mechanisms.*

Descriptive Pathway Overview

- **2013:** National ART guideline revisions formally positioned VL testing as the preferred treatment-monitoring tool, progressively replacing CD4-based monitoring.
- **2014–2016:** Phased expansion of NHLS laboratory infrastructure, specimen referral networks, and information systems supported early scale-up.
- **2016–2018:** National VL scale-up achieved routine coverage across all provinces, supported by guideline alignment and centralised service delivery.
- **2018–2023:** VL testing volumes increased steadily, enabled by high-throughput molecular platforms, centralised procurement, and donor-supported system strengthening.
- **2023–2024:** VL testing was embedded as a core national HIV programme indicator, with sustained national volumes exceeding six million tests annually and routine reporting through NHLS and Tier.Net systems.

Current Status (as of 2024)

- Regulatory status: Established NHLS laboratory service, using SAHPRA-regulated in-vitro diagnostic assays
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Routine national delivery via NHLS laboratories

17. Reflex Cryptococcal Antigen (CrAg) Screening

Purpose of this Summary: This summary provides an overview of the adoption and implementation of reflex cryptococcal antigen screening for people with advanced HIV disease.

Innovation

- **Type:** Laboratory-based reflex diagnostic
- **Intended use:** Early detection of cryptococcal infection among individuals with low CD4 counts

Policy and Health System Context

- Persistent cryptococcal meningitis mortality among people with advanced HIV disease was documented through national surveillance.
- Existing CD4 laboratory infrastructure enabled reflex testing without provider initiation.

Time Period Covered: 2011–2014

Descriptive Pathway Overview

- **2011–2013:** Global guidance and local surveillance highlighted the potential role of CrAg screening.
- **2012–2015:** NICD and provincial pilot studies demonstrated feasibility, high disease burden, and superior coverage of laboratory-based reflex screening compared with provider-initiated approaches.
- **2015 onward:** Successive national HIV/ART guideline updates progressively incorporated CrAg screening for advanced HIV disease as evidence and feasibility data accumulated.
- **2016:** National reflex CrAg screening was formally initiated, transitioning from pilot implementation to routine national delivery through NHLS laboratories.
- **2018–2020:** CrAg screening was incorporated into PHC STGs/EML, enabling nurse-initiated management at PHC level (with pre-emptive treatment and referral) and reinforcing national policy alignment.
- **2019 onward:** Routine national implementation through NHLS CD4 laboratories, with automated reporting via laboratory information systems and integration into national surveillance platforms.
- **2018–2023:** National scale-up achieved high and equitable coverage (>95%), supported by centralised procurement, LIS automation, and NHLS/NICD quality-assurance systems.
- **August 2022:** The Western Cape adapted national policy by expanding the reflex screening threshold from CD4 ≤100 to ≤200 cells/μL, informed by surveillance data and aligned with conditional WHO guidance.
- **2023–2024:** Centralised NHLS tendering secured long-term supply of CrAg test kits; routine surveillance continued to inform debate on optimal screening thresholds and downstream linkage to care.

Current Status (as of 2024)

- Regulatory status: Established NHLS laboratory service, using SAHPRA-regulated in-vitro diagnostic assays
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Routine reflex screening nationwide

18. Donated COVID-19 Antigen Rapid Diagnostic Tests (Ag-RDTs) for SARS-CoV-2 testing

Purpose of this Summary: This summary provides an overview of the emergency integration of donated and donation-funded COVID-19 antigen rapid diagnostic tests (Ag-RDTs) into South Africa's public health response during the COVID-19 pandemic.

Innovation

- **Type:** Point-of-care diagnostic
- **Intended use:** Rapid detection of SARS-CoV-2 infection to expand testing access, support timely case identification, and complement RT-PCR testing

Policy and Health System Context

- Early pandemic testing was constrained by global reagent shortages, centralised laboratory capacity, and regulatory uncertainty.
- Declaration of a national state of disaster enabled emergency regulatory, procurement, and donation-management mechanisms.
- Hybrid public–private financing, including large-scale donations, supported rapid expansion of diagnostic capacity.

Time Period Covered: 2020–2021

Descriptive Pathway Overview

- **15 March 2020:** Declaration of a national state of disaster created the legal basis for emergency diagnostic pathways, including donations and expedited procurement.
- **April-June 2020:** SAHPRA implemented expedited Section 21 regulatory authorisation for donated COVID-19 diagnostics, informed by WHO guidance and national public-interest considerations.
- **May-September 2020:** NHLS and NICD conducted risk-based performance evaluations of donated Ag-RDTs to assess quality, sensitivity, and fitness for purpose.
- **September–October 2020:** WHO interim guidance (September 2020) formally endorsed Ag-RDTs as complementary to RT-PCR. On 8–9 October 2020, the NdoH announced the operational rollout of Ag-RDTs at ports of entry, signalling formal policy adoption.
- **October 2020–March 2021:** Donated and donation-funded Ag-RDTs were distributed nationally through public-sector platforms, including ports of entry, outbreak investigations, mobile testing units, and primary healthcare services. This rollout was supported by NHLS infrastructure and hybrid financing, notably through the Solidarity Fund.
- **March 2021-February 2022:** Ag-RDT results were integrated into national NHLS and NICD surveillance and reporting systems, enabling consolidated monitoring alongside RT-PCR testing, supported by external quality assessment schemes and routine reporting to national oversight structures.

Current Status (as of 2021)

- Regulatory status: SAHPRA-authorised IVDs under emergency Section 21 provisions, with NHLS validation and oversight.
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Used during emergency response period

19. Dual HIV/Syphilis point-of-care testing for antenatal care

Purpose of this Summary: This summary provides an overview of the introduction of dual HIV/syphilis rapid diagnostic tests (RDTs) into public-sector antenatal care (ANC) services in South Africa.

Innovation

- **Type:** Point-of-care diagnostic
- **Intended use:** Same-day HIV and syphilis screening at first ANC visit to improve early detection, treatment initiation, and prevention of vertical transmission

Policy and Health System Context

- High antenatal HIV testing coverage contrasted with persistent gaps and delays in syphilis screening
- WHO guidance and market-shaping initiatives supported integrated dual testing as a feasible and affordable ANC strategy

Time Period Covered: 2019–2024

Descriptive Pathway Overview

- **2019:** WHO recommended dual HIV/syphilis RDTs as the preferred first test for antenatal screening.
- **2021–2022:** Market-shaping initiatives (including price-volume guarantees) improved affordability of dual RDTs.
- **2022–2023:** NICD conducted technical evaluations of WHO-prequalified dual RDTs, advising NdoH and National Treasury on

product performance, specifications, and quality-assurance requirements.
- **2022:** National Treasury established transversal procurement mechanisms for HIV/syphilis RDTs, informed by NICD technical evaluations
- **2023:** Dual HIV/syphilis point-of-care testing (POCT) was endorsed in the National Vertical Transmission Prevention Guideline, alongside mono-syphilis testing for women already on ART.
- **2023–2024:** Dual testing pathways were integrated into PHC STGs/EML, aligned with national programmatic guidelines, and existing procurement and QA frameworks.
- **2024:** Public-sector rollout through ANC services was supported by national clinical guidance, training materials, and ongoing NICD/NHLS surveillance and quality-assurance systems.

Current Status (as of 2024)

- Regulatory status: SAHPRA-regulated IVDs for routine use, supported by WHO prequalification and national procurement frameworks.
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Early routine implementation in the public-sector ANC

20. Tuberculosis Lipoarabinomannan (TB-LAM) urine test for advanced HIV disease

Purpose of this Summary: This summary provides an overview of the introduction of TB-LAM urine testing as an adjunct diagnostic for TB among people with advanced HIV disease in South Africa.

Innovation

- **Type:** Point-of-care diagnostic
- **Intended use:** Adjunct TB diagnosis in people with advanced HIV disease, particularly hospitalised patients and those unable to produce sputum

Policy and Health System Context

- TB-related mortality among people with advanced HIV disease remained high despite ART scale-up.
- Conventional sputum-based diagnostics were often infeasible in severely ill patients, creating demand for non-sputum-based tests.
- TB-LAM was positioned as a complementary diagnostic within TB/HIV programmes, rather than a stand-alone test.

Time Period Covered: 2018–2024

Descriptive Pathway Overview

- **2018:** STAMP trial findings demonstrated that urine TB-LAM testing improved access to TB diagnosis among hospitalised people with advanced HIV disease unable to produce sputum and was associated with reduced all-cause mortality when used within defined diagnostic algorithms.
- **2019:** WHO policy guidance recommended TB-LAM use for people with advanced HIV disease, providing international technical legitimacy for national policy consideration.
- **2020–2021:** National policy formulation was supported by technical input from the National TB Think Tank, the Southern African HIV Clinicians Society (SAHCS), and the Clinton Health Access Initiative (CHAI), informing national guidance on the role of TB-LAM within TB diagnostic algorithms and the Advanced HIV Disease service package.
- **2020:** TB-LAM was incorporated into PHC STGs/EML, translating national guidance into routine clinical practice and enabling wider implementation.
- **2021–2022:** Early scale-up identified implementation constraints, including clinician hesitancy to initiate treatment following TB-LAM–positive results, limited point-of-care quality-assurance systems, and unclear governance for POCTs.
- **2021–2024:** Routine monitoring and implementation experience reinforced TB-LAM's role within an integrated diagnostic cascade, supported by SOPs, training, and strengthened QA and reporting mechanisms.

Current Status (as of 2024)

- Regulatory status: SAHPRA-regulated IVD medical device, implemented as a routine POCT under national TB/HIV guidelines, with programme oversight coordinated through NdoH and NHLS systems
- Guideline status: Included in national programmatic guidelines and STGs/EML
- Implementation status: Targeted routine use in defined high-risk populations

Annexure B: Detailed case timelines, mapped to ALIGN pillars

Authors: TD Leong, Sumaya Dadan, Natalie Leon, with support for TB case studies cases from Oelfah Patel, Earl Prinsloo

Purpose of Annexure B: Annexure B collates descriptive timelines of key decision points across selected health technology innovation cases. For each case, it documents the sequence of major policy, regulatory, financing, procurement, and implementation events captured in the underlying documentary record. Each timeline is mapped to the relevant ALIGN pillar(s) to indicate which system function(s) were active at each step.

Cross-case synthesis and analytical linkage to ALIGN: The timelines presented in this annexure provide the empirical basis for a cross-case synthesis using the ALIGN framework, which analyses decision points across four core system functions: evidence for decision-making (P1), portfolio logic (P2), whole-of-government coordination (P3), and whole-of-market engagement (P4). Across 22 cases and 166 mapped decision points, this synthesis identifies recurring patterns in how innovations move through policy, regulatory, financing, procurement, and implementation pathways, highlighting strong evidence use and coordination, alongside more selective application of portfolio logic and more variable engagement beyond government.

This annexure also contributes to the development of the ALIGN mapping tool, a structured, forward-looking diagnostic approach intended to identify system misalignments across these pillars and support more coordinated and timelier introduction and scale-up of health technologies.

ALIGN pillars applied in this annexure

The ALIGN pillars (P1–P4) are used as a classification schema for system functions represented at each decision point:

- **Pillar 1 (P1) Market intelligence and evidence used for decision-making**: Use of integrated information (e.g., pipeline intelligence, burden, performance metrics, and system capacity) to support prioritisation and decisions.
- **Pillar 2 (P2) Portfolio logic**: Coordination or bundling of related innovations across a programme area to reduce duplication and leverage complementarities.
- **Pillar 3 (P3) Whole-of-government coordination:** Alignment across government departments and agencies involved in policy development, regulation, procurement, and implementation.
- **Pillar 4 (P4) Whole-of-market engagement:** Engagement across public sector, private sector, and civil society actors relevant to policy development and implementation.

Scope and structure of the cases

Annexure B covers 22 health technology innovations grouped into four categories: medicines, vaccines, devices, and diagnostics (Table 1). For each category, Table 1 summarises:

(iii) the dominant entry signal that typically brings health technology innovation onto the policy agenda;

(ii) the common institutional anchor(s) through which introduction is formally documented; and

(iii) the typical implementation mode through which uptake and routinisation occur in the public sector.

Table 8: Health technology category, the dominant entry signal, common institutional anchor and the typical implementation mode

Category	No. of Cases	Dominant Entry Signal	Common Institutional Anchor	Typical Implementation Mode
Medicines	10	Evidence + programme need	SAHPRA0F[15], NEMLC1F[16], STGs/ EML2F[17]	Phased public-sector rollout
Vaccines	3	Burden + surveillance	NAGI3F[18] + EPI4F[19]	Routine schedule or campaigns
Devices	3	Audit + service pressure	Norms / guidelines	Facility-readiness dependent
Diagnostics	6	Programme surveillance/ monitoring needs + global/ national guidance (and emergency response in COVID-19)	National laboratory and surveillance platform led by NHLS5F[20]/ NICD6F[21], with regulatory/ procurement anchors via SAHPRA7F[22] and National Treasury	Hybrid model: (a) centralised laboratory scale-up through NHLS networks for high-volume tests (e.g., VL; reflex CrAg) and (b) targeted point-of-care rollout via service platforms (ANC, inpatient/ advanced HIV, outbreak/ points of entry), typically phased and dependent on Quality Assurance/ training/ reporting integration (e.g. dual HIV/ syphilis POCT, TB-LAM urine test, donated COVID-19 Ag-RDTs).

Key decision points and mapping to ALIGN pillars

Timelines for decision points were identified through a structured retrospective document review (and validated by key informant interviews for selected cases). Annexure B presents:

- the decision step and associated date/time period;
- the decision level (e.g., national, provincial, institutional); and
- the ALIGN pillar(s) represented at that step (P1–P4).

This approach provides a standardised descriptive record of decision sequences across cases and a consistent way to identify which system functions were active at different points in the pathway.

15 *South African Health Products Regulatory Authority*
16 *National Essential Medicines List Committee*
17 *STGs/EML – Standard Treatment Guidelines/ Essential Medicines List*
18 *NAGI – National Advisory Group on Immunisation*
19 *EPI – Expanded Programme on Immunisation*
20 *National Health Laboratory Service*
21 *National Institute for Communicable Diseases*
22 *South African Health Products Regulatory Authority*

B1. MEDICINES

PERIOD	KEY EVENT	LEVEL	ALIGN
[1] Rifapentine + Isoniazid weekly for 3 months (3HP) – TB Preventive Therapy (TPT) (2017 to 2025)			
2017–2019	Short-course preventive therapy was referenced in national policy discussions and strategic plans, including a conditional target for scale-up of 3HP by 2022 *[P2: 3HP sits within the TB prevention portfolio - TPT regimens included 3HP, 6H and 1HP]*	National	P1, P2, P3
2018	World Health Organization (WHO) recommends 3HP for TPT	Global	P1
2019–2021	Research trials, donor-supported pilot and demonstration projects in selected settings, generated supportive evidence	Global, National, Sub-national	P1, P4
2019 & 2022	The National Essential Medicines List Committee (NEMLC) deferred inclusion of 3HP on the EML due to the absence of a registered fixed-dose combination (FDC) and budgetary constraints	National	P1, P3
2019-2024	Ongoing advocacy for 3HP uptake was undertaken by international & local donor and civil society organisations	Global, National	P4
2022	South African Health Products Regulatory Authority (SAHPRA) approved a 3HP fixed-dose combination (FDC)	National	P3
2024	3HP was included in national STGs/EML	National	P1, P3
2025	Nationally, public-sector procurement was initiated	National	P3
[2] Dolutegravir (DTG), antiretroviral treatment in women of childbearing potential (WoCP) and pregnancy (2018 to 2024/5)			
2018	The Tsepamo study identified a safety signal indicating an increased prevalence of congenital neural tube defects associated with DTG exposure at conception	Global	P1
2018-2019	Initial WHO interim guidance that reflected caution regarding DTG use in WoCP and during pregnancy	Global	P1
July 2019	Expanded Tsepamo data showed attenuated risk leading to revision of WHO guidelines, recommending DTG for all populations, including WoCP and pregnant women	Global	P1
2019	South Africa incorporated DTG into national antiretroviral therapy (ART) guidelines (initially cautioning WoCP using DTG to use reliable contraception)	National	P1, P3
2018–2020	Ongoing review by NEMLC and advisory structures, initially retaining caution for WoCP and during pregnancy	National	P1, P3
June 2021	NEMLC removed restrictions and recommends DTG for all populations, including pregnant women	National	P1
2023	Updated programmatic guideline recommendations were issued reflecting revised recommendations (including in pregnant/ breastfeeding women) with strengthened counselling and family planning integration	National	P1

PERIOD	KEY EVENT	LEVEL	ALIGN
2024-early 2025	Primary healthcare (PHC) STGs/EML updated; Consolidation and system integration of DTG across maternal and adult care pathways. Procurement contracts were awarded for December 2025–November 2028, with non-awards of certain TAF products as no tender bids were received. *[P2: DTG is core to the ART portfolio, but sequencing across i) maternal, and ii) PMTCT pathways reflects portfolio-based system integration, reducing duplication in procurement and pharmacovigilance]*	National	P1, P2, P3
[3] Tenofovir alafenamide (TAF), antiretroviral treatment in patients with TDF-intolerance (2019 to 2024/5)			
2015-2017	Global regulatory approvals were granted, and TAF-based regimens were shown to be non-inferior to existing ART regimens, with improved renal and bone safety profiles	Global	P1
2019	First NEMLC review declined inclusion of TAF in national STGs/EML, citing the adequacy of TDF-based regimens; limited pregnancy data; and the absence of SAHPRA approval	National	P1, P3
2019-2024	Evidence systematically reviewed across treatment-naïve, treatment-switch, pregnancy, and renal/bone subpopulations; emerging considerations included rifampicin compatibility during TB co-treatment and signals of weight gain	National	P1
March 2022	SAHPRA approved a TAF-containing FDC (Biktarvy®)	National	P3
2022	NEMLC again did not recommend TAF, due to uncertainty regarding safety in pregnancy and cost considerations	National	P1, P2, P3
2024	NEMLC reviewed new evidence and recommended a conditional and restricted STGs/EML inclusion for patients with contraindications to TDF, including HIV-associated renal impairment (eGFR 30–50 mL/min), reduced bone mineral density, and hepatitis B co-infection, with an additional renal-impairment pathway for non-HIV hepatitis B infection *[P2: Targeted portfolio optimisation—TAF positioned for defined subgroup (TDF intolerant) as i) part of ART-regimen, ii) hepatitis B co-infection in PLHIV, and iii) non-HIV hepatitis B co-infection]*	National	P1, P2, P3
2024-early 2025	Implementation remained delayed and limited. Early access occurred primarily through tertiary-level services, clinical trials, or Section 21 mechanisms (when registered TAF was not available on the South African market). Procurement contracts were awarded for December 2025–November 2028, with non-awards of certain TAF products as no tender bids were received	National, Facility-level	P3
[4] Donated oral fluconazole for cryptococcal meningitis (CM) in advanced HIV			
Pre-2000	Patented Diflucan® was unaffordable; legal generic supply/importation was constrained by patent and regulatory barriers (TRIPS flexibilities debate as context)	Global, National	P1, P3
2000	Treatment Action Campaign (TAC), supported by Médecins Sans Frontières (MSF), launched the "Christopher Moraka Defiance Campaign". Activists also pursued Section 21/exceptional access and high-profile generic importation to highlight barriers to access	Global, National	P3, P4
December 2000	Pfizer rejected voluntary licensing/pricing demands; offered Diflucan® donation programme	Global, National	P3, P4

PERIOD	KEY EVENT	LEVEL	ALIGN
2001–2002	Agreement was formalised (2001) and extended; Regulatory approval enabled donation for CM and oesophageal candidiasis; the Diflucan Partnership Program (DPP) was established with NDoH, with training/ distribution partners	Global, National	P3, P4
2001–2004	Rollout was initiated in tertiary hospitals; scale-up to ~300 facilities within ~3 years; monitoring noted large volume dispensed and extensive health worker training *[P2: Positioned CM prevention and treatment within South Africa's emerging public HIV treatment framework, linked to CD4-based risk identification, cotrimoxazole prophylaxis, and TB screening, and implemented alongside the hospital-based, eligibility-restricted rollout of public-sector ART from 2004 onward]*	National	P2, P3, P4
2004	Patent expiry reduced reliance on the donation route over time as generics/ART expansion evolved	National	P3
2007–2011	Global consolidation: WHO EML inclusion (2007/2009), and Rapid Advice was issued in 2011 for cryptococcal disease	Global	P1
2018-2022	WHO guidance emphasised Cryptococcal Antigen (CrAg) screening for CM and pre-emptive therapy in advanced HIV disease *[P2: Integrated CM prevention and treatment into a comprehensive advanced HIV disease package including CrAg + pre-emptive therapy + ART]*	Global	P1, P2
[5] Tranexamic Acid (TXA) for Post-Partum Haemorrhage (PPH) at primary healthcare level (2018 to 2024)			
2017–2018	WHO recommended TXA for the treatment of PPH, based on emerging evidence, noting a time-dependent benefit when administered within three hours	Global	P1
2017–2019	NEMLC recommends TXA as a second-line intervention restricted to hospital settings; use at PHC was not recommended	National	P1, P3
2022–2023	A subsequent NEMLC review reaffirmed the hospital-only restriction for TXA use	National	P1, P3
Early 2023	The KwaZulu-Natal Pharmaceutical and Therapeutics Committee submitted a formal appeal, prompting an expedited reassessment	National, Provincial	P3, P4
March 2023	An accelerated NEMLC review process was reopened	National	P1, P3
June/July 2023	NEMLC endorsed TXA IV (1 g) as part of the WHO-aligned E-MOTIVE first-response bundle across all levels of care, including PHC, subject to prior medical practitioner approval *[P2: Explicit bundling within E-MOTIVE maternal emergency package strengthened portfolio coherence]*	National	P1, P2, P3
2024	TXA was integrated into PHC STGs/EML; procurement contracts were awarded (2024–2027), with monitoring planned through Maternal Morbidity and Mortality Audit System (MaMMAS) and future Saving Mothers reports	National	P3

PERIOD	KEY EVENT	LEVEL	ALIGN
[6] Noradrenaline for the management of adult septic shock (2021 to ongoing)			
Pre-2020	Adrenaline was established as the first-line vasopressor in South African public-sector guidance.	National	P3
2021	International guidance (Surviving Sepsis Campaign Guidelines update) strongly recommended noradrenaline as first-line therapy.	Global	P1
October 2023	NEMLC determined not to adopt noradrenaline as first-line, citing no clinically important outcome advantage and significant feasibility, cost, and equity concerns.	National	P1, P3
March 2024	Adult Hospital STGs/EML were ratified, reaffirming adrenaline as first-line therapy for septic shock unresponsive to fluid resuscitation.	National	P3
Ongoing	Use continues to be monitored, with future review dependent on stronger, context-specific evidence and improved health-system readiness	National	P1
[7] Etonogestrel implant for family planning (FP) (2012 to 2023/4)			
2012	National guidelines mandated the integration of long-acting reversible contraceptives (LARCs), including implants, as part of an expanded contraceptive method mix *[P2: Positioned implants within expanded contraceptive method mix portfolio and LARC mandate]*	National	P2, P3
2013	Although WHO-prequalified and SAHPRA-registered, NEMLC deferred adoption due to bleeding and efavirenz (EFV) interaction concerns	Global / National	P1, P3
February–June 2014	The Minister of Health announced a national launch, and public-sector rollout began by June, supported by interim clinical guidance and initial UNFPA donations	Global, National	P3, P4
2014–2016	Rapid initial uptake was followed by a marked decline as gaps in counselling, removal services, and overall service readiness emerged	National	P1
2015	A national dialogue was convened to address misinformation and strengthen system readiness, including training, counselling, and removal capacity	National	P3, P4
2018	Included in the PHC STGs/EML, formalising existing standards for nurse scope, insertion and removal, and counselling	National	P3
2019–2021	Policies were iteratively adapted to improve service quality, with a focus on training, counselling, removal services, and EFV interaction counselling	National	P3
2022–2023/24	Routine monitoring demonstrated sustained uptake of implant use, despite persistent variation across provinces	National / Provincial	P1
[8] DMPA-SC (depot-medroxyprogesterone acetate, subcutaneous injection) for family planning (2019 to 2025)			
2019	National contraception clinical guidance incorporated DMPA-SC for provider-administered use *[P2: Added as complementary injectable within contraceptive method mix]*	National	P2, P3
2020	NEMLC conditionally endorsed DMPA-SC, subject to regulatory approval, an affordable access price, and stronger evidence on the feasibility and acceptability of self-administration	National	P1, P3

PERIOD	KEY EVENT	LEVEL	ALIGN
2022	WHO self-care guidance recommended self-administration of injectable contraception	Global	P1
2024	SAHPRA updated professional information to permit self-injection following appropriate training	National	P3
2024–2025	Procurement governance and tender-cycle timing affected procurement readiness, and operational roll out had not yet commenced at the time of analysis	National	P3
2025	Updated NEMLC appraisal reinforced training, counselling, and pharmacovigilance requirements during scale-up. DMPA-SC was added to the PHC STGs/EML, with donors and partners supporting national training and planning *[P2: Integrated into self-care and contraceptive method mix portfolio with training alignment]*	Global, National	P2, P3, P4
[9] Methadone for Opioid Substitution Therapy (OST) for clinical management of opioid dependence (2013 to 2024)			
2013–2017	OST (methadone and buprenorphine) entered national policy agenda under National Drug Master Plan (NDMP) 2013-2017, and reinforced in the HIV/TB/STI National Strategic Plan (NSP) (2023-2028), as rising heroin/nyaope-related harms and links to HIV and TB elevated policy attention *[P2: OST (methadone or buprenorphine) was framed within an integrated harm-reduction framework in the NDMP and HIV/TB/STI NSP, linking substance use, HIV, and TB responses rather than as a standalone intervention.]*	National	P2, P3
Pre-2016	Methadone access was largely confined to private and donor-supported services, with public-sector use limited to detoxification and acute withdrawal management.	Global, Sub-national, Private	P4
2016–2018 onward	Municipal and donor-funded programmes (e.g. COSUP) demonstrated feasibility, acceptability, and retention, but remained project-based and unevenly distributed.	Global, Sub-national	P1, P4
Aug 2021	NEMLC review called for multidisciplinary, supervised models (psychosocial support, dosing and monitoring protocols, and diversion mitigation) and recommended implementation-research pilots; maintenance therapy not included in STGs/EML, with methadone retained for acute detoxification only	National	P1, P3
2022	2022: Methadone was included in the national STGs/EML for opioid detoxification in hospital settings, subject to defined conditions, but not for maintenance therapy.	National	P3
2024	NDoH advanced implementation-research pilots to generate evidence for future STGs/EML deliberations on maintenance OST	National / Sub-national	P1, P3

PERIOD	KEY EVENT	LEVEL	ALIGN
[10] Bedaquiline + Pretomanid + Linezolid (BPaL) regimen for Drug-resistant TB (DR-TB)8F[23] (2013 to 2025)			
2013–2014	Bedaquiline registered in South Africa (precursor drug later used in BPaL regimens)	National	P3
2019	Pretomanid receives regulatory approval internationally (FDA), enabling BPaL regimen development	Global	P1
2020	WHO policy communication supporting shorter, all-oral regimens for DR-TB, including BPaL	Global	P1
2021	Pretomanid registered by SAHPRA in South Africa	National	P3
2022	WHO consolidated TB treatment guidelines endorse 6-month BPaL/ BPaLM9F[24] regimens for DR-TB	Global	P1
2022–2023	National Department of Health reviews global guidance and begins policy appraisal and guideline development	National	P1, P3
2023	NEMLC review and recommends inclusion of BPaL on the EML	National	P3
Early 2023	South Africa approves BPaL regimen for eligible DR-TB patients	National	P3
Sept 2023	Updated national clinical guidelines were released, introducing BPaL/ BPaLM regimens	National	P3
Sept 2023	National launch and phased patient enrolment under BPaL implementation programme	National / Provincial	P3,P4
Late 2023–2024	National rollout expands across provinces with programmatic implementation in DR-TB care	National / Provincial	P3,P4
Aug 2024	WHO rapid communication reaffirming BPaL/BPaLM regimens and monitoring guidance	Global	P1
2024–2025	National monitoring and pharmacovigilance integrated into DR-TB programme	National	P1, P3

B2. VACCINES

PERIOD	KEY EVENT	LEVEL	ALIGN
[11] Human Papillomavirus Vaccine (HPV) for preventing cervical cancer (2014 to 2024)			
Pre-2014	A high cervical cancer burden, especially among women living with HIV, justified HPV vaccination policy in South Africa.	National	P1, P3
2014	A national decision to introduce a school-based HPV vaccination programme as part of South Africa's Integrated School Health Programme (ISHP), was formalised through ministerial resolutions and endorsement by the National Health Council *[P2: HPV vaccination was integrated into the ISHP portfolio, leveraging an established school health platform (education, screening, outreach and referral) rather than being implemented as a standalone programme]*	National	P2, P3

23 *BPaL for DR-TB: 6-month, all-oral regimen (bedaquiline, pretomanid, linezolid) for drug-resistant tuberculosis*
24 *BPaLM: 6-month, all-oral regimen (bedaquiline, pretomanid, linezolid, moxifloxacin) for drug-resistant tuberculosis*

PERIOD	KEY EVENT	LEVEL	ALIGN
2014	Regulatory approval and ring-fenced conditional grant financing enabled the launch of a public-school–based HPV vaccination programme targeting Grade 4 girls.	National	P1, P3
2015–2019	Annual campaign-based delivery was implemented in public primary schools, supported by coordinated action between the health and education sectors; inclusion of private schools remained under consideration	National / Provincial	P3
2017	Global guidance reaffirmed HPV vaccination as a cost-effective cervical cancer prevention strategy.	Global	P1
2020	Programme delivery was severely disrupted by COVID-19, resulting in a sharp decline in coverage.	National/ Sub-national	P1, P3
2023/4	National guidelines were adapted following global policy shifts, with NAGI endorsing single-dose HPV vaccination aligned with updated WHO guidance. In 2024, selected provinces adopted single-dose delivery, while registration remained two-dose pending revision; private-school delivery remained limited	National, Provincial	P1, P3
[12] Quadrivalent Influenza Vaccine (QIV) for preventing seasonal influenza (2005 to 2025)			
2005–2014	National surveillance showed prolonged co-circulation of both influenza B lineages, raising concerns about trivalent influenza vaccine (TIV) mismatch, as it covers two A subtypes and only one B lineage	National	P1
Pre-2020	Public-sector influenza programmes relied on TIV; while modelling and economic analyses indicated QIV would yield incremental benefits and likely be cost-effective with ongoing influenza B circulation	National	P1
2020	Private-sector availability of QIV increased policy salience via clinician and manufacturer advocacy	Private	P4
2021–2023	Public policy permitted limited QIV procurement alongside TIV, restricted by budget constraints	National	P3
2024	National programmatic guidelines and STGs/EML permitted either TIV or QIV, contingent on cost, availability, and seasonal considerations	National	P1, P3
2024–2025	Surveillance and evolving global influenza ecology continued to shape seasonal vaccine policy and procurement	Global, National	P1
2025	With B/Yamagata's lineage apparent disappearance, WHO guidance repositioned TIV as the preferred option	Global	P1
[13] Pneumococcal Conjugate Vaccine (PCV) for preventing invasive pneumococcal disease (IPD) (2009 to 2025)			
Pre-2009	Surveillance identified high IPD burden, especially among young children and people living with HIV	National	P1
2009	PCV7 (7-valent PCV) introduced into national EPI as part of child-survival and under-five mortality reduction priorities	National	P3
2010s	Routine reporting and laboratory GERMS-SA10F[25]/NICD surveillance documented major declines in vaccine-type IPD	National	P1

25 *Group for Enteric, Respiratory and Meningeal Disease Surveillance in South Africa*

PERIOD	KEY EVENT	LEVEL	ALIGN
2011	PCV13 (13-valent PCV) registration enabled consideration of expanded serotype coverage	National	P1, P3
2014	PCV13 replaced PCV7 following NAGI advice and National Health Council (NHC) approval, informed by residual non-PCV7 serotype disease	National	P1, P3
2016-2021	Rising EPI costs within a fully domestically funded programme prompted policy discussions on optimisation and long-term sustainability	National	P1, P3
2023-2024	NAGI supported the substitution of PCV13 with PCV10 (10-valent PCV) on technical equivalence and cost grounds, with phased implementation via national tenders and no schedule change	National	P1, P3
2024–2025	PCV13-to-PCV10 transition was implemented via tender and phased stock replacement without schedule changes; savings supported reinvestment, including Tdap procurement within the EPI *[P2: Explicit portfolio reinvestment - savings from PCV optimisation were reallocated to strengthen another antigen (Tdap), demonstrating cross-vaccine sequencing and bundled EPI resource planning]*	National	P1, P2, P3

B3. DEVICES

PERIOD	KEY EVENT	LEVEL	ALIGN
[14] Apnoea monitors for neonatal respiratory and heart-rate monitoring (2000/2003 to 2024)			
Early 1990s –early 2000s	Perinatal audits and Saving Babies reports documented high neonatal mortality and equipment gaps, including lack of apnoea monitors.	National	P1
2003–2005	Saving Babies recommended apnoea monitors as essential for neonatal and resuscitation care.	National	P1, P3
2006	Apnoea monitoring was incorporated into national Paediatric Hospital STGs.	National	P3
Mid-2000s–early 2010s	Evidence and professional consensus supported scale-up, with provincial initiatives (notably LINC11F[26]) and academic partners advancing implementation.	National, Provincial, Facility-level	P3, P4
2010s	District-level adoption expanded via provincial programmes and facility equipment committees, using capital equipment governance structures rather than formal HTA	National	P3
2013	Apnoea monitors designated essential in national newborn care norms and operationalised through the Essential Newborn Care QI Toolkit; challenges: training, maintenance, false alarms, persisted	National	P1, P3
Mid-2010s–early 2020s	Procurement improved through bundling within neonatal equipment packages, though fiscal and inter-provincial disparities remained *[P2: Explicit bundling within neonatal equipment package reduces procurement fragmentation]*	National, Provincial	P2, P3
2023	Updated neonatal guidelines reaffirmed apnoea monitoring as standard care; audits continued to note provincial procurement and maintenance gaps	National, Provincial	P1, P3

26 *Limpopo Initiative for Newborn Care*

PERIOD	KEY EVENT	LEVEL	ALIGN
2024	Inclusion in National Treasury transversal procurement strengthened standardisation, pricing, and scale-up	National	P3
[15] Continuous Positive Airway Pressure (CPAP) for non-invasive respiratory support during COVID-19 (2020 to 2025)			
March–June 2020	Rapid COVID-19 surge and saturation of bed capacity in intensive care units (ICU), elevated CPAP as a ward-based strategy, preserving preserve critical-care capacity.	National	P1, P3
May 2020	Emergency national guidance positioned CPAP for selected patients failing conventional oxygen therapy	National	P1, P3
November 2020	Audits (national/ provincial) confirmed CPAP's safe use outside ICUs under defined conditions	National, Provincial	P1, P3
2020–2022	CPAP procurement expanded alongside major oxygen infrastructure investments *[P2: Bundles CPAP scale-up with oxygen-system investments as a linked respiratory platform portfolio]*	National	P2, P3
September 2021	CPAP was incorporated into national COVID-19 clinical management guidelines	National	P3
2021–2022	Scale-up linked CPAP deployment to oxygen-system strengthening, infection control, staff training	National	P3, P4
2023–2024	Inclusion in STGs, essential equipment lists, and training materials supported transition to routine use	National	P3
2024–2025	CPAP indicators were integrated into quality assurance and health information systems, signaling institutionalisation of its routine use.	National	P1, P3
[16] HHFNO12F[27] for low-and extremely low-birthweight (LBW/ELBW) neonates (2015 to 2025)			
2015–2019	Perinatal audits identified high mortality from respiratory distress among LBW/ELBW neonates, highlighting gaps in non-invasive respiratory support	National, Provincial	P1
2018–2021	Western Cape province pilots demonstrated operational feasibility of HHFNO using existing oxygen systems and standardised protocols	Provincial	P1, P4
2019-2020	Global evidence positioned CPAP as first-line therapy and HHFNO as step-down support for selected preterm infants	Global	P1
2020–2021	COVID-19 pressures strengthened oxygen governance and monitoring, indirectly enabling HHFNO scale-up	Provincial	P3
June 2021	HHFNO was adopted in the Western Cape via the Periviable Preterm Care Framework	Provincial	P3
2023	Inclusion in Paediatric Hospital-Level STGs/EML signaled national alignment	National	P3
April 2024	HHFNO was incorporated into national neonatal training materials	National	P3

27 *Heated Humidified High-Flow Nasal Oxygen*

B4. DIAGNOSTICS

PERIOD	KEY EVENT	LEVEL	ALIGN
[17] Viral load (VL) testing for HIV treatment monitoring (2013 to 2024)			
2013	National ART guideline revisions (aligned with WHO guidance) positioned VL testing as the preferred monitoring tool	Global, National	P1, P3
2014–2016	NHLS laboratory expansion, strengthened referral and information systems enabled early scale-up	National	P1, P3
2016–2018	Nationwide rollout achieved routine VL coverage across provinces	National, Provincial	P3
2018–2023	Testing volumes rose steadily, supported by high-throughput platforms, centralised procurement, and donor-backed system strengthening	National	P3
2023–2024	VL testing embedded as core national HIV programme indicator; annual volumes exceeded six million tests	National	P1, P3
[18] Reflex Cryptococcal Antigen (CrAg) Screening for cryptococcal meningitis (CM) in advanced HIV care (2011 to 2024)			
2011–2013	Global guidance and local surveillance highlighted the role of CrAg screening	Global, National	P1
2012–2015	NICD and provincial pilots demonstrated feasibility, high burden, and superior coverage of laboratory-based reflex screening	National	P1, P3
2015 onward	National HIV/ART guidelines progressively incorporated CrAg screening for advanced HIV disease	National	P3
2016	National reflex CrAg screening launched through NHLS, transitioning from pilot to routine delivery *[P2: Reflex screening explicitly integrated CrAg into existing CD4 laboratory workflow (shared platform sequencing)]*	National	P2, P3
2018–2020	Inclusion in PHC STGs/EML enabled nurse-initiated management and reinforced policy alignment	National	P3
2019 onward	Routine national implementation via NHLS CD4 laboratories, with automated reporting and surveillance integration	National, Provincial	P1, P3
2018–2023	Scale-up achieved >95% coverage, supported by centralised procurement, LIS automation, and QA systems	National, Sub-national	P1, P3
August 2022	Western Cape province expanded the reflex threshold from CD4 ≤100 to ≤200 cells/μL, aligned with conditional WHO guidance	Global, Provincial	P1, P3
2023–2024	Centralised NHLS tendering secured supply, while surveillance continued to inform threshold optimisation and linkage to care	National	P1, P3
[19] Donated COVID-19 AgRDTs13F[28] for decentralised SARS-CoV-2 testing (2020 to 2022)			
15 March 2020	National state of disaster enabled emergency diagnostic pathways, including donations and expedited procurement	National	P3
April–June 2020	SAHPRA implemented expedited Section 21 authorisation for donated COVID-19 diagnostics	National	P3

28 *COVID-19 Antigen Rapid Diagnostic Tests*

PERIOD	KEY EVENT	LEVEL	ALIGN
May–Sep 2020	NHLS/NICD conducted risk-based evaluations of donated Ag-RDTs	National	P1, P3
Sep–October 2020	WHO endorsed Ag-RDTs as complementary to laboratory-based RT-PCR; NDoH announced national rollout, including at ports of entry	Global, National	P1, P3
Oct 2020–March 2021	Donated Ag-RDTs were distributed nationally across public platforms, supported by NHLS systems and hybrid financing (including the Solidarity Fund)	National, Private	P3, P4
March 2021–Feb 2022	Ag-RDT results were integrated into NHLS/NICD surveillance, with consolidated reporting and external quality assurance	National	P1, P3
[20] Dual HIV/ syphilis point of care test (POCTs) for antenatal care (2019 to 2024)			
2019	WHO recommended dual HIV/syphilis rapid diagnostic tests (RDTs) as the preferred first antenatal screening test.	Global	P1
2021–2022	Market-shaping measures improved dual RDT affordability	Global	P1
2022–2023	NICD evaluated WHO-prequalified dual RDTs and advised NDoH and National Treasury on performance and QA requirements	Global, National	P1, P3
2022	National Treasury established transversal procurement for dual HIV/ syphilis RDTs	National	P3
2023	Dual POCT was endorsed in the National Vertical Transmission Prevention Guideline, alongside mono-syphilis testing for women on ART *[P2: Dual HIV/syphilis POCT was positioned within the antenatal screening portfolio to streamline HIV and syphilis testing in a single visit, while preserving mono-syphilis POCT testing where clinically indicated]*	National	P1, P2
2023–2024	Dual testing incorporated into PHC STGs/EML, aligned with national procurement and QA frameworks.	National	P1
2024	Public ANC rollout was supported by national guidance, training, and ongoing NICD/NHLS surveillance and QA systems.	National	P1, P3
[21] TB LAM14F[29] urine tests for advanced HIV disease (2018 to 2024)			
2018	STAMP trial showed TB-LAM urine tests improved TB diagnosis in hospitalised patients with advanced HIV unable to produce sputum and reduced mortality within defined algorithms	Global	P1
2019	WHO recommended TB-LAM for advanced HIV disease, supporting national policy consideration	National	P1
2020–2021	National guidance was developed with input from the National TB Think Tank, SAHCS, and CHAI, positioning TB-LAM within TB diagnostic algorithms and the advanced HIV disease package *[P2: Explicit integration into TB diagnostic cascade and advanced HIV disease package]*	National	P1, P2, P3
2020	TB-LAM added to PHC STGs/EML, enabling routine implementation	National	P3

29 *Tuberculosis – Lipoarabinomannan urine text*

PERIOD	KEY EVENT	LEVEL	ALIGN
2021–2022	Early scale-up revealed constraints, including clinician hesitancy, limited POCT QA systems, and unclear governance	Sub-national, Facility	P1
2021–2024	Ongoing monitoring reinforced TB-LAM's role within an integrated diagnostic cascade, supported by SOPs, training, and strengthened QA and reporting *[P2: Reinforces role within integrated diagnostic cascade – TB-LAM + Xpert + clinical algorithm]*	National	P1, P2, P3
[22] GeneXpert MTB/RIF rapid molecular test for TB and rifampicin resistance			
Dec 2010	WHO issues a conditional recommendation for GeneXpert MTB/RIF as a rapid molecular TB diagnostic	Global	P1
Early 2011	South Africa makes a strategic policy decision to replace smear microscopy with GeneXpert	National	P1, P3
Mar 2011	Phase 1 instrument placement begins (World TB Day launch)	National	P3
Oct 2011	Official start of GeneXpert diagnostic testing nationally	National	P3
2011-2013	Phased national rollout with placement of instruments across provinces	National / Provincial	P3
2011-2013	Integration with NHLS laboratory information systems and training programmes	National	P3
2012	Operational research (e.g., XTEND trial) generates local evidence supporting scale-up	National / Global	P1
2013	GeneXpert effectively replaces smear microscopy in most high-burden districts	National	P3
2013-2017	Operational optimisation and expansion of testing capacity	National	P3
2017-2018	Transition to GeneXpert MTB/RIF Ultra platform	National	P3
2018-2024	Continued national programme optimisation and integration into routine TB diagnostics	National	P3

Annexure C: Stakeholder categories across all technology groups

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Scope and source basis: Stakeholder categories were derived mainly from the documentary record reviewed for each case (including policy, guideline, committee, procurement, and programme materials). To strengthen accuracy and sequencing of institutional decision points, targeted consultations were conducted with a limited subset of stakeholder types. These engagements were undertaken to validate the sequencing of events, clarify mandates and confirm institutional decision points. In line with the confidentiality provisions of the approved protocol, participant identities are not disclosed in this annexure. Ethical approval was granted by the Stellenbosch University Health Research Ethics Committee (Ref: S25/03/046), and we received institutional permission to access relevant laboratory service information from the National Health Laboratory Service (Ref: PR2562944).

How to read this annexure:
This annexure presents a category map of stakeholder types engaged across the case studies. It is not a list of named individuals, nor does it seek to attribute actions to specific persons. Instead, it reflects institutional roles, functional groupings, and system-level actors involved at different stages of policy development, financing, regulatory approval, market shaping, implementation, and service delivery.

Stakeholders are grouped by functional domains (e.g., policy and regulation; financing and market actors; technical and research expertise; advocacy and civil society; implementation and service delivery). Inclusion in a category reflects participation or relevance within the documentary record for one or more case studies and does not imply uniform involvement across all cases.

Categories are organised as follows:
- C1. Medicines (9 cases)
- C2. Vaccines (3 cases)
- C3. Devices (3 cases)
- C4. Diagnostics (5 cases)

Within each domain, stakeholder types are aligned to the relevant case studies and reflect the multi-level governance architecture spanning global normative bodies, national and provincial institutions, donors and market actors, technical advisory groups, civil society formations, and frontline implementers.

Stakeholder categories were mapped from documentary sources; consultations were targeted and limited, and are reported without identifiers to protect confidentiality.

C1. Medicines (9 cases): Stakeholder categories

- *Aligned to 3HP, Etonorgestrol, DTG, TAF, Fluconazole, TXA, Noradrenaline, Methadone case studies*

- **Policy, Governance & Regulation:** Develop policies, guidelines, standards, and regulatory approvals (global and national level)

Includes: World Health Organization (WHO); South African National AIDS Council (SANAC); National Department of Health (NDoH); National Essential Medicines List Committee (NEMLC); South African Health Products Regulatory Authority (SAHPRA); U.S. Food and Drug Administration (FDA); National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD); Surviving Sepsis Campaign (SSC); Reproductive Health Supplies Coalition (RHSC); Ministerial Working Groups; Provincial Pharmaceutical & Therapeutics Committees (e.g., KZN PTC)

- **Financing & Market Actors:** Fund, procure, price, supply, and expand access to medicines

Includes: PEPFAR; The Global Fund to Fight AIDS, Tuberculosis and Malaria; UNITAID; Bill & Melinda Gates Foundation; Children's Investment Fund

Foundation (CIFF); Sanofi; Pfizer; Merck Sharp & Dohme (MSD); Clinton Health Access Initiative (CHAI); PATH; Diflucan Partnership Programme (DPP); Tender awardees

- **Technical & Research Expertise:** Generate evidence, conduct research, develop clinical guidance, and provide expert consensus

Includes: Southern African HIV Clinicians Society; South African Medical Research Council; Cochrane; International Association of Providers of AIDS Care (IAPAC); AURUM Institute; TB Think Tank; Clinical trial researchers; Academic partners; Local researchers; International researchers

- **Advocacy & Civil Society:** Mobilise communities, influence political will, ensure accountability, and advocate for access:

Includes: Treatment Action Campaign; Médecins Sans Frontières (MSF); Global Sepsis Alliance; IMPAACT4TB; Professional associations; NGOs; International HIV solidarity networks

- **Implementation & Service Delivery:** Deliver services, prescribe, dispense, and operationalise policies at facility and community level

Includes: Municipal health departments; Health care workers; Prescribers; Community pharmacies

C2. Vaccines (3 cases): Stakeholder categories

- *Aligned to HPC, QIV and PCV case studies*

- **Policy, Governance & Regulation:** Technical appraisal, immunisation policy adoption, intergovernmental endorsement, regulatory approval, national EPI alignment

Includes: National Advisory Group on Immunisation (NAGI); National Department of Health (NDoH) EPI leadership; National Health Council (NHC); South African Health Products Regulatory Authority (SAHPRA); National Treasury (budget concurrence); WHO normative guidance; Provincial Departments of Health; STGs/EML structures

- **Financing, Donors & Market-Shaping Actors:** Vaccine financing, price negotiation, pooled procurement, supplier contracting, conditional grants

Includes: National Treasury (ring-fenced HPV conditional grant); vaccine manufacturers; procurement agents; UNICEF (where applicable); Gavi (historical/technical support context); Provincial supply chain management; depot systems

- **Technical, Research & Clinical Expertise:** Epidemiological modelling, burden-of-disease analysis, cost-effectiveness studies, surveillance

Includes: National Institute for Communicable Diseases (NICD); academic epidemiologists; Government Technical Advisory Centre (GTAC); public health research partners; cancer registry platforms; surveillance units

- **Advocacy & Civil Society:** Vaccine confidence, equity advocacy, cervical cancer awareness, professional endorsement

Includes: Civil society partners; school health stakeholders; public health advocacy groups; professional associations; vaccine confidence and communication networks

- **Implementation & Service Delivery:** Programme roll-out, cold chain, school-based campaigns, workforce mobilisation

Includes: National and provincial EPI managers; cold-chain managers; provincial depots; district managers; PHC vaccinators; school health teams; education sector partners; monitoring through DHIS

C3. Devices (3 cases): Stakeholder categories

- *Aligned to Apnoea monitors, CPAP and HHFNO case studies*

- **Policy, Governance & Regulation:** Inclusion in STGs/Norms & Standards, oxygen infrastructure governance, regulatory approval, equipment prioritisation

Includes: NDoH; Provincial Health Technology Directorates; Departmental Equipment Committees (DEC); SAHPRA (device registration, Section 21 where relevant); South African Bureau of Standards (SANS oxygen standards); National Treasury transversal tenders (e.g., RT contracts); Provincial equipment governance structures

- **Financing, Donors & Market-Shaping Actors:** Capital equipment budgeting, procurement frameworks, oxygen ecosystem investments, supplier contracting

Includes: Provincial SCM; National Treasury; equipment suppliers; maintenance contractors; UNICEF (in neonatal strengthening context); oxygen suppliers; transversal procurement mechanisms

- **Technical, Research & Clinical Expertise:** Clinical evidence appraisal, operational HTA, neonatal and critical care guidelines, biomedical oversight

Includes: Neonatology and paediatrics leadership; Critical Care societies; biomedical engineering units; clinical engineering services; academic neonatal researchers; provincial oxygen task teams; NICD (COVID advisory inputs where applicable)

- **Advocacy & Civil Society:** Newborn survival advocacy, pandemic equity framing, professional mobilisation

Includes: Newborn health networks; professional societies; public health coalitions; emergency task teams (COVID context); patient-safety networks

- **Implementation & Service Delivery:** Facility-level procurement, bedside use, oxygen system readiness, maintenance and training

Includes: Hospital CEOs; ward managers; nursing leadership; biomedical engineering units; facility fixed-asset committees; oxygen plant managers; district/regional hospitals; ICU and ward clinical teams

C4. Diagnostics (5 cases): Stakeholder categories

- *Aligned to VL, CrAg, TB-LAM, Dual HIV/syphilis RDT, COVID-19 Ag-RDT case studies*

- **Policy, Governance & Regulation:** Diagnostic guideline integration, STGs/EML inclusion, regulatory approval pathways, laboratory governance

Includes: National Department of Health (HIV/TB/MCH directorates); National Health Laboratory Service (NHLS) leadership; SAHPRA (including emergency Section 21 pathways); STGs/EML committees; National Treasury transversal tenders; NICD; WHO normative guidance

- **Financing, Donors & Market-Shaping Actors:** Laboratory platform procurement, donor financing, price-volume guarantees, donation coordination

Includes: PEPFAR (VL, TB support); Solidarity Fund (COVID); MedAccess/CHAI (dual RDT price guarantee); Abbott & Roche (VL platforms); diagnostic manufacturers (SD Biosensor etc.); National Treasury; provincial SCM; donation coordination structures

- **Technical, Research & Clinical Expertise:** Validation studies, operational research, quality assurance, diagnostic stewardship

Includes: NHLS validation laboratories; NICD surveillance teams; academic trialists (e.g., STAMP trial for TB-LAM); Southern African HIV Clinicians Society; National TB Think Tank; laboratory QA units; Cochrane/WHO evidence reviews

- **Advocacy & Civil Society:** Access advocacy, treatment literacy, equity mobilisation

Includes: Treatment Action Campaign; Médecins Sans Frontières; Treatment Action Group; Section27; civil society coalitions advocating diagnostic access; People's COP21 (TB-LAM context)

- **Implementation & Service Delivery:** Specimen referral networks, point-of-care testing, result reporting, clinical uptake

Includes: NHLS laboratories (centralised VL); Tier.Net managers; clinicians/nurses using POCT; antenatal clinic staff; TB wards; hospital clinicians; facility managers; district outreach teams; logistics and distribution units

Stakeholder categories were mapped from documentary sources; consultations were targeted and limited, and are reported without identifiers to protect confidentiality.

Annexure D: Case study - Umbiflow™

Table 9. Summary of Umbiflow™ field testing, implementation research, and demonstration projects in South Africa

Project	*Status*	*Study focus*	*Role in evidence pathway*	*Key findings*
Technical validation & early comparative studies (2013-2016)	Completed	Device validation	Effectiveness & Safety	Early laboratory and comparative clinical studies established agreement between Umbiflow™ continuous-wave Doppler and conventional pulsed-wave Doppler for umbilical artery resistance indices before large-scale field implementation (Mufenda 2015, Nkosi 2019)
Mamelodi Study (2015-2017)	Completed	Community-based cohort using Umbiflow™ at PHC level	Clinical effectiveness	Screening low-risk pregnancies at 28–32 weeks improved the detection of abnormal umbilical artery Doppler findings. Associated reduction in perinatal mortality compared with standard care (11.4 vs. 21.3 per 1,000 births; ARR 0.99%; NNT ~101). Provided proof-of-concept that PHC-based Umbiflow™ screening improves outcomes (Nkosi 2019).
UmbiBaby (2018-2020)	Completed	Multi-facility implementation research using Umbiflow™	Effectiveness & Feasibility	Confirmed midwives could reliably perform Umbiflow™ Doppler screening with limited training. Improved identification of FGR risk and referral quality. Follow-up showed infants with abnormal in utero Doppler findings had altered growth/body composition patterns in early childhood, supporting the biological validity of placental insufficiency detection (Nel 2023).

Project	*Status*	*Study focus*	*Role in evidence pathway*	*Key findings*
UmbiGodisa (2020-2022)	Completed / Late-Stage Implementation Research	Remote-supervised Umbiflow™ screening in resource-limited PHC settings	Scalability & Sustainability	Demonstrated operational sustainability and feasibility of remote quality assurance. Infants with abnormal Doppler findings showed higher rates of stunting and early growth impairment. Also examined interaction between placental insufficiency and maternal HIV exposure (Nyofane 2022).
Implementation Study (19-Clinic Rollout) (2023)	Completed	Large-scale use of Umbiflow™ across 19 clinics	Scaled Implementation Evaluation	Screened 7,088 women using Umbiflow™. Focused on workflow integration, training needs, referral pathways, and system performance at scale (Hlongwane 2023). This study evaluated real-world use of the Umbiflow™ device within routine ANC services.
UmbiTshwane (2025)	Planned / Early Implementation	Integration of Umbiflow™ across 22 PHC clinics	Early Scale-Up Phase	Operational framework confirmed by CSIR. No outcome data yet available. Represents transition from implementation research to district-level institutionalisation (SAMRC 2023–2024).
Siyakubona Ultrasound Programme (2025)	2025 District Initiative	Introduction of general pregnancy ultrasound services	Complementary Imaging Expansion	A district initiative introducing pregnancy ultrasound services in selected PHC clinics. Although devices are not specified, the programme signals a commitment to expanding prenatal imaging access and may complement Umbiflow™ use (TimesLive 2025).

Note: These studies preceded SAHPRA registration and formal policy adoption. They represent preparatory evidence-generation and implementation learning intended to inform potential future policy appraisal.

Annexure E: Concept for ALIGN mapping tool

Authors: TD Leong, N Leon

- *Strengthening System Readiness for the Introduction of Health Technologies*

Executive Summary
A multi-case landscape analysis of health technology introductions in the South African public sector showed that innovations often fail to achieve impact, not because of product limitations, but because health system conditions are misaligned for adoption and scale. Retrospective case studies demonstrate that breakdowns most frequently occur at the intersection of policy, financing, governance, coordination, and market engagement.
The ALIGN Mapping Tool is a structured, policy-oriented framework designed to identify and address these misalignments during late-stage development, regulatory transition, introduction, and early scale-up. It provides a shared diagnostic platform for governments, funders, developers, and partners to:
- Identify systemic alignment risks
- Visualise coordination and sequencing gaps
- Prioritise corrective actions

ALIGN is not a benchmarking instrument. It does not rank or judge performance. Rather, it enables prospective course correction, addressing structural constraints before they translate into implementation failure.

Problem Statement

Despite expanding investment in health innovation pipelines, many technologies experience delayed uptake, stalled scale-up, or fragmented implementation upon entry into public health systems. Retrospective analyses consistently identify systemic failures: evidence not translated into policy action; misaligned regulatory, guideline and financing processes; weak cross-ministerial coordination; insufficient early engagement of market and supply actors; and portfolio decisions poorly matched to country readiness. These patterns reflect structural misalignment rather than technical inadequacy. However, no concise, policy-oriented framework currently exists to diagnose such alignment gaps prospectively, before introduction and scale-up falter.

The ALIGN Framework

ALIGN organises system readiness across four interdependent pillars, described in Figure 1.

Figure 1. ALIGN Framework and key activities across the four pillars

Methodology

ALIGN uses a structured five-step process, outlined in Table 9

Table 9. ALIGN process steps

Step	Action
Step 1: Define the case	Clarify: • The innovation • Country or regional context • Stage of introduction • Key actors
Step 2: Map each pillar	For each pillar: 1. Describe what should be in place 2. Describe what is observed 3. Assign traffic-light status: o **Green:** Aligned o **Yellow:** Partial alignment o **Red:** Significant misalignment
Step 3: Identify critical gaps	Focus on the single most important misalignment per pillar
Step 4: Review the ALIGN snapshot	Visual traffic-light summary reveals: • High-risk domains • Coordination breakdowns • Cross-pillar dependencies
Step 5: Translate gaps into action	Develop: • Priority actions • Responsible actors • Indicative timelines

Expected Outputs

ALIGN generates four integrated outputs:

(i) an Alignment Snapshot (traffic-light visualisation of system readiness)
(ii) a structured Gap Analysis Table
(iii) a Priority Action Framework to sequence corrective measures; and
(iv) a Coordination Risk Profile identifying cross-institutional vulnerabilities.

Together, these outputs support coordinated decision-making and proactive risk mitigation.

Application Contexts

- ALIGN is most effective in late-stage development, around regulatory approval, and during early introduction and scale-up planning - when alignment gaps can still be addressed.
- It can be applied at single- or multi-country level by ministries, financing and procurement bodies, developers, and multi-stakeholder platforms involved in technology introduction.

Value Proposition for Financing and Strategic Partners

In a context of constrained health financing, ALIGN may support more strategic allocation of limited resources. It can provide early signals of introduction risk, help strengthen investment sequencing, and improve coherence between portfolio priorities and country readiness. By identifying coordination gaps across financing and implementation streams, it may reduce the risk of delayed and fragmented scale-up.

Rather than responding to implementation breakdowns once they occur, stakeholders could use ALIGN prospectively to strengthen system alignment and readiness ahead of large-scale introduction.

Proposed Next Steps

A phased approach could support refinement, testing, and potential institutionalisation of ALIGN.

- **Phase 1: Tool refinement and standardisation** would involve development of standardised mapping templates, preparation of a guidance manual, and piloting across two to three retrospective case studies to assess feasibility and analytic coherence.
- **Phase 2: Prospective application** could include deployment of three to five live innovation introductions, systematic documentation of lessons, and iterative refinement of scoring approaches and visualisation formats.
- **Phase 3: Institutional integration** may involve embedding ALIGN within routine introduction planning processes, developing a digital or dashboard-based interface, and creating training modules to support uptake and consistent application.

Conclusion

ALIGN reframes the central question from "Is the innovation ready?" to "Is the system aligned for the innovation?"

By supporting early identification and remediation of misalignment, ALIGN may strengthen system readiness, enhance cross-institutional coordination, and reduce the risk of implementation failure during introduction and scale-up.

Annexure F: Relationship between ALIGN outputs and doctoral research

Purpose: This annexure clarifies the relationship between the ALIGN Landscape Assessment work and report, and the parallel **PhD**0F[1] **by publication registered in the Faculty of Medicine and Health Sciences, Stellenbosch University.** It delineates the scope and boundaries of each body of work to ensure alignment with faculty and institutional requirements regarding originality, examinable scholarship, and prior disclosure.

ALIGN Landscape Assessment (Technical Report)

The ALIGN Landscape Assessment is based on research for the ALIGN research project with programme deliverable products to support system-level understanding, programme learning, and policy dialogue related to health innovation introduction in South Africa. It is a technical report intended to support system-level understanding, programme learning, and policy dialogue on health innovation introduction in South Africa. The report is descriptive and synthetic in nature. It draws on framework-based system mapping, illustrative case material, and process descriptions to inform programme objectives. As this work is embedded in parallel PhD work with a similar, but broader scope, it is important to clearly delineate boundaries between the outputs of the ALIGN project and the PhD research, to protect the domain of each of the projects. This is needed to ensure the PhD work outputs are protected as original and independent scholarship that is examinable by external examiners and that is publishable as original work.

Guided by the Stellenbosch University FMHS doctoral requirements, the ALIGN report:

- does **not** constitute examinable doctoral work,
- does **not** present original scholarly analysis or theory development intended for academic examination, and
- is **not submitted** as part of the doctoral thesis by publication.

Doctoral Research (PhD by Publication)

The PhD by publication undertaken by the lead author (Trudy D Leong) is an independent academic programme governed by Stellenbosch University and FMHS doctoral requirements.

The doctoral thesis consists exclusively of:

- peer-reviewed journal publications authored by the PhD candidate and supervisors, and
- an integrating thesis text situating these publications within a coherent scholarly framework.

These publications are guided by clearly defined research questions and established qualitative methodologies, and they present original scholarly analysis. They are submitted for independent external examination in accordance with university requirements.

Contextual Overlap and Boundary Conditions

Both the ALIGN programme and the PhD research are situated within the same national policy and health systems context. This represents contextual overlap only and does not constitute duplication of examinable work.

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1 *PhD protocol approved by Stellenbosch University - Ethical approval was granted by the Stellenbosch University Health Research Ethics Committee (Ref: S25/03/046) for research project: Exploring and evaluating evidence-informed decision-making processes for selecting essential medicines and diagnostic tests in sub-Saharan Africa, and additionally devices in South Africa, at the primary level of care in the public sector: a mixed-methods study.*

To ensure compliance with FMHS requirements:

- No ALIGN deliverable is submitted for doctoral examination.
- No ALIGN programme report or draft is presented as a scholarly publication, duplicating PhD work and publications.
- Interpretive qualitative analysis of documents or interviews is undertaken solely within the PhD publications, in accordance with the approved doctoral protocol.
- Draft ALIGN materials with shared content from the PhD may be shared with ALIGN project funders, but this will be for information-sharing purposes only and does not constitute prior disclosure of examinable doctoral analysis.

Statement of Compliance

All original scholarly analysis and contributions to knowledge arising from this work reside exclusively within the PhD by publication and its associated peer-reviewed outputs, in compliance with Stellenbosch University Faculty of Medicine and Health Sciences doctoral requirements.

Landscape Assessment of Health Technology Introduction in South Africa's Public Health Sector - medicines, vaccines, diagnostics and devices

June 2026